Biographies - Pre-Satellite Symposium: Pharmacovigilence and Patient Safety (R 1)

BIO R1-0

BIOGRAPHY C.C.F. VIDOTTI

C.C.F. Vidotti
Federal Council of Pharmacy Brazil

Pharmacist, Master in Pharmacology and doing Ph.D. in Health Sciences.

Technical Manager of the Brazilian Drug Information Center (CEBRIM), within the Federal Council of Pharmacy(CFF). I have expertise in drug information, Medicines Information Center management, edition of drug bulletins, team work, drug nomenclature, selection of drugs, pharmacovigilance, pharmacoepidemiology and public health. I have helped training of many pharmacists to set up Medicines Information Centers in Brazil and in Latin America. Currently, I am member of the three Brazilian government committees of drug nomenclature, drug selection and pharmacovigilance in community pharmacies.

BIO R1-0

BIOGRAPHY M. FREITAS DIAS

M. Freitas Dias
Brazilian Health Surveillance Agency Brazil

Pharmacist. Master in Pharmacology. Head of Pharmacovigilance, Brazilian Health Surveillance Agency (ANVISA), since July of 2001. Member of The Advisory Committee on Safety of Medicinal Products (ACSoMP), World Health Organization, since October, 2003. Member of The Joint CIOMS/WHO Working Group on Vaccines, since November 2005. Member of Pan American Network for Drug Regulatory Harmonization – Working Group on Pharmacovigilance, since March 2006. I have expertise on regulatory pharmacovigilance, rational drug use and pharmacoepidemiology. Since 2005, I am responsible for a new programme for community pharmacies and pharmacovigilance in nationwide.

Biographies - Pre-Satellite Symposium CEP (R 2)

BIO R2-1

BIOGRAPHY C. DUGGAN
C. Duggan
University of London United Kingdom

Catherine is Director of the Academic Department of Pharmacy and Senior Clinical Lecturer at the School of Pharmacy, University of London. She has responsibility for integrating research into practice, ensuring that professional education and training is seamless and lifelong. Her research interests include development and evaluation of evidence-based practice from policy level to practice implementation and improving communication between professionals and patients.

Catherine has published over 50 papers and articles and more than 80 abstracts. She is regularly invited to speak at national and international conferences and meetings and has been successful in securing £550,000 in research income. Catherine has worked with primary care research networks; with academics and practitioners both nationally and internationally and has experience of managing PhD, Masters and audit projects. She has wide experience of developing and delivering modules and options for both undergraduates and postgraduates, linking these courses to professional practice. Catherine regularly reviews papers for academic journals and sits on several committees to judge grant applications She sits on an ethics committee and has been commissioned to work at the Department of Health to co ordinate pharmacy R&D at policy level.

BIO R2-2

BIOGRAPHY N.J. MACKINNON
J. MacKinnon
Dalhousie University Canada

Dr. Neil MacKinnon is the Associate Director for Research and an Associate Professor at the Dalhousie University College of Pharmacy in Halifax, NS, Canada. Neil is also cross-appointed to the Department of Community Health and Epidemiology, Faculty of Medicine, and to the School of Health Services Administration, Faculty of Health Professions.

Neil completed a BSc (Pharm) degree from Dalhousie, a M.Sc. in Hospital Pharmacy degree and an Advanced Administrative Residency at the University of Wisconsin Hospital and Clinics, a Ph.D. in Pharmacy Health Care Administration at the University of Florida and a Research Fellowship at the DuBow Family Center for Research in Pharmaceutical Care with Dr. Charles D. Hepler.

Neil's primary research interests include studying adverse consequences of medication use such as preventable drug-related morbidity and medication errors. He is currently the PI or co-investigator on several research grants studying these issues including a study developing medication safety indicators funded by the Canadian Patient Safety Institute.

Neil edited a book on seamless care published in April 2003 by the Canadian Pharmacists Association and he is currently working on a book on the safety and quality of the medication use system. Neil has authored or co-authored over 60 papers in the peer-reviewed literature and has given over 100 presentations at scientific meetings, speaking frequently on medication safety issues. Neil is a two-time recipient of the Jessie I. MacKnight Award for Teaching Excellence, as selected by the senior year pharmacy students at Dalhousie University.

BIO R2-3

BIOGRAPHY J.C. MCELNAY
J.C. McElnay
Queen's University Belfast Northern Ireland

James C. McElnay is Professor of Pharmacy Practice and Chairman of the Clinical and Practice Research Group in the School of Pharmacy at the Queen's University of Belfast, N. Ireland. He is a past president and Fellow of the Pharmaceutical Society of Northern Ireland, a Fellow of the American College of Clinical Pharmacy and a Fellow of the Royal Pharmaceutical Society of Great Britain. He has recently taken up the position of Dean of the Faculty of Medicine, Health and Life Sciences at Queen's. His main research interest is in developing processes and systems which lead to the safe and effective use of medicines within both primary and secondary care. As such he is an active member of the Pharmaceutical Care Network Europe (PCNE).

BIO R2-4

BIOGRAPHY R.J. MOLES
R.J. Moles
The University of Sydney Australia

Rebekah Moles is a young Australian Pharmacist working in the Faculty of Pharmacy at the University of Sydney. She has recently completed her PhD thesis which explored pharmacy services in Private Hospitals. She is currently the Vice President of Australasia in the Hospital Pharmacy Section, a National Councillor on the Society of Hospital Pharmacists of Australia and an active member of the Pharmaceutical Society of Australia's NSW Branch of Young Pharmacists.

Biographies - Pre-Satellite Symposium CEP: (R 2)

BIO R2-5

BIOGRAPHY TH.F.J. TROMP
Th.F.J. Tromp
QIPC/Flevowijk pharmacy Netherlands

- Graduated at Groningen University in 1973;
- Community pharmacist in Kampen in 1980 (until today), a staff of 3 pharmacists and approx 10 assistants and supporting team members. Taking care of approx 12.000 patients;
- PhD Thesis in 1983;
- President of the Royal Dutch Association for the Advancement of Pharmacy (KNMP), 1988-1993. Active in many committees covering e.g. quality, ethics, pharmaceutical care and care protocols;
- Professor in Pharmaceutical Care, University of Groningen, 1991-2002;
- Member and president of the executive committee of the European Association for Faculties of Pharmacy and chairman of the Task Force for the development of a curriculum for Pharmaceutical Care in the European Faculties, 1997-2002;
- (Founding) member of the Pharmaceutical Care Network Europe (PCNE);

- Member of the Dutch delegation of the Pharmaceutical Group in Europe (PGEU), 1988-1998;

- (Founding) member of and delegate to the EuroPharm Forum (EPF), 1992-today;

- Vice and (immediate past) president of the Community Pharmacy Section (CPS) of FIP, 1991-2000;

- Chairman of the Board of Pharmaceutical Practice (BPP) of FIP, 2002-..;

- Member of FIP Bureau, 2002-..;

- Founder and director of the Quality Institute for Pharmaceutical Care (QIPC),1997-..., to support pharmacists to develop and implement Pharmaceutical Care in their pharmacies.

BIO R2-6

BIOGRAPHY Y. GOMITA
Y. Gomita
Okayama University Hospital Japan

Dr. Gomita is Professor of Okayama University and Director of Pharmacy Department of Okayama University Hospital as well as Head of the Center for Clinical Research of New Drug and Therapeutics. He has responsibilities for educating clinical pharmacology and clinical pharmacy to the students of medical/dental school and pharmacy school, and for integrating the pharmaceutical works of hospital pharmacists including the dispensing, manufacturing , therapeutic drug monitoring and pharmaceutical caring to patients in Pharmacy Department, and also controlling the various kinds of works in Center for Clinical Research of New Drug and Therapeutics. His research interests include experimental and clinical pharmacology, and clinical pharmacy, especially in aspect of psychopharmacology, neuropharmacology, and clinical trials. He has published over 180 papers in English and Japanese.

Dr. Gomita acted as one of the directors of Japanese Society of Hospital Pharmacists (1998 1999, 2004 2005) and Japanese Society of Pharmaceutical Health Care and Sciences (2004-2005), respectively. Further he sponsored as a president of The 15th Annual Meeting of Japanese Society of Pharmaceutical Health Care and Sciences (2005). Regionally he is acting as a president of Okayama Hospital Pharmacist Association from 1993 and promoting to provide better pharmaceutical care for patients by making net-work with hospital pharmacists and community pharmacists.

BIO R2-7

BIOGRAPHY R.W.HOLLAND
R.W. Holland
Management Sciences for Health United States of America

Ross W. Holland, Ph.D., Ed.D., FPS, FASHP, FAIPM, FACPP, has been actively involved in community pharmacy ownership or management for almost 40 years. In addition he has been involved in clinical pharmacy, hospital pharmacy management, the vocational education of pharmacists and nurses, educational administration and medical education.

Over the years Ross has been involved in many areas of practice change relating to the implementation of pharmacy services. His doctoral studies in the faculty of medicine at the University of New South Wales revolved around practice change for pharmacists. This lead to working with a colleague with similar interests, Dr Christine Nimmo, to jointly create a systematic approach to implementation of new practices amongst health care practitioners, a system that is now employed in many countries. Together they have written extensively about practice change in both community and hospital pharmacy.

Prior to his relocation to the United States of America four years ago Ross was Dean of the Australian College of Pharmacy Practice. Ross is still actively involved in education and training as Senior Manager, Capacity Building for Performance Improvement at Management Sciences for Health, a not-for-profit international organization providing pharmacy management systems support to developing countries. Currently he is designing, developing and implementing programs for medical and pharmacy professionals working to improve reliable access to and rational use of medications and pharmaceutical supplies of medicines for HIV/AIDS, malaria, tuberculosis, infectious diseases and child and maternal health in over 50 countries worldwide.

BIO R2-8

BIOGRAPHY L.C. VERMEULEN
L.C. Vermeulen
University of Wisconsin Hospital United States of America

Lee Vermeulen is the Director of the Center for Drug Policy in the Department of Pharmacy at the University of Wisconsin Hospital and Clinics, and Clinical Associate Professor at the UW-Madison School of Pharmacy. He received a Bachelors Degree in pharmacy from the University of Buffalo, and a Masters in pharmacy administration from the University of Wisconsin-Madison. He completed residency training in pharmacy practice and pharmacy administration at the University of Wisconsin Hospital and Clinics, and served a fellowship in medical technology assessment at the University Healthsystem Consortium. In his role at the UW Hospital and Clinics, he leads a large team of pharmacists responsible for drug policy analysis and drug formulary management for both his academic medical center and for Unity Health Insurance, an 85,000 member managed care organization owned by the UW Health system. Mr. Vermeulen also conducts health services research with a focus on studies that measure the value of both medication therapy and clinical pharmacy services. He is involved in the evaluation of technology development and diffusion, particularly in the pharmaceutical market, and he publishes annual forecasts of the medication development pipeline and forecasts of the rising cost of medications. His previous scholarly work has focused on measuring the impact of various health-system medication use policies and programs. Mr. Vermeulen is active in several professional organizations, including the Pharmacy Society of Wisconsin, ASHP, ACCP, and currently serves as the Assistant Secretary of the Hospital Pharmacy Section of FIP.

Abstracts - Pre-Satellite Symposium CEP(R 2)

ABS R2-1

MEDICINES MANAGEMENT AS PATIENTS MOVE BETWEEN HOSPITAL AND COMMUNITY: LEARNING LESSONS FROM SEAMLESS CARE

C. Duggan
University of London United Kingdom

For more than a decade, it has been widely known that patients moving between hospital and community are at risk of unintended changes to supplies of medicines. These risks increase with age and corresponding increases in prescribed drugs and have been shown to occur as a result of communication breakdowns between the two healthcare sectors. Many interventions have determined the information required by pharmacists working in the community to resolve these problems and, indeed, the positive effects providing such information has: for every 19 patients discharged with simple information about the drugs they have been prescribed at the point of discharge to take to their community pharmacist, an adverse event as a result of an unintended change to therapy is prevented. The costs of such an intervention were minimal at the time, especially given the measurable benefits to patients and with the implementation of electronic communication, will continue to decrease. In addition, the community pharmacists were shown to be competent to deal with such information and resolve any drug related problems with their general practitioner colleagues. The barriers to resolving such problems seem to be breaking down.
Further research has gone on to identify the potential risks for a readmission to hospital as a direct result of such drug related problems. The study found an increased time to readmission in the trial group who were provided with more detailed information regarding changes made to medicines whilst in hospital for patients to take to their community pharmacist. Previous admissions to hospital, increased numbers of prescribed drugs, complex acute diagnoses and changes to medicines all contributed significantly to this increased risk. All were related to prescribed drugs, all required the input from a medicines expert, the pharmacist. In addition to the wide body of research, policy documents have been produced in response to adverse events that occurred due to such communication breakdowns. These have provided detailed accounts of why such events occurred and guidance on how to prevent such breakdowns in the future. Lessons should be learnt. Pharmacists as the experts in medicines should now rise to the challenge of proving ourselves as experts in medicines management. Both my lecture and accompanying workshops will discuss the evidence, the research and the policies, share experiences from different settings and different countries to increase our understanding and to learn the lessons of seamless care.

ABS R2-2

WHAT DOES SEAMLESS PHARMACEUTICAL CARE LOOK LIKE?

J. MacKinnon
Dalhousie University Canada

Abstract - This presentation will introduce the eight essential elements of a safe and effective medication use system. Each element will be discussed in turn with attention paid to the importance of each element and what happens when that element is not in place. Practical solutions will be provided for each element. Participants should leave this presentation with a greater understanding of what encompasses a seamless pharmaceutical care system and how to obtain it in their practice setting.

ABS R2-3

INTEGRATED MEDICINES MANAGEMENT (IMM)

J.C. McElnay
Queen's University Belfast Northern Ireland

In Northern Ireland we (a collaboration between the Antrim Area Hospital and the School of Pharmacy at Queen's University Belfast) have developed an 'integrated medicines management' (IMM) service which addresses the three main stages of the 'patient's journey' while in hospital i.e. (i) admission, (ii) inpatient stay, and (iii) discharge. The service is delivered primarily by clinical pharmacists, with some aspects delivered by accredited pharmacy technicians. On admission an accurate drug list (Kardex) is constructed using information from the patient and/or carer, the patient's own drugs, the patient's GP and the patient's community pharmacist, and a pharmaceutical care plan is developed. During the inpatient stay the patient's drug treatment is reviewed and monitored, taking into account therapeutic goals, clinical laboratory findings and the patient's response to treatment. Data relating to this inpatient management are accessed and/or recorded via a handheld computer which connects wirelessly to the main hospital IT system. Counselling, tailored to meet the patient's needs, is carried out on a routine basis. At patient discharge, the clinical pharmacist draws up the discharge prescription and a medicine information sheet, while a pharmacy technician assesses which drugs need to be dispensed (taking account of the patient's own drugs which have been collected on admission. To help ensure continuity of care, letters are faxed to the patient's general medical practitioner (GP) and community pharmacist, outlining all medications, any changes in medication and pertinent findings while in hospital. Finally the patient is advised on follow-up care. The impact of the IMM service on a range of outcome measures e.g. length of hospital stay and hospital readmissions in the 12 months post discharge (both of which have been significantly improved) will be presented.

ABS R2-4

FROM HOSPITAL TO HOME - AUSTRALIAN RESEARCH

R.J. Moles
The University of Sydney Australia

In recent times, there has been much focus on the gap between health care settings, particularly with regard to patient discharge from hospital. Mechanisms to improve continuity including co-ordination and collaboration between providers and discharge planning, are processes by which continuity may be achieved. The Australian Pharmaceutical Advisory Council (APAC) in 1998 published the 'National guidelines to achieve the continuum of quality use of medicines between hospital and community'. Despite the wide distribution of such guidelines, the literature shows that there has been poor compliance with the guidelines. Processes and outcomes of Australian research in this area will be presented and discussed.

ABS R2-5

DATA EXCHANGE AS AN ESSENTIAL TOOL FOR IMPROVING SEAMLESS CARE

J.W.F. Van Mil[1], Th.F.J. Tromp[2]
[1]Van Mil Consultancy Netherlands [2]QIPC/Flevowijk pharmacy Netherlands

As far back as the eighties in the last century, the importance of data exchange in the interest of the patient was already recognised in the Netherlands. At that time GPs and community pharmacies in the same town or region started to use the same software for prescribing and dispensing and were linked by dedicated telephone lines.

With the increasing emphasis put on quality control in healthcare, other providers and the insurances also realised that data exchange could be beneficial for the patient. In 2000 NICTIZ, a platform between different umbrella organisations from patients, doctors and other providers, and insurances founded to stimulate the exchange of data between all workers in healthcare. By the end of 2006, all health care providers should be linked and ready for three types of data exchange: e-locum, e-medicines, and e-invoicing. This deadline probably will be postponed with another 1-2 years because of a number of practical problems, including the lack of necessary infrastructure, differences between systems (handshakes, coding), different sources for data about the same patient (GP/pharmacy/hospital), and identification and privacy issues. However, pharmacies, GPs, locums and hospitals already exchange information on a regional scale though OZIS or E-zorg.

During the presentation the current situation in the Netherlands will be outlined, and the barriers and facilitators for data exchange will be discussed.

ABS R2-6

THE PHARMACEUTICAL CARE INCLUDING RISK MANAGEMENT FOR PATIENTS IN JAPAN --COOPERATION BETWEEN HOSPITAL AND/OR COMMUNITY PHARMACIES AND PHARMACY SCHOOL--

Y.G. Gomita
Okayama University Hospital Japan

In Japan, to offer patients appropriate pharmaceutical care including risk management, the separation of pharmacy from hospital (or clinic) was institutionalized legally by the law for physician, dentist and pharmacist approximately 40 years ago. However, it had not been readily advanced for many years because of the long history that the physician gave medication. During the past two decades, the division of dispensing and pharmaceutical care in pharmacy has been developed and spread rapidly. At present, over 50 % of the dispensing of prescriptions given by hospitals and clinics to out-patients is being done at pharmacies in Japan. Some problems have not been completely cleared off this system yet. For example, the lack of rapid correspondence to emergency, insufficient skills of prescription-check & dispensing and the lack of medical instruction with sufficient information from the hospital are arisen as demerits in patient side. Effort is being done by the associations of hospital pharmacists and community pharmacists in some prefectures and areas to solve those problems that we have and to provide better pharmaceutical care for patients. Recently we initiated cooperation with medical doctors and community pharmacists have begun to visit patients' home for pharmaceutical care. It might become possible to carry out the individual medical treatment and care including risk management separately by physicians and pharmacists. In addition, collaboration between pharmacy school and hospital/community pharmacists is another key aspect in today's pharmaceutical care system with risk management. In many cases, immediate measures should be taken to cope with clinical emergency, such as an immediate assay of blood concentration of drug, drug information of new medicine and so on.

Therefore, a tie-up between pharmacy school and clinical sites as mentioned above is necessary for offering patients appropriate pharmaceutical care, and it may contribute to the risk management in medical scene.

BIO P1-1

BIOGRAPHY J.J. SASEEN

J. Saseen
University of Colorado United States of America

Dr. Joseph Saseen is an Associate Professor of Clinical Pharmacy and Family Medicine at the University of Colorado at Denver and Health Sciences Center in the United States. He received his B.S. and Doctor of Pharmacy degrees from the State University of New York at Buffalo, and completed an Ambulatory Care Research Fellowship at the University of Illinois/University of Colorado. Dr. Saseen is a Clinical Pharmacy Specialist in the Department of Family Medicine at the University of Colorado Hospital. Dr. Saseen is a board certified pharmacotherapy specialist with added qualifications in cardiology. He is a member of the board of regents and is a fellow of the American College of Clinical Pharmacy. Dr. Saseen has several publications and text book chapters related mostly to cardiovascular pharmacotherapy. He has won several teaching awards at the University of Colorado, most recently he was the recipient of the President's Excellence in Teaching Award in May of 2006.

BIO P1-2

BIOGRAPHY C-M. LEHR

C.-M. Lehr
Saarland University Germany

Professor Lehr is head of the Department of Biopharmaceutics and Pharmaceutical Technology at Saarland University, Germany since 1995. His scientific interest is focusing on biological barriers. One line of his research is dedicated to new cell culture models (e.g. lung, skin, eye), another one to advanced drug carrier systems (e.g. nanoparticles, liposomes and specific bioadhesion). Recently, his work has been recognized by the APV Research Award 2006 for Outstanding Achievements in the Pharmaceutical Sciences. Moreover, he coordinates the EU-funded GALENOS network (www.galenos.net) and the program 'Euro-PhD in Advanced Drug Delivery' to foster in-depth scientific training and international mobility of young pharmaceutical scientists.

ABS P1-1

THE FUTURE OF DRUG THERAPY AND THE EFFECTS ON PATIENT CARE

J. Saseen
University of Colorado United States of America

Cardiometabolic (hypertension, dyslipidemia, diabetes) and rheumatologic (rheumatoid arthritis) diseases cause significant morbidity and mortality. Pharmacotherapy options for these diseases have exploded over the past decade. Many new drug classes have been developed to treat these conditions, and this trend will continue over the next decade. Many new therapies are based on scientific discoveries have identified new components regarding the pathophysiology of disease. These novel agents represent treatment approaches that target the development and evolution of disease rather than just the subsequent clinical manifestations. The goal of this presentation is to use cardiometabolic and rheumatologic diseases as examples of how innovations in drug therapy can influence patient care. Predictions for advances in the near future that have the potential to significantly advance patient care will also be discussed.

ABS P1-2

DRUG TARGETING - VISIONS OF THE FUTURE

C.-M. Lehr
Saarland University Germany

Due to the advances of molecular biotechnology and bioinformatics, there is a strong increase of new candidate drug molecules. However, apart from their affinity to the target receptor, bioavailability and transport to the actual site of action is an important issue when it comes to developing such molecules to actual drug products. This holds in particular for macromolecular biopharmaceuticals, such as peptides, proteins, oligonucleotides or gene vectors, which normally cannot be administered orally. Instead, alternative routes of drug administration and new technologies for their controlled delivery have to be developed.

While the oral delivery of peptides and proteins still appears as a far goal, the transpulmonal delivery of peptides, such as e.g. insulin, is making good progress, and several drug products are currently being tested in advanced clinical studies. Unfortunately, there are no established in-vitro models of the blood-air barrier yet to screen compounds and to study the mechanisms of pulmonary drug transport. As a model of the alveolar mucosa, we use human alveolar epithelial cells in primary culture on permeable filters, which have a good morphological and functional resemblance to the alveolar air-blood barrier, as well as some bronchial epithelial cell lines.

In order to improve the delivery of still larger molecules, such as gene vectors, some special formulation will probably be required. Nanoparticles, prepared from lipids, polymers or inorganic materials may represent an alternative to viral gene vectors, especially with respect to cost and safety aspects.

Biographies - Innovative Healthcare Delivery (P 2)

BIO P2-1

BIOGRAPHY F.CHEN

F. Chen
The University of Sydney Australia

Dr Timothy F Chen

B Pharm, DipHPharm, PhD, MPS

Dr Tim Chen is a Senior Lecturer in Pharmacy Practice at The University of Sydney, Faculty of Pharmacy. He is an experienced researcher and educator. His doctoral research involved the first major Australian study evaluating the role of the pharmacist in conducting Home Medicines Review (HMR) and interprofessional collaboration with medical practitioners. This research and his subsequent studies in HMR have helped inform a national model for practice which has been taken up by the Australian Commonwealth Government. In recognition for his contribution to the advancement of Pharmacy Practice, he was awarded the Young Australian Pharmacist of the Year Excellence Medal, (2001). Dr Chen currently serves on a number of peak national pharmacy advisory boards. He is the principal author for two process-based case studies books for pharmacists and pharmacy students, in Medication Review (2002) and Pharmacist Only and Pharmacy Medicines (2003). He leads an active research team which includes PhDs, Masters and Honours candidates.

BIO P2-2

BIOGRAPHY M. SCHULZ

M. Schulz
ABDA Germany

Curriculum vitae

Professor Martin Schulz, PhD

Martin Schulz, PhD (born 1959, married, 3 boys), is an Adjunct Professor at Johann Wolfgang Goethe University, Department of Pharmacology, Frankfurt at Main, Germany. In his main job, he is Head of the Centre for Drug Information and Pharmacy Practice (ZAPP) of the ABDA - Federal Union of German Associations of Pharmacists, Berlin. In addition, Dr. Schulz is Director Pharmacy of the German Institute for Drug Use Evaluation (DAPI). He graduated as a pharmacist from the University of Hamburg, Germany, in 1983. From 1983-1984, he was a hospital pharmacist, and studied Medicine at the University of Hamburg from 1984-1986. In 1988, he obtained his Ph.D. in Pharmacology from the University of Hamburg. In 1989, he was named 'Expert in Pharmacology DGPT' by the German Society for Experimental and Clinical Pharmacology and Toxicology (DGPT). He specialized as a Drug Information Pharmacist in 1993. Evaluation and implementation of the pharmaceutical support (pharmacy practice, pharmaceutical care); Promotion of an effective and safe self-medication; Pharmacoepidemiology and -economics; Drug information and drug supply and -usage etc. are some of the areas where Dr. Schulz has expertise. Main interests: Outcomes research; Quality and effectiveness of interventions (in particular medicines); Drug information and regulation; Health-/pharmacoeconomics. He has nearly 350 publications to his name and has also delivered 215 lectures, seminars and has written some books as well. Dr. Schulz is a member in various committees and commissions like BfArM, Bonn; BMG, Berlin; FIP, The Hague, and serves on various advisory/expert committees.

BIO P2-3

BIOGRAPHY S. HUDSON

S. HUDSON
UNIVERSITY OF STRATHCLYDE United Kingdom

I graduated from the University of Nottingham in 1973 and registered as a pharmacist in 1974 and with Masters in Clinical Pharmacy from the University of Bradford in 1977, specialising in research in poisons information. I have worked as a hospital pharmacist specialising in drug information, intensive care, adverse drug reaction reporting and applied pharmacokinetics. From 1983 I worked as a joint appointment lecturer/clinical pharmacist and developed a MSc programme in Clinical Pharmacy first in Edinburgh then in Glasgow. From 1995 I have been in the post of Professor of Pharmaceutical Care at the University of Strathclyde and have developed postgraduate research in primary and secondary care settings by building a joint health service-university academic- practice team. I was a founder member, editor and chairman of the UK Clinical Pharmacy Association and was granted Fellowship of the Royal Pharmaceutical Society in 1998. I have developed courses in patient centred teaching with the European Society of Clinical Pharmacy over the past ten years. My current research interests are in developing and testing tools in pharmaceutical public health, the quality of medication use in various therapeutic areas and in methods of documentation and analysis of patients' pharmaceutical care needs.

BIO P2-4

BIOGRAPHY R.B. BAZOTTE

R.B. Bazotte
State University of Maringá Brazil

Degree in Pharmacy from the State University of Maringá, PR, Brazil (1980)

Master of Science (1983) and Ph.D (1989) from University of São Paulo, SP, Brazil

Postdoc (1990), University of Texas, Houston, USA

Faculty, Department of Pharmacy and Pharmacology, State University of Maringá

Researcher, National Council of Scientific Development and Technology (CNPq/Brazil)

Professional activities: 1. Teaching: 1.1 'Pharmacology' to undergraduate students; 1.2. 'Pharmaceutical care to diabetic patients' to Pharmacists; 1.3 – 'Effect of Natural Products on glycemia' to the Pharmaceutical Sciences Program (Master of Science and Ph.D). 2. Adviser: undergraduate, Master of Science and Ph.D students. 3. Researcher: 3.1 Experimental and clinical investigation of diabetes and related disorders.

Additional information:
http://buscatextual.cnpq.br/buscatextual/visualizacv.jsp?id=E61615.

Abstracts - Innovative Healthcare Delivery (P 2)

ABS P2-1

THE HOME AS THE CENTRE FOR HEALTHCARE DELIVERY

F. Chen
The University of Sydney Australia

The role of the pharmacist has changed significantly in recent decades, with a philosophical shift away from the traditional supply role, to a more professional role which encompasses the provision of pharmaceutical services for individual patients. The provision of home healthcare services by pharmacists is a good example. In general terms, this refers to provision of complex pharmaceutical products (eg home infusion therapy), clinical assessment and monitoring, in the patient's home. Moreover, increasingly, the boundaries between conventional healthcare settings, such as hospitals and community-based primary care centres, are disappearing. This presents a unique opportunity and challenge for pharmacists. The aim of this paper is to provide an overview of current pharmacy practice with respect to the provision of healthcare in the patient's home. The first part will describe, amongst other issues, a general process for patient assessment, clinical monitoring and education. It will also focus on why pharmacists are well positioned to provide home healthcare; and the challenges faced by them in the provision professional services in this context, such as the importance of maintaining continuity of care; professional role delineation and responsibilities; participation in specific educational and training programmes; documentation systems for pharmacists; and their role within a multidisciplinary healthcare environment. The second part of this paper will elaborate on the specific role of the pharmacist in facilitating the quality use of medicines through domiciliary medication management review. This is also known as Home Medicines Review in Australia, and is now a remunerable service in a number of countries. In particular, the mechanisms for introducing and integrating a pharmacist-led domiciliary medication management review service into existing processes of care will be discussed. In summary, pharmacists are well positioned to play a central role in the provision of healthcare for patients living at home. This opportunity for pharmacists is likely to expand as the home healthcare market expands and as the expertise of pharmacists in medication management is increasingly recognized by other members of the healthcare team, policy makers and government.

ABS P2-2

INNOVATIVE HEALTH CARE DELIVERY 'THE HOSPITAL OF THE FUTURE

S. Thielke
University of Wisconsin Hospitals United States of America

The structure of the hospital of the future in the United States has been changing from a facility providing primarily inpatient services to patients to a health system offering a broad array of services such as ambulatory care (specialty and primary car), long term care, home health care, outreach services through Tele-medicine, and an extensive retail service portfolio. In order to provide theses new services hospitals have reorganized into strategic business units with a combination of for profit and not for profit corporate structures. Hospitals of the future will market their business units through several service lines which they profess to have regional market growth potential such as Cardiac, Oncology and Neuroscience Services. The hospital of the future has invested heavily in information technology to provide care givers seamless electronic medical record information to their patients care across the continuum i.e. inpatient care, ambulatory care, long term care, home care etc. These health systems are also investing in an information technology infrastructure to support an extensive Tele-medical service for Cardiology, Intensive Care and Neuroscience specialty services to smaller hospitals in their geographic region. In addition ancillary services such as radiology, clinical laboratories and pharmacy are providing Tele-Services for specialty care via Tele-Radiology, Referral Laboratory Service and Tele-Pharmacy order review for after hours services and Drug Policy decision making.

The health systems will market these specialty area services directly to consumers based on outcome data demonstrating their safer and improved quality services. The successful health systems of the future will align the organization decision making and shared governance with the medical staff. Medical staff organizations will develop risk sharing agreements with the health system to assure evidence based practice. Marketing these evidence based patient care practices across the service lines will become the norm. Patient care referral agreements with smaller hospitals in the health systems region will be based on access to secondary and territory care through shared service agreements supported by outcome data. The referring physicians will have direct access to the patient's electronic medical record to assume seamless communication.

The health system pharmacy structure of the future will mimic the health system structure. The pharmacy will provide a wide array of patient care clinical services from inpatient to outpatient to long term care and to home care. The pharmacy service will also provide contract management services to small hospitals, drug information services, a network of retail pharmacy services, mail order services as well as managed care services through pharmacy benefit management services. Extensive drug dispensing and information technology will be utilized by these health system pharmacy operations.

ABS P2-3

TRADITIONAL AND ALTERNATIVE ROUTES IN THE SUPPLY CHAIN

M. Schulz
ABDA Germany

Pharmaceuticals provide health benefits for people worldwide. Attention has recently not only focused on the price of pharmaceuticals but also on the dispensing costs within the different supply chains. More and more the way of distribution from the manufacturer to the patient stands in the center of reforming processes. Brand and generic drugs are traditionally distributed from the manufacturer through wholesalers to the pharmacy and then to the patient who presents a prescription for the medicine. Additional distribution channels also exist that exclude wholesalers and/or pharmacies. Parallel and cross border trading of pharmaceuticals or availability of medicines through mail order (via the Internet, fax or post) services exist in many countries. Outlets or retailers other than pharmacies can provide some pharmaceuticals. For example, home care or disease management services already include pharmaceutical services and supply of devices for the treatment of diseases such as diabetes, asthma, cancer, HIV/AIDS, or hypertension. Repackaging of pharmaceuticals and unit dose services are being implemented more often outside secondary or long-term care facilities. Different players are entering the global pharmaceutical markets. For example, a parallel- and cross border trading company in the middle of Europe announced to provide 600,000 primary care patients with a unit dose/blister service soon, suitable only for 400 different solid, oral dosage forms of drugs. This company has already announced that it will try to catch up to 10 million patients all over Europe in the coming years. In the very near future, smart card technologies or E-pharmacy - E-prescription including electronic patient record systems - will offer new opportunities, also for new routes in the supply chain, in Europe and North America and probably other continents. The more widespread application of pharmacogenomics may further change the supply chain for pharmaceuticals. Home and integrated care programs (e.g., 3rd party payers, HMO/PBMs, health plans), OTC marketing, and direct-to consumer (DTC) advertising and selling, patient tracking technologies, an increasing number of hospital outpatients, and products being switched from prescription-only to OTC-status and made available outside pharmacy, will also have an influence. These alternative supply chains will increasingly challenge the traditional ones. Pharmacists in the future will need to develop and implement more than one supply chain system and have a strong strategy and an innovative business model to maintain control over the quality of pharmaceuticals and there availability to patients. Some promising examples will be highlighted.

ABS P2-4

INNOVATIONS AND THEIR EFFECT ON HEALTHCARE PROFESSIONALS

S. Hudson
University of Strathclyde United Kingdom

Health care advances involve innovations in procedures or treatments (new technologies) and in ways of working. Innovations in healthcare can lead to

- More specialised care in some cases.
- Widening of the use of technology in other cases, to include non-specialists.
- Standardised treatment allowing it to be delivered to an assured quality
- Improved teamwork in the delivery of care
- Changes in patients' expectations, their needs and wants.
- Organisational change affecting quality/efficiency
- Major demands on continued education and professional development.
  Generation of the need for research

Health care professionals now, as always, function in a climate of technological change in health care. For this presentation I wish to consider how the pharmacy profession is adapting to the need to evolve the delivery of pharmaceutical care in response to the demand for more effective healthcare. The above consequences of innovations will be illustrated with examples from pharmaceutical care developments.

The common ground linking universities to hospitals has been established through the need to teach healthcare practitioners in patient care settings. That common ground also provides opportunities for collaboration in research. In the past two decades the concept has emerged of an academic practice unit sited within a hospital as a focal point for research. This concept has shifted to be rather less about a physical site and more about an effective network.

An academic practice network of pharmacists linked to a School of Pharmacy has emerged in various countries.. The establishment of joint research with hospital pharmacists has created the opportunity to include such research within the pre-graduate students' experience. The presentation will examine the effects of practice research on the development of pharmacists and their relationship with other healthcare professionals.

ABS P2-5

INVESTIGATION OF RISK FACTORS TO CORONARY HEART DISEASE IN TWO COUNTRYSIDE BRAZILIAN VILLAGES

R.B. Bazotte
State University of Maringá Brazil

The aim of this study was to investigate risk factors to coronary heart disease, in two countryside Brazilian villages, typical in terms of the poverty and lack of access to public health care. All population was invited to participate in the study. The 462 volunteers (mean age = 42 years) showed high prevalence of hypercholesterolemia (7.0%), hypertriglyceridemia (19.0%), hyperglycemia (11.0%), hypertension (30.0%) and obesity (16.0%). The majority of the individuals, during the interview did not report the diseases detected by the exams. The results obtained from the exams and interviews showed that the high prevalence of hyperlipidemia, obesity, hypertension and diabetes mellitus resulted of the delayed detection of these diseases or inadequate treatment after diagnostic

ABS P2-6

PHARMACY RESIDENCY TRAINING IN THE UNITED STATES

F. Ivey
Health Alliance of Greater Cincinnati United States of America

Pharmacy residency training in the United States will be presented. Important characteristics of successful graduate pharmacist applicants, 2007 training standards, expected residency training outcomes and specialty residency training

will be reviewed. Logistics for the national pharmacy resident matching program and career positions after residency certificate completion will be presented. The growth of residency training in both applicants and training sites will be reviewed.

Certificate of pharmacy residency training as a credential for future practice and for public scrutiny will be reviewed.

Biographies - Using Innovations to Improve Patient Safety (P 3)

BIO P3-0

BIOGRAPHY F.SCHMIDT
F.S. Schmidt
ABDA-Federal Union of German Association Germany

Friedemann Schmidt, MSc pharm,born 1964, married, 3 children; degree in pharmacy 1988 University of Greifswald; owner of a community pharmacy in Leipzig.

President of the chamber of pharmacists in Saxony, one of the german federal states, Vice-President of ABDA – Federal Union of German Associations of Pharmacists, the head organisation of the 17 chambers of pharmacists and 17 community pharmacy owners' associations in the Federal States, i.e. all pharmacists in Germany.

BIO P3-1

BIOGRAPHY R. GONÇALVES
R.G. Gonçalves
Plataforma Saúde em Diálogo Portugal

Universitary Education
PhD – Queen's College – University of London
MD - Nutrition- Queen's College – University of London
DM – King's College – 3 years; Internship – University Hospital- London
DM – First 3 years- Medical College- University of Lisbon

Remunerated Work
Professor of Nutrition at the Queen Elizabeth College – Department of Prof. Yudkin - University of London (until 1971);
Superior Technic of Nutrition - Ministério do Trabalho- Direcção Geral de Assistência – Lisbon- Portugal (until 1986);
Retired – 1986

Voluntary Work
Teacher of Nutrition of the Third Age Academy of Lisbon- of the Union of Portuguese from 1987 to 1997.
As a patient of Sistemic Lupus Erythematosus since 1971, co-founded with another MD and patient an Association for Lupus Patients in 1992 –we have now about 2 800 Patients as Associates.
From 1998 since now represent the Association at the Platform Health in Dialogue, having been re-elected as representative of the Patients Associations at the Permanent Secretariat.
As one of the founders of IAPO collaborate with them by Email at Documents, Congresses, etc.
As representative of the patients was invited to meetings by the WHO and EU.
Congresses, Forums, Meetings
During these years I attended more than sixty, of different kinds and at several countries.
Communications, Conferences and Written Articles
As professional and also as a patient, I have done quite a lot, especially in Portuguese, English and French languages.
Languages: Portuguese, English, French, Spanish – proficiency- speaking, reading and writing Italian, German – able to read and understand when talking.

BIO P3-2

BIOGRAPHY H. HERBORG
H.H. Herborg
Pharmakon, Danish College of Pharmacy Pr Denmark

Hanne Herborg, MSc (Pharm), Director R&D, Pharmakon, Danish College of Pharmacy Practice.

Hanne Herborg is Director for Competence Development and Research and Development for community pharmacy at Pharmakon. Ms Herborg has been responsible for the large controlled multicentre trials of pharmaceutical care programmes in Denmark and for developing an evidence database for community pharmacy. At present, patient safety, implementation research ,and patient adherence in primary care is the research focus. Hanne Herborg has been author, co-author and editor of several reports and general and scientific articles, lecturer at national and international congresses. She is affiliated as external examiner in Social Pharmacy at the Danish University of Pharmaceutical Sciences and is a member of the board of the University's master programme: Master in Drug Management. Ms Herborg was the first chairman of the Pharmaceutical Care Network Europe (PCNE), she is Danish task force member for EuroPharm Forum's Hypertension Project and she is a member of FIP's Post Graduate Education Planning Commitee.

BIO P3-3

BIOGRAPHY C.A. CATIZONE
C.A. Catizone
NABP United States of America

Mr. Catizone is the executive director of the National Association of Boards of Pharmacy (NABP) and secretary of the Association's Executive Committee. NABP is an international organization whose membership includes every state boards of pharmacy in the United States including the District of Columbia, boards of pharmacy in Guam, Puerto Rico, and the Virgin Islands, eight provincial pharmacy regulating agencies in Canada, two state boards of pharmacy in Australia, New Zealand, and South Africa.

The purpose of NABP is to: (1) assist the state boards of pharmacy in protecting the public health and welfare, (2) serve as an information and disciplinary clearinghouse for the interstate transfer of licensing among the state boards of pharmacy, and (3) provide model regulations in order to assist the state boards of pharmacy with the development of uniform practice, educational, and competency standards for the practice of pharmacy.

Abstracts - Using Innovations to Improve Patient Safety (P 3)

ABS P3-1

THE INCREASINGLY IMPORTANT ROLE OF PATIENTS ORGANISATIONS

R.G. Gonçalves
Plataforma Saúde em Diálogo Portugal

1. The patients organizations were born not very long ago, and had not very good beginnings. A long way has been done step by step, and nowadays we are quite well accepted.

2. In a very strange way we have been helped and fighted by doctors. The WHO and EU are nowadays hearing patients organisations and patients, about several matters.

3. The patients knowledge is increasing with the work of patients organisations, the media help and the internet. However health illiteracy is still a serious problem ,that we are trying to solve.

4. Health teams are larger than doctors and nurses, and pharmaceutics have been on our side.

5. Patients safety, prescriptions, new drugs, pharmacovigilence, new health services,

health education- these are some new fields where we all must cooperate.

6. Protocols with Universities, Scientific Societies, etc, are means the patients organizations are using to develop and better their work.

ABS P3-2

INTEGRATIVE MANAGEMENT OF PRESCRIPTION AND PATIENT RISK FACTORS

H.H. Herborg
Pharmakon, Danish College of Pharmacy Pr Denmark

Objective: To present and discuss integrated pharmacy based primary care programmes aimed at ensuring safe and effective drug-use among users of anti-hypertensive and Type 2 Diabetes medicines.
Methods: Two programmes have been developed and are currently being tested in research projects.
I.'Implementation of drug therapy. Improved adherence and self-management among users of anti-hypertensive medicines'. Program development took place in 2004-5. From February 2006 to February 2007, the program is being tested in 250 patients in a controlled study.
II.'Safe and effective use of medicines in Type 2 Diabetes'. Programme development is finalized summer 2006. Test in 80 patients will take place from October 2006.
Intervention:
Patients showing signs of non-adherence are included in the studies. The patients are assigned to either a comprehensive or a basic version of the multidimensional intervention programmes.
The programmes consist of:
·Quick screening for non-adherence and identification of problem types
·Patient story-telling as the key starting point
·Assessment and possibly adjustment of drug therapy
·Finding resources in the patient-system
·Individual coaching, in order to tailor solutions to individual needs and resources
·Offering relevant reminder technology
·Offering patient information, instruction, and education
·Follow up
·Close collaboration with patient's GP
Conclusion
The projects have developed a wide range of tools to support professionals in assessment of risks and resources and patients in medicine taking, building concordance relations, and getting their medication problems assessed. They have induced change in pharmacy performance and competence in relation to implementation of drug therapy. Both versions of the programmes are feasible.

ABS P3-3

THE ROLE OF THE INTERNET-THREATS AND OPPORTUNITIES FOR PATIENT SAFETY

C.A. Catizone
NABP United States of America

The Internet is a remarkable medium that offers unparalleled opportunities for improving how we live and how pharmacist care and information about medications can be delivered to patients. Legal and legitimate Internet pharmacies serving patients in the United States are providing valuable and innovative services to their patients as well as a wealth of valuable information and patient resources. The innovations of the Internet when used effectively and in conjunction with traditional face-to-face patient interactions can dramatically improve patient safety. However, among legal and legitimate operating Internet pharmacies are the activities of rogue pharmacy sites whose concerns do not rest with the best interest of the patient or compliance with state and federal laws.

The presentation will explore the Internet's impact on the delivery of pharmacist care and impact on patient safety in an environment of legal and illegal pharmacy sites.

BIO P4-0

BIOGRAPHY C. ANDERSON

C .W. Anderson
University of Nottingham United Kingdom

Claire Anderson is Professor of Social Pharmacy and Director of the Centre for Pharmacy Health and Society at the School of Pharmacy, University of Nottingham, UK. She is President of the Academic Section of International Pharmaceutical Federation (FIP) and on the board of the College of Pharmacy Practice. Her major research interest is about the role of community pharmacists in improving the health of the public. Claire Anderson has published over 60 refereed papers and numerous conference abstracts. Perhaps the most important piece of research she has produced is the strategic research for Pharmacy HealthLink and the Royal Pharmaceutical Society of Great Britain, investigating the broader public health role of pharmacy. She has also been Nottingham's principal investigator in a high profile, collaborative research project that has the potential to radically restructure the role of community pharmacists. The Community Pharmacy Medicines Management Project, a Department of Health funded multi-centre, randomised controlled trial, has evaluated the role of pharmacists in advising patients and prescribers concerning appropriate treatment for coronary heart disease. Her team along with reserachers at The univeristy of Sheffiled are evaluating supplementary prescribing by nurses and pharmacists for the Department of Health, this is a major study which will inform both policy and practice in this area.

BIO P4-1

BIOGRAPHY B.J. JÖNSSON

B. Jönsson
Lund University Sweden

Bodil Jönsson,

Professor of Rehabilitation Engineering, Lund University, www.english.certec.lth.se/bodil

Honorary Doctorate from the Faculty of Education, Göteborg University, Sweden

Ph.D. in physics, Lund University, Sweden

Cooperation with Apoteket AB, Sweden, on a consultant basis

Member of the former International Forum on Medicines, www.ifom.org

Author of 'Ten Thoughts on Time', Brombergs, 1999, available in more than 15 languages

BIO P4-2

BIOGRAPHY A.M. IVAMA

A.M.I. Ivama
National Health Surveillance Agency Brazil

Adriana Mitsue Ivama, PhD in Pharmacy (Public Health, Health Legislation and History of Sciences, University of Alcalá, Alcalá de Henares, Madrid, Spain, 1999) and Specialist in Teaching Methodology (State University of Londrina, Brazil, 1998).

She has been appointed Specialist in Regulation and Health Surveillance from National Health Surveillance Agency - Anvisa (Ministry of Health, Brazil) in 2005. She works at the chief of Staff office supporting the projects of the cooperation agreement PAHO/WHO and Anvisa, the rational use advisory board and related issues.

From 2002 – 2005, she worked as a national professional officer at the Unit of Medicines and Health Technologies of the Pan American Health Organization/World Health Organization – PAHO/WHO, Brasilia, Brazil. She was professor and researcher at the Collective Health Department/Health Sciences Centre (2000 and 2002). She is member and was part of the executive board of the Rede Unida: a national network for education of healthcare professionals.

Her major areas of interest are related to regulation of medicines and pharmaceutical services, rational use of medicines and pharmacy education and pharmacy practice in public health settings.

BIO P4-3

BIOGRAPHY J. LYLE BOOTMAN

J. Bootman
University of Arizona United States of America

Dr. Bootman is Dean of the University of Arizona, College of Pharmacy. He is a Professor of Pharmacy, Medicine and Public Health, and a Fellow of several professional associations including the American Pharmacists Association, American Association of Pharmaceutical Scientists and the American College of Apothecaries. He is the Founding and Executive Director of the University of Arizona Center for Health Outcomes and PharmacoEconomic (HOPE) Research, one of the first such centers developed in the world. He is a former President of the American Pharmacists Association and currently serves as President of the Pharmacy & Therapeutics Society. Dr. Bootman received his pharmacy education at The University of Arizona and his doctorate at The University of Minnesota where he was given the 'Outstanding Achievement Award', the University's highest Alumni honor. Additionally, he completed a clinical pharmacy residency at the world-renowned National Institutes of Health. Dr. Bootman has authored over 250 research articles, books and monographs, and has been an invited speaker at more than 400 professional healthcare meetings and symposia. In 1997, he was selected as one of the 50 most influential pharmacists in the U.S. by American Druggist, and has received numerous outstanding scientific achievement awards, most notably from the American Association of Pharmaceutical Scientists and the Academy of Pharmaceutical Science and Research. He was the recipient of the George Archambault Award, the highest honor given by the American Society of Consultant Pharmacists and the Latiolais Honor Medal, the highest honor in managed health care. He has published several books including the first text introducing the Principles of Pharmacoeconomics, which is utilized in more than 35 countries and translated in six languages. His research regarding the outcomes of drug-related morbidity and mortality receives worldwide attention by the professional and public media. He serves as an advisor to leading pharmaceutical companies, universities and health care organizations throughout the world. Dr. Bootman is an elected member of the Institute of Medicine of the National Academies, where he currently serves on the Board of Health Care Services.

BIO P4-4

BIOGRAPHY J.J. DE GIER

J.J. De Gier
University of Groningen Netherlands

J.J. de Gier (Han) PharmD, PhD, born 1951, received his Pharmacy B.S, M.Sc. and Ph.D. degrees (the latter in 1980) from the University of Utrecht. He started his private company to serve as scientific consultant in 1984. He has been appointed professor of Pharmaceutical Care at Groningen University in the Netherlands since 2003.

Prof. De Gier is President of the Section of Pharmacy Information (since 2000) and a member of the Board of Pharmaceutical Practice Programme Committee within the International Pharmaceutical Federation (FIP). He serves as President on the Executive Board of the International Council on Alcohol, Drugs and Traffic Safety (ICADTS). He is consultant specialized in issues concerning drugs and driving to the Dutch Ministry of Transport, Public Works and Water Management, the Directorate General for Transport of the Commission of the European Communities and the Pompidou Group of the Council of Europe.

Abstracts - Innovations in Learning and Education (P 4)

ABS P4-1

THE PATIENT AS A TEACHER

B. Jönsson
Lund University Sweden

The patient as a teacher
Bodil Jönsson, professor, Lund University, Sweden
The concepts of empowerment, learning and enabling have all undergone basic changes during the rise of the information age. This has in turn yielded substantial operational changes in the healthcare and medication sectors – better information, second opinions, e-prescriptions, new forms for distribution, etc. However, there are other levels than the operational ones to consider – 'the enlightened patient' is not only about improving patient information leaflets, no matter how important these may be. When reconsidered and given due status, the experienced/ lived health and illness will increasingly influence the course that health as well as illness takes. The 'subjective', i.e. the experienced, has a value of its own, not only when answering questions from the professionals.
Superficially, the approach may appear to be about the power of the consumer, but it is even more about enabling, empowering and learning than about conflict and demands. Mutual respect for and coexistence of personal experiences and professional knowledge does not arise on its own, especially not since it must at times rely on overlap, at times on pure complementarity. On the experiential side, the lived side, there is a need for new concepts, new personal measuring methods, and new formulations of demands on medication subordinated to the life you want to live. The patient community of practice requires tools and opportunities to develop its knowledge as has been the case for centuries for the professional community of practice. Meanwhile, old phenomena such as the 'placebo effect' (the 'meaning effect' for the patient) and side effects of different kinds might acquire another flavour.

This will be the context and the aim of my lecture, 'The patient as a teacher'. At the latest FIP conference in New Orleans, I had the opportunity to introduce 'Patient Experiences and the Value of Medicines' with thoughts and a report from the International Forum on Medicines, http://www.ifom.org , the former think-tank of FIP. Now, I will try to go a few steps further, both practically and conceptually. The majority of examples will come from Sweden, as does the book 'Is the medicine helping?' (written in close co-operation with the Swedish Apoteket AB). The book will be available during the conference.

ABS P4-2

A COMMON UNDERGRADUATE CURRICULUM FOR ALL HEALTHCARE PROFESSIONALS – DREAM OR REALITY?

A.M.I. Ivama
National Health Surveillance Agency Brazil

The guarantee of access, care quality and user's safety in a sustainable and rational form are issues that are in the daily agenda of most countries in the world, when also health issues suffer reforms and budgetary restrictions, and the fast renewal and availability of health technologies, not always cost-effective or necessary are witnessed. We also live another challenge, resulting from the (re) professionalization of the pharmacist.
In Brazil, the Unified Health System (SUS), although still undergoing a developing process has provided important steps ahead towards the guarantee of its presuppositions of universal access, equity, integrality, resolution, hierarchization, regionalization and participation of the community.
It is not sufficient for the pharmacist to possess knowledge, he/she also needs to have adequate abilities and attitudes to face this scenario as a constant apprentice. In Brazil, although discussions over the possibility of the existence of a Public Health professional have already taken place, that was not the model adopted by the country. With the higher education reform, National Curricular Guidelines where established for underdegree courses and a common profile for all heath professionals was defined which establishes the following competencies: healthcare; decision-making capacity; communication; leadership; administration and management, lifelong learning and education orientation towards the Health System and the community.
These curricula are currently being implemented and the main difficulties have been the restricted availability of trained professors for the activities that are more directly related to healthcare or health promotion, such as pharmaceutical care, pharmaceutical services, health surveillance or rational use of drugs as well as in teaching and learning methodologies;
It is worth outlining that the country has a tradition in the social participation for the definition of public policies in the health area. The Ministries of Health and Education, in a partnership with the academic world, the representatives of health managers and non-governmental institutions have not just been involved in the reorientation of public policies, but also in the training of change activators in education and apprenticeship processes, in the promotion of curricular reform processes with the strengthening of a community-oriented education. As access to medicines and healthcare, the strengthening of human resources is also incorporated in State Policies, in order to guarantee a common basis for the performance as health professionals in an integrated form.

ABS P4-3

COMPETENCIES FOR HEALTH PROFESSIONALS IN THE 21ST CENTURY

J. Bootman
University of Arizona United States of America

J. Lyle Bootman, Ph.D., Sc.D.

Professor of Pharmacy, Medicine and Public Health

World Congress of Pharmacy & Pharmaceutical Sciences

August 30, 2006

Salvador Bahia, Brazil

The purpose of this presentation is to discuss the need for changes in health professions education to attain core competencies. Over the past decade, the delivery and financing of healthcare in the United States and the world has been changing rapidly. For the past several years the major concern continues to center around the rising costs of healthcare as well as serious issues centering on quality and safety. As we move through this century, there appears to be more of an attempt to balance the outcomes of care with the costs so that cost effective decisions can be made relevant to various medical interventions such as drug therapy. Much work has been published from the National Academies' Institute of Medicine that delineate the possible solutions. Highlights will be discussed with implication for the health professions and pharmacy in particular. In order for the pharmacist to optimally practice pharmaceutical care various educational strategies need to be further refined and implemented across all of the health disciplines. New subject areas or emphasis topics should be considered to improve the pharmacy curriculum. Discussion on these areas, along with the process in which this material should be incorporated into the program will be put forth. Addressing the necessary competencies for the 21st Century will better enable the graduate to directly influence the drug therapy needs of patients so to achieve appropriate outcomes of care.

ABS P4-4

NEW EDUCATIONAL TOOLS

J.J. De Gier
University of Groningen Netherlands

This paper describes a pharmacy practice game GIMMICS (the Groningen Institute Model for Management in Care Services) as a model for teaching and training students in managing pharmaceutical services and care processes. It provides a teaching environment for integrating knowledge with social, managerial and communicative skills under controlled conditions. It allows participants to initiate, plan, execute and control activities themselves, and to reflect on their actions.

The design of the game will be clarified and its format, rules and assessment system will be discussed. During a period of 4 weeks pharmacy teams of 5 students have to manage, on a full time basis, a community pharmacy. They are confronted with assignments divided in 3 categories: routine assignments (e.g. processing prescriptions), long-lasting assignments (e.g. negotiations with third parties) and incidents, like a visit of the Healthcare Inspectorate. The team that shows the best performance, based on outcomes of assignments and reflections on their own activities, becomes the winner.

Student surveys (2000-2005) clearly indicate that GIMMICS is a successful educational provision. Student state that they not only enjoy playing the game, but it really helps them to integrate knowledge and skills and be better prepared for their internships. GIMMICS is a successful innovation in the pharmacy curriculum at the Groningen University that has also been adopted by other schools of pharmacy (e.g. Utrecht, Brussels).

Biographies - Combating Counterfeiting (P-S 1)

BIO PS1-1

BIOGRAPHY V.R. REGGI

V.R. Reggi
WORLD HEALTH ORGANIZATION Switzerland

Valerio Reggi, graduated in 1978 from the University of Milan, Italy, Faculty of Pharmacy, and received his Post-doctoral Degree in Pharmacological Research in 1982 from the Mario Negri Institute for Pharmacological Research in Milan, Italy. He worked at the Mario Negri Institute as researcher until 1986 when he joined Unicef in New York as Programme Manager, Essential Drugs. He joined the World Health Organization in Geneva in 1989 where he has occupied different positions. He is currently responsible for the International Medical Product Anti-Counterfeiting Taskforce (IMPACT).

BIO PS1-2

BIOGRAPHY J. M. NICHOLSON

M.J.N. Nicholson
FIP WG on Counterfeit Medicines United Kingdom

Jane is an industrial pharmacist and was a Vice -President of FIP from 1994-2002. She is a Fellow of FIP and is currently an Expert Member of the Board of Pharmacy Practice and Convenor of their Working Group on counterfeit medicines.

She is a past President of IPSF and Chairman of Information and Education for the Federation.

Author of a number of articles on product registration and regulatory requirements for pharmaceuticals, patient access and labelling of medicinal products and on the reclassification from prescription to pharmacy status.

Speaker on regulatory affairs, pharmaceutical education and the practice of pharmacy at meetings in the U.K., most other countries of Europe and in Canada, Australia and the U.S.A. Jane is British representative to EIPG and currently holds the presidency of the European Industrial Pharmacists Group.

BIO PS1-3

BIOGRAPHY D. N. AKUNYILI

N. Akunyili
NAFDAC Nigeria

Prof. Dora Nkem Akunyili (OFR) is an internationally renowned Pharmacist, Pharmacologist, Erudite Scholar, Seasoned Administrator, and a visionary leader. She assumed office as the Director General of National Agency for Food and Drug Administration and Control (NAFDAC), on the 12th of April 2001.
Born on 14th of July 1954, she got her first Degree in Pharmacy B.Pharm (Hons) in 1978 and her P.hD in 1985 from University of Nigeria Nsukka (U.N.N.) and was promoted to the rank of a Professor in October, 2000 by the same University.
Prof. Akunyili started her working career as a Hospital Pharmacist from 1978-1981, in the University of Nigeria Teaching Hospital (U.N.T.H) Enugu, after which she ventured into Academics as a Graduate Assistant (Research Fellow) in the Faculty of Pharmaceutical Sciences, U.N.N. from 1982-1986. In the University system, she made a steady progress from lecturer I in 1986 until she was made Senior Lecturer in 1990.
She transferred to College of Medicine, U.N.N. in 1992, where she was made a Consultant Pharmacologist in 1996, a position she held until 12th April 2001.
Prof. Akunyili is a Post Doctorate Fellow of University of London and a Fellow of the West African Post Graduate College of Pharmacists.
As a Scientist and a Scholar, she has presented 20 papers in various Local and International Scientific Conferences, published two books and 33 Journal Articles.
Prof. Dora Akunyili is a member of many learned societies among which are; the Pharmaceutical Society of Nigeria (P.S.N.), New York Academy of Sciences, Nigerian Society for Pharmacology, West African Society for Pharmacology, International Union of Pharmacology, International Pharmaceutical Federation, to mention but a few.
For her industry and commitment to the values of honesty and transparency, Prof. Akunyili has received over 288Awards and Recognitions from organizations and governments in Africa, Europe and America.

Prof. Akunyili is a devout Catholic and is happily married to Dr. J.C. Akunyili, of the University of Nigeria Teaching Hospital, Enugu, Nigeria and they are blessed with six children.

Her hobbies include reading and writing.

ABS PS1-1

COMBATING COUNTERFEIT DRUGS: THE INTERNATIONAL MEDICAL PRODUCT ANTI-COUNTERFEITING TASKFORCE

V.R. Reggi
WORLD HEALTH ORGANIZATION Switzerland

The need for greater international cooperation in combating counterfeit medical products has been reiterated several times. The establishment of an International Medical Products Anti-Counterfeiting Taskforce, IMPACT, has been endorsed at the Conference on 'Combating Counterfeit Drugs: Building Effective International Collaboration' held in Rome on 16-18 February 2006 by 160 participants representing 57 national drug regulatory authorities, 7 international organizations, 12 international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers.. The Rome conference issued a set of principles and recommendations, enshrined in the Declaration of Rome, calling for WHO to lead the establishment of IMPACT and set the conceptual framework for IMPACT's work. In order to strengthen WHO action against counterfeit medical products and to ensure the implementation of the recommendations of the Rome Conference WHO has established the IMPACT Secretariat which will ensure the effective operation of IMPACT through effective cooperation with other agencies and NGOs such as INCB, Interpol, OECD, WCO, WIPO, WTO, World Bank, European Commission, Council of Europe, ASEAN Secretariat, IFPMA, WSMI, IPGA, IAPO, FIP, WMA, ICN, IFPW, GIRP.

ABS PS1-2

FIP ANTI-COUNTERFEITING ACTIVITIES

M.J.N. Nicholson
FIP WG on Counterfeit Medicines United Kingdom

It has been called 'the emerging crime of the 21st century'. The counterfeit medicines business is now worth an estimated 50 billion dollars a year. The increasing complexity of the supply chain and the use of mail order and internet purchasing of medicines have made the counterfeiter's job easier. Countries cannot tackle counterfeiting in isolation.

For the past 3 years, an FIP Working Group has been helping to implement the Federation's Policy on Counterfeit Medicines. This presentation will provide an update of our activities which include:

* Publication of further advice to pharmacists and patients on the FIP website

* Collection of training materials on counterfeiting for pharmacy students

* Worldwide review of the current national laws with the aim of generating model anti-counterfeiting legislation

* Analysis and detection of counterfeits and the evaluation of medicines distributed through alternative channels

It is a war out there and the fight to safeguard the patient is the role of every pharmacist.

ABS PS1-3

COMBATING COUNTERFEITING

N. Akunyili
NAFDAC Nigeria

Counterfeiting especially of pharmaceuticals is the greatest evil of our time and the highest weapon of terrorism against public health. It is an act of economic sabotage, an ill wind that blows nobody any good.

Criminal networks that perpetrate counterfeiting of products have operated unchallenged in many countries for over two decades. The business of counterfeiting of pharmaceuticals had minimal risk and was so lucrative that it slowly became a global menace with no geo-political boundaries. Countries that hitherto did not have counterfeit medicines are beginning to detect such products even in their official distribution channels. The driving force being corruption and conflict of interest, insecure and unfriendly environment, discriminatory regulation by exporting countries, inadequate legislation, sophistication in clandestine drug manufacture, etc. Concerted efforts are being made globally by countries and international organizations to combat counterfeiting especially of pharmaceutical products and ensure that there is no safe haven in any country for counterfeiters. In 2001, the present Management of the National Agency for Food and Drug Administration and Control (NAFDAC) came on board with drastic measures to tackle the scourge of counterfeit drugs and has recorded tremendous success. This article throws more light on global trend in counterfeiting, factors encouraging the evil act, implications as well as challenges faced in combating counterfeiting. It also lays emphasis on measures taken by Nigeria to combat the menace.

BIO PS2-0

BIOGRAPHY F.J. VAN DE VAART

F.J. Van de Vaart
KNMP/WINAp Netherlands

Dr. Frans van de Vaart graduated as a pharmacist in 1979. He joined the Royal Dutch Association for the advancement of Pharmacy (KNMP) in 1980, where he worked in the analytical laboratory. In 1986 he finished a dissertation on the analysis of creams. In 1988 he became head of the laboratory. In the early nineties he explored the possibilities to introduce quality management in the pharmacy. This resulted e.g. in the Dutch Pharmacy Standard and a certification system for pharmacies. In 1996 all professional activities of KNMP were bundled in the Scientific Institute of the Dutch Pharmacists (WINAp). Since 2001 Frans van de Vaart holds the position of director of this institute.

BIO PS2-0

BIOGRAPHY S. KEITEL

S. Keitel
Federal Institute for Drugs and Med. Dev Germany

Dr. Susanne Keitel is a licensed pharmacist and holds a Ph.D. in pharmaceutical technology. Her working experience includes 10 years in pharmaceutical development in industry, 5 years of which as head of the department 'Pharmaceutical Development' at Schering AG, Berlin. From October 1997 to June 2005, Dr. Keitel held the position of Division Head Pharmaceutical Quality at the Federal Institute for Drugs and Medical Devices (BfArM), Germany. In addition, she served as Acting Head of the division European Procedures.

As of July 2005, Dr. Keitel is now head of EU and International Affairs at BfArM. She is vice-chair of the Joint CHMP/CVMP Quality Working Party and a member of the EMEA Paediatric Working Party, the Notice to Appliciants Group and has been rapporteur for the ICH stability guidelines. At present, she is EU topic leader of the Expert Working Group 'Pharmaceutical Development' (ICH Q8). Furthermore, Dr. Keitel chairs the Special Interest Group 'Quality of Pharmaceuticals' of FIP as well as the Expert Group 'Drug Regulatory Affairs' of APV.

BIO PS2-1

BIOGRAPHY T.P. LAYLOFF

P. Layloff
Supply Chain Management System United States of America

Thomas Layloff, Ph.D.

Dr. Layloff serves as Quality Assurance Manager, Supply Chain Management System (SCMS), for the US 'President's Emergency Plan for AIDS Relief' in Arlington, VA. He also is a Special Government Employee to the U.S. Food and Drug Administration Center for Drug Evaluation and Research (CDER) as a member of the Manufacturing Advisory Sub-Committee and Past-Chair of the Pharmaceutical Analytical Technology (PAT) Sub-Committee. These committees are advisory to CDER in the development of a guidance documents which will address the incorporation of new technologies into the approval and inspection processes.

Prior to joining SCMS he served as Principal Program Associate for Pharmaceutical Quality, Management Sciences for Health (MSH), Arlington, VA on the Bill and Melinda Gates Foundation funded 'Strategies to Enhance Access to Essential Medicines' (SEAM) primarily in Tanzania and Ghana. Prior to joining MSH he was Vice-President and Director of the Pharmaceutical Division for the United States Pharmacopeia. He also previously served in CDER as Associate Director for Standards Development (Rockville, MD) and for over 20 years as the Director of FDA's leading pharmaceutical testing laboratory in St. Louis, MO.

He is a Past-President and Fellow of AOAC International and Fellow of the American Association of Pharmaceutical Scientists.

BIO PS2-2

BIOGRAPHY S.H. JIN

S.H.J. Jin
Nat. Inst. for Control of Pharm.& Biol China

Prof. Shaohong Jin received the BS in Medicinal Chemistry from Beijing Medical College in 1970. From 1980 to 1982 he was an invited Visiting Scholar engaged in quality control of antibiotics at the Bureau of Drug Research, Health Protection Branch (HPB) Canada. During 1990's he spent two and half years as a Senior Visiting Scholar for study on mechanism of bacteria resistance at Istituto Superiore di Sanità Italy.

Since 1996 Prof. Jin has been promoted as the Deputy Director and Executive Deputy Director of National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) and he has been appointed as the Director General of National Center for ADR monitoring since 2006. He was former Chief of Division of Antibiotics of NICPBP for over 10 years. He is the Adjunct Professor of Chinese Academy of Medical Sciences and China Pharmaceutical University.

Prof. Jin is the member of Chinese Pharmacopoeia Committee and Chairman of Sub-Committee on Antibiotics, the member of China National Accreditation Board for Laboratories. He is also the member of WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations. In 2005 he was elected as a member of the Reference Standards Expert Committee of United States Pharmacopoeia (USP).

For the past 30 years, his research interests have focused on safety evaluation and quality control of pharmaceutical products. Prof. Jin has published over 150 scientific papers and received more than 10 National Awards for Development of Science and Technology.

BIO PS2-3

BIOGRAPHY A.C. MOFFAT

A.C. Moffat
School of Pharmacy, University of London United Kingdom

He is Professor of Pharmaceutical Analysis at The School of Pharmacy, University of London where he heads the Centre for Pharmaceutical Analysis. The Centre provides a focus for research and education in pharmaceutical analysis within The School and is extending the world-class knowledge base in that field. In particular, Near-Infrared Spectroscopy is being used: to further the technique, increase its use in the pharmaceutical industry and get it accepted by the regulatory authorities.

He was previously Chief Scientist at the Royal Pharmaceutical Society of Great Britain where he gave advice on scientific matters to the Society's Council and other departments within the Society. Part of his duties was to write policy papers concerning the scientific aspects of pharmaceutical health care and how it may be delivered to the community at large. He has extensive knowledge at first-hand of pharmacy in the community, academic and hospital settings, and has excellent links to the pharmaceutical industry. He also acted as the Society's scientific spokesperson for the media.

He has over 300 publications as well as the co-authorship of 7 books (including Clarke's Analysis of Drugs and Poisons).

His awards include the British Pharmaceutical Conference Science Award, Society of Analytical Chemistry Silver Medal, Philip Allen Award of the Forensic Science Society, joint award of the BUCHI 2002 Award, the Academy of Pharmaceutical Sciences Medal and the Royal Pharmaceutical Society's Charter Gold Medal.

He is currently a member of a number of Committees including the British Pharmacopoeia Commission.

ABS PS2-1

SCREENING TESTS TO DETECT COUNTERFEIT PRODUCTS

P. Layloff
Supply Chain Management System United States of America

Implementing rapid screening test procedures to detect counterfeit products at Ports of Entry (POE) is the best means to protect the marketplace. Since at the POE the products have not been admitted through customs they have no legal status and since they are not in distribution entry denial provide thorough protection. Rapid screening tests do not appreciably stall the entry process so essential medicines which are of good quality may be cleared quickly. Some experience with the use of Thin Layer Chromatography (TLC) to screen product quality will be presented.

ABS PS2-2

A POWERFUL SCREENING SYSTEM FOR THE DETECTION OF COUNTERFEITS DEVELOPED IN CHINA

S.H.J. Jin
Nat. Inst. for Control of Pharm.& Biol China

Since Counterfeit drug is a vile and directly impacts on human health. The State Food and Drug Administration (SFDA) China has made great effort to combat this serious criminal offence. The National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) in China developed a mobile laboratory vehicle for drug screening tests, which mainly consists of information system, TLC system, wet chemical reaction system and non-destructive detection system-----Near Infra-Red spectrometer (NIR) in a modified vehicle. There are more than 600 drug preparations including anti-malaria, anti-AIDs, anti-TB and other essential drugs could be tested in

mobile laboratory. Both qualitative and quantitative NIR models of macrolide antibiotics were established. According to the pilot study in Hubei province China in 2005 more than 60% of suspected samples screened by drug mobile laboratory were confirmed as counterfeit, adulterated or substandard drugs. The Chinese government has allocated 70 million USD to equip 400 drug mobile laboratory vehicles for local drug regulatory authorities, which will play very important roles in health protection for patients living in Chinese rural areas.

BIO S1

BIOGRAPHY P.W. SWAAN

W. Swaan
University of Maryland at Baltimore United States of America

Dr. Peter Swaan is an Associate Professor of Pharmaceutical Sciences and Vice-Chair for Research at the University of Maryland in Baltimore, MD. He received his Ph.D. in Biopharmaceutical Sciences from Utrecht University in The Netherlands (1993) He was a postdoctoral fellow at the University of California, San Francisco until he accepted a faculty position at the Ohio State University in 1996. He received the AAPS New Investigator Award in Pharmaceutics and Pharmaceutical Technology in 2000. He is a member of the editorial board for The AAPS Journal, the Journal of Pharmaceutical Sciences and serves as Editor for Pharmaceutical Research. He has published over 60 original research articles focusing on all aspects of transport proteins in drug targeting and delivery, pharmacokinetics and pharmacodynamics.

BIO S1

BIOGRAPHY A. MEHTA

A. Mehta
Mehta Consulting LLC United States of America

Dr. Atul Mehta recieved a Ph.D. in Pharmaceutics from the University of Maryland in 1981. He was associated with Ayerst Laboratories (now Wyeth Ayerst) from 1981 to 1984 in the solids fromulation section as Group Leader. His responsibilities included development of formulations and processes for ethical drugs for conventional and controlled-release dosage forms both for the USA and international markets.Dr. Mehta joined Nortec, a Glatt group company in 1984 and was Vice-President until 1989. He was responsible for the procurement and development of products for several multinational pharmaceutical companies. In addition, the products selected and developed by Dr. Mehta at Nortec have led to several U.S. Patents, licensures and commercialization both in the United States and overseas markets. In 1990 he founded Elite Laboratories, Inc., a company specializing in Oral Drug Delivery Systems and he served as Chairman, President and CEO of Elite until June 2003.

Dr. Mehta is a Registered Pharmacist in the State of Maryland and has practiced retail and hospital pharmacy. He has also worked for United States Pharmacopoeia and several pharmaceutical companies overseas (Roche, Pfizer, Pharmpak).

He is an inventor in over 15 U.S. and International Patents and several more applications have been filed. He is currently working as a consultant for Mehta Consulting LLC in the pharmaceutical/biotechnology area.

BIO S1

BIOGRAPHY R.O. WILLIAMS III

R.O. Williams III
University of Texas at Austin United States of America

Bill Williams is the Johnson & Johnson Centennial Professor of Pharmaceutics at the College of Pharmacy, University of Texas at Austin. He earned a B.S. in Biology from Texas A&M University, a B.S. in Pharmacy from the University of Texas at Austin and Doctor of Philosophy in Pharmaceutics in 1986 from the University of Texas at Austin. Dr. Williams worked 9 years in the pharmaceutical industry in the United States and France before returning to the University of Texas at Austin. Dr. Williams is a member of the American Association of Colleges of Pharmacy, American Association of Pharmaceutical Scientists, American Chemical Society, Association de Pharmacie Galenique Industrielle, Controlled Release Society, and European Federation of Biotechnology. Dr. Williams' research interests include development of novel drug delivery systems for oral, pulmonary, nasal, injectable, buccal and topical applications, development of novel particle engineering technologies for low molecular weight drugs, peptides and proteins, and analytical technologies to characterize actives, excipients and polymers. He has published over 80 articles and book chapters in the fields of pharmaceutical technology and drug delivery. He is an inventor on numerous patents and patent applications. Dr. Williams is the Editor-in-Chief of the research journal Drug Development and Industrial Pharmacy, and serves as a reviewer for International Journal of Pharmaceutics, Pharmaceutical Research, European Journal of Pharmaceutics and Biopharmaceutics, S.T.P. Pharma Sciences, AAPS PharmSciTech, Journal of Pharmaceutical Sciences, Pharmaceutical Development and Technology, Journal of Membrane Science, and Journal of Controlled Release.

BIO S1

BIOGRAPHY R.L. WILLIAMS

R.L.W. Williams
U.S. Pharmacopeia United States of America

Roger L. Williams, M.D., has been the executive vice president and chief executive officer of the United States Pharmacopeia (USP) since April 2000. Working with a staff of nearly 400, Dr. Williams provides strategic leadership for USP at the direction of USP's Board of Trustees. Dr. Williams also serves as chair of the Council of Experts, USP's scientific body, which continuously revises the United States Pharmacopeia and National Formulary. Since joining USP, Dr. Williams has led a re-engineering effort designed to assure that USP's products and services meet the needs of its constituencies. These constituencies include practitioners and patients/consumers who seek safe, effective, and good quality therapeutic products as well as pharmaceutical manufacturers, compounding professionals, and many other stakeholders. Dr. Williams has reorganized the structure of the Council of Experts, brought focus to its science-based decisions, and has aligned USP's efforts with other pharmacopeias throughout the world. He has established stakeholder forums that promote communication with and input from pharmaceutical and dietary supplement manufacturers, compounding professionals, patient safety advocates, and USP's membership. He is USP's lead representative for international activities and outreach efforts to the many professional groups and societies who share USP's public health mission. The strength of USP's public programs has allowed USP to expand its public health mission both nationally and internationally. For instance, USP will soon be establishing a site in India and will also be publishing the USP-NF in Spanish. Dr. Williams received his undergraduate degree at Oberlin College and his medical degree and training in internal medicine at the University of Chicago. He served in the United States Army, both in Korea and at Walter Reed Army Institute of Research, where he conducted anti-malarial drug research. After completing a fellowship in clinical pharmacology at the University of California, San Francisco, in 1974, he continued as a faculty member until 1989. He joined the Food and Drug Administration in 1990 as the director of the Office of Generic Drugs in the Center for Drug Evaluation and Research, moving to associate director in the Center in 1993 and deputy center director for pharmaceutical science in 1995. In this capacity, he had oversight for the Center's Office of New Drug Chemistry, Office of Generic Drugs, Office of Clinical Pharmacology and Biopharmaceutics, and Office of Research and Testing. Dr. Williams is a member of the medical honor societies Phi Beta Kappa and Alpha Omega Alpha. He is a fellow of the American Association of Pharmaceutical Scientists, an expert member of the International Pharmacy Federation (FIP) Board of Pharmaceutical Sciences, and represents USP at the World Health Organization. He has authored or co-authored approximately 175 reports in the areas of clinical pharmacology, patient safety, biopharmaceutics, and pharmaceutical chemistry, and has published books on clinical pharmacology and regulatory science. He retains an adjunct appointment at UCSF, serves on the Board of Overseers for the University's School of Pharmacy, is a member of Pharmaceutical Foundation Advisory Council of the College of Pharmacy at the University of Texas at Austin, and serves on the Board of Directors for the American Society for Clinical Pharmacology and Therapeutics. Dr. Williams is a board-certified internist and clinical pharmacologist.

ABS S1

APPLICATION OF FLUIDBED PROCESSING TECHNOLOGY FOR DRUG DELIVERY

A. Mehta
Mehta Consulting LLC United States of America

Fluidbed processors are being increasingly employed to develop and manufacture modified release drug delivery dosage forms. This is particularly true for multi-particulate systems such as coated powders, actives, crystals, granules, ion exchange resins and pellets. Different types of fluidbed equipment and their applicability in the manufacture of such dosage forms will be reviewed. Pertinent process variables that can influence the end perfomance of these products will be discussed along with case studies.

ABS S1

MANUFACTURING CHALLENGES FOR PRODUCTION OF NANOPARTICLES

R.O. Williams III
University of Texas at Austin United States of America

Nanotechnology is a rapidly expanding field and its applications in the pharmaceutical industry are becoming more apparent as advancements continue to develop. Much of the current pharmaceutical research is focused on developing nanoparticle technologies that enhance drug delivery by increasing efficacy or improving safety and patient compliance. Some of the drug nanoparticle production methods that have been investigated include various mechanical processes, emulsification techniques, as well as supercritical fluid and cryogenic technologies. Recently, four particle engineering technologies have been reported specifically aimed at reducing drug particle size to enhance the wetting, dissolution rate and bioavailability of drugs that exhibit dissolution rate-limited absorption. These processes are known as Evaporative Precipitation into Aqueous Solution (EPAS), Controlled Precipitation (CP), Spray-Freezing into Liquid (SFL), and Ultra-Rapid Freezing (URF). The EPAS technology utilizes rapid phase separation to produce an aqueous dispersion of stabilized drug nanoparticles. This is accomplished by spraying a solution of drug dissolved in a water miscible organic solvent into an aqueous solution at elevated temperatures. As the organic solvent evaporates, the aqueous phase quickly supersaturates with drug causing rapid precipitation in the form of suspended particles. These particles may be stabilized to prevent particle agglomeration and growth during re-crystallization by a variety of stabilizing excipients present in either the aqueous or organic phases. With the CP process, hydrophobic drug is dissolved in a water miscible organic solvent that is rapidly, yet controllably mixed with an aqueous phase (antisolvent) causing sudden supersaturation of drug in the aqueous phase leading to rapid nucleation and formation of small particles. Similar to the EPAS process, stabilizers can be added either to the organic or aqueous phases to prevent particle agglomeration during solvent evaporation and to enhance wetting and dissolution of the resulting powder containing CP micronized drug. The benefit of this controlled process is that it allows drug particles to be formed with the desired particle size and morphology. SFL is a cryogenic process that uses atomized spraying and rapid freezing to produce primary drug nanoparticles that are amorphous. With this process, a solution of drug and excipient stabilizers is sprayed through an atomizing nozzle below the surface of a liquid cryogen reservoir. The atomized droplets of feed solution are rapidly frozen upon contact with the cryogenic liquid preventing phase separation of solute and resulting in the formation of amorphous, high surface area nano-structured aggregates. The resulting frozen product is lyophilized to produce a dry, free flowing powder. URF also utilizes rapid freezing of drug/excipient feed solutions to produce micron to sub-micron aggregates of amorphous drug nanoparticles. In contrast to the batch SFL process, URF can be a continuous process whereby the feed solution is rapidly frozen when applied onto a cryogenically cooled solid substrate. The frozen product is continuously collected from the surface of the substrate for downstream solvent removal by lyophilization with the end product being a dry, free-flowing powder. For each of these four processes, it has been shown that with the incorporation of appropriate hydrophilic stabilizers the dissolution rate and bioavailability can be dramatically increased for drugs that exhibit dissolution rate-limited absorption. The enhanced dissolution rates have been attributed to one or more of the following particle attributes (1) increased surface area available for dissolution resulting from reduced drug particle size, (2) metastable morphology, (3) optimized wetting characteristics by adsorption of hydrophilic stabilizers to the drug surface. These attributes all relate directly to the nanoparticle production processes, and therefore illustrate the importance of nanoparticle technology for enhancing the performance of pharmaceutical products.

ABS S1

NANOTECHNOLOGY: NEW TECHNOLOGIES IN DRUG DELIVERY AND DRUG DEVELOPMENT

R.L.W. Williams
U.S. Pharmacopeia United States of America

New technologies in drug delivery have offered many benefits to practitioners and patients. These include modified release dosage forms, first for oral administration, and more recently for parenteral administration, new approaches to deliver medicines topically and transdermally, new routes of administration, and increasingly sophisticated ways to bring life-saving medicine directly to the site of action. While advances have been impressive, the human body generally allows only five primary routes of administration: by-injection (parenteral), by inhalation, oral, topical, and mucosal. Nanotechnology is being explored from a number of standpoints to determine whether it will join the impressive array of new drug delivery and other technologies that have advanced patient care. Its applications are prodigious and cover virtually all types of medicines, devices, cosmetics, and foods. Overarching issues and opportunities for nanotechnology are considered in the US National Nanotechnology Initiative, which involves 23 US government agencies. FDA is one of these agencies and has formed an internal group (Nanotechnology Interest Group) to monitor progress and coordinate activities. Key issues arising in connection with FDA regulation include: a) determination of primary mode of action for drugs and devices employing nanotechnology; b) regulatory action occurring well after development of a specific application relying on nanotechnology; and c) absence of a regulatory approval process for many FDA-regulated articles, thus precluding careful scrutiny of safety and allied issues. At this time, there are few if any medicines under FDA's purview that explicitly rely on nanotechnology. Nonetheless, expectations are high that nanotechnology may be used in many positive ways, e.g., to promote absorption and/or delivery to the site of action of both noncomplex (small) and complex (proteins, other) drug substances. USP believes that some aspects of a drug substance or dosage form that rely on nanotechnology may require control, depending on safety and efficacy impact. USP at this time has not produced a General Chapter that provides information on such control, although several General Information Chapters in development speak to specialized aspects of nantechnology, like the use of DNA and RNA microarrays. Also, no monograph in the United States Pharmacopeia-National Formulary provides control specific to nanotechnology, although some documentary standards in USP control particle size. To keep abreast of cutting edge science and technical approaches, the USP 2005 Convention concluded the following resolution:

USP resolves to work with appropriate stakeholders to track emerging sciences and technologies, and when appropriate, to develop information, best practices, and standards that have direct application to the public health and patient care.

To address this resolution, the Council of Experts Executive Committee for the 2005-2010 cycle formed an Advisory Panel (Chair: Dr. James Akers). This Panel will be populated with experts in a number of rapidly advancing science and technical areas, and representation on the topic of nanotechnology is planned. USP welcomes exchange of information about the deliberations of this Advisory Panel and will work to provide such information to interested parties.

BIO S2-0

BIOGRAPHY D.M. BARENDS
D.M. Barends
RIVM Netherlands

Dirk Maarten Barends was educated as a pharmacist and high school teacher in chemistry.

After having obtained this grade in pharmacy in 1976 he hold a position at the University of Utrecht, lecturing on quality control/quality assurance. After his Ph.D. in 1985 he took a position as Head of Quality Control in the pharmaceutical industry.

Joining the Dutch Authority in 1987 he became Head of Pharmaceutical Assessments of the Medicines Evaluation Board in1988, being the Dutch representative in the Quality Working Party of the CPMP until 1998. He was chemical-pharmaceutical Expert of the EMEA, Expert of the Certification Scheme of the Ph.Eur. and member of its Technical Advisory Board.

He is now employed by the RIVM, the Dutch National Institute of Public Health. His main responsibility is running a research programme to support the evaluation of the technical quality of medicines by Dutch and European health authorities. The core of this research program is the development of biorelevant analytical methods and specification setting, based on in-vivo/in-vitro relationships. His is (co) author of 50 scientific publications and contributes to conferences & workshops with invited lectures.

Dirk Barends is co-chairman of the Groupe BCS of the International Pharmaceutical Federation FIP and project leader of its Biowaiver Monographs project.

Besides pharmacy his main interests are hill walking in France on 'les sentiers de grande randonnée' and writing short stories, inspirited by these activities.

BIO S2-1

BIOGRAPHY A.O. ARANCIBIA
O. Arancibia
Universidad de Chile Chile

Graduated as pharmaceutical chemist at the University of Chile. Postgraduate training at the universities of Pavia, Italy, and California, San Francisco, USA.

Profesor of the Department of Pharmaceutical Sciences and Technology. Faculty of Pharmaceutical Sciences and Technology. Has published about 150 works in pharmaceutical sciences, education and professional. Doctor Honoris causa of the University of Auvergne, France. FIP Scientific Award 2000.

BIO S2-2

BIOGRAPHY S. STORPIRTIS
S.S. Storpirtis
BRAZILIAN AGENCY SANITARY SURVAILLENCE Brazil

Sflvia Storpirtis is a pharmacist who received her PhD degree in 1992. She is also specialist in Clinical Pharmacy and Pharmacokinetics and member of the Brazilian Society of Hospital Pharmacy.

She has been teaching at the Faculty of Pharmaceutical Sciences of the University of Sao Paulo in Brazil since 1988, since 2000 as Associated Professor. She is the Director of Hospital Pharmacy and Laboratory Division at the University Hospital, since 1992.

Her research is related to Biopharmaceutics, specially Dissolution, Bioavailability and Bioequivalence. She has been collaborated in investigations of formulation properties using thermo analytical techniques.

As a consultant for the Brazilian Agency for Sanitary Surveillance (ANVISA), she has been working actively in the elaboration and revision of the technical regulations for generic and similar products in Brazil.

More recently she is in charge of the Committee of Pharmaceutical Equivalence, Dissolution, Bioavailability and Bioequivalence linked to Brazilian Pharmacopoeia (FARBRAS) and member of the Bioequivalence Working Group in the scope of the Pan American Network for Drug Regulatory Harmonization – PANDRHA, supported by the Pan American Health Organization/World Health Organization – PAHO/WHO, since 2000.

BIO S2-3

BIOGRAPHY J.E. POLLI
J.E. Polli
U of Maryland School of Pharmacy United States of America

Dr. James E. Polli is Associate Professor of Pharmaceutical Sciences at the University of Maryland School of Pharmacy. He received a B.S. in Pharmacy from the Philadelphia College of Pharmacy and Science and a Ph.D. (pharmaceutics) from the University of Michigan. Dr. Polli's research interest evolves around the performance and pharmaceutical quality of orally administered medicines. His two main research interests are maximizing oral bioavailability through formulation and chemical approaches and developing public quality standards for oral dosage forms. He has published in the areas of dissolution, drug intestinal permeability, prodrug design, oral bioavailability, in vitro - in vivo correlation, and bioequivalence. He serves as AAPS PDD Chair-Elect, Co-Chair of the FIP BCS Working Group, and member of the WHO Special Interest Group on BA/BE and the USP Expert Committee on Biopharmaceutics. He is an Editorial Board member of Journal of Pharmaceutical Sciences, Molecular Pharmaceutics, Pharmaceutical Research, European Journal of Pharmaceutical Sciences, AAPS PharmSci, and Pharmaceutical Technology. Dr. Polli has received the AAPS New Investigator Award in Pharmaceutics and Pharmaceutical Technology. He is a licensed pharmacist and teaches professional pharmacy students and graduate students.

BIO S2-4

BIOGRAPHY K.K. MIDHA

K . Midha
University of Saskatchewan Pharmalytics Canada

Dr. Midha is Adjunct Professor of the College of Pharmacy and Nutrition, University of Saskatchewan, Saskatoon, Canada. Dr. Midha's innovative approaches to drug studies have yielded over 300 research articles, and he has received numerous research awards from all over the world, which include the Kolthoff Gold Medal from the American Pharmaceutical Association, Washington D.C. USA; Research Achievement Award from The World Congress of Pharmaceutical Sciences Kyoto, Japan; Eminent International Scientist Award from the Indian Drug Manufacturers Association, Mumbai, India. In 1995, Dr. Midha was invested with Canada's highest award, The Order of Canada. Dr. Midha is Vice-President of the International Pharmaceutical Federation (FIP) and his leadership in pharmaceutical sciences has included chairmanship of the Board of Pharmaceutical Sciences of FIP, co-chairmanship of Bio-International Conferences sponsored by FIP and the American Association of Pharmaceutical Scientists, and membership on the editorial boards of several journals. He is a recognized authority on issues of bioavailability, bioequivalence, bioanalysis, pharmacokinetics, and pharmacodynamics. Dr. Midha works globally with pharmaceutical industry as an advisor.

Abstracts - Bioequivalence and BCS (S 2)

ABS S2-1

OVERVIEW OF GENERIC DRUG APROVAL PROCESS

O. Arancibia
Universidad de Chile Chile

The national health and drug regulatory authotorities should ensure that all the pharmaceutical products subjects to their control are in conformity with acceptable standards of safety, efficacy, and quality, and comply with Good Manufacturing Practice (GMP) standards. Generic or multisource products to be accepted should meet GMP, quality control specifications, and pharmaceutical product interchangeability. These points are discussed in thispresentation.

ABS S2-2

APPLICATION OF BIOANALYTICAL METHODS VALIDATION IN BIOAVAILABILITY, BIOEQUIVALENCE AND PHARMACOKINETIC STUDIES

S.S. Storpirtis
BRAZILIAN AGENCY SANITARY SURVEILLANCE Brazil

Method validation is the process of demonstrating that the analytical method is suitable for its intended use. The validation process establishes documented evidence that provides a high degree of assurance that the test method will consistently provide accurate test results that evaluate a product against its defined specification and quality attributes.

Validation of bioanalytical methods is considered as an essential part required in support of drug products registration in the case of new drug applications (NDA) and abbreviated new drug applications (ANDA). The development of a bioanalytical method validation protocol should be based on the requirements of the product specification and regulatory guidelines. A protocol should include the target method to be validated, pre-approved validation elements, and acceptance criteria, as well as the description of the requirements for protocol execution, experimental design, and a procedure when acceptance criteria are not met.

It is important to stand out that the instrumentation selection, the standards qualification, and the adequate number of trained personnel are critical aspects. For bioavailability, bioequivalence and pharmacokinetic studies, mainly when the quantification of metabolites is required, the HPLC and GC procedures are widely used specially with mass spectrometric detection (LC-MS, LC-MS-MS, GC-MS, GC-MS-MS).

A typical validation includes accuracy, precision, linearity, quantification limit, specificity, stability, recovery, and robustness parameters. The validation report should also contains the documented discussion of any deviation from the protocol, justification of the deviation, and the analysis of the impact on the results obtained.

As the Brazilian experience with bioavailability and bioequivalence studies is growing since 1999 with the implementation of technical requirements for generic drug applications, general issues are discussed about the guideline of bioanalytical methods validation used by ANVISA, the evaluation process of these dossiers and the measures adopted to improve the knowledge in this field.

ABS S2-3

BCS: MEASUREMENTS OF SOLUBILITY AND PERMEABILITY

J.E. Polli
U of Maryland School of Pharmacy United States of America

The BCS allows for the waiver of in vivo bioequivalence studies for certain IR products, by considering solubility, permeability, and drug product dissolution. The objective of this presentation is to discuss methodological approaches to measure solubility, permeability, and dissolution to BCS classify a drug, including literature sources and in silico approaches. Permeability assessment will be emphasized. Additionally, example classifications will be discussed (Potthast H et al. J Pharm Sci 94:2121-31 2005)

The shake-flask method is well accepted to measure solubility. After equilibration between excess drug and volume, suspension is filtered and quantified. Final pH should be verified; re-adjusting pH and re-equilibration is often necessary. Literature references (e.g. Merck Index) have been employed to estimate solubility class (e.g. Kasim NA et al. Mol Pharm 1:85-96 2004; Lindenberg M et al. Eur J Pharm & Biopharm 58:265-78 2004). Regarding drug product dissolution, compendial apparati are favored, although the selection of specific parameters is often product specific. The FDA BCS defines rapidly dissolving as no less than 85% dissolved in 30 min, using USP Apparatus 1 at 100 rpm (or Apparatus 2 at 50 rpm) in 900mL or less in each of three specific media that differ in pH.

The FDA BCS guidance defines highly permeable as 90% or more extent of human absorption, based on mass balance or comparison to IV. Such data are often not available, such that permeability is desirable. High permeability is assessed relative to a reference compound (e.g. metoprolol). Scientific consensus favors reducing 90% cut-off to 85%, with some Class 3 biowaivers possible (Polli JE et al. J Pharm Sci 93:1375-81 2004). Permeability methods include in situ animal intestinal perfusion, excised animal tissue, and cell culture. Cell culture (e.g. Caco-2) will be discussed, along with other issues (e.g., active drug efflux, method suitability).

ABS S2-4

WHO GUIDELINES ON REGISTRATION REQUIREMENTS TO ESTABLISH INTERCHANGEABILITY

K . Midha
University of Saskatchewan Pharmalytics Canada

This guideline makes recommendation to sponsors for the requirements of a multisource (generic) pharmaceutical product approval in their respective countries. The appropriate in vitro and in vivo requirements are discussed. It is imperative that the national health and drug regulatory authorities by which a particular product is controlled assures that the acceptable standards of safety, efficacy, quality and good manufacturing practice are met to assure interchangeability and thus therapeutic equivalence to the comparator product. In turn this can be achieved when the multisource product is both pharmaceutically equivalent or pharmaceutical alternative and bioequivalent. Test methods often used to establish equivalence may include comparative pharmacokinetic studies in humans, comparative pharmacodynamic studies in humans, comparative clinical trials and comparative in vitro tests. Acceptance of such tests in the documentation of equivalence will depend on many factors, i.e. formulation and the active pharmaceutical ingredient (API).

The guideline deals with bioequivalence issues of drugs with long half lives, considerations for genetic phenotyping, standardization of study conditions and selection of the comparator product. The need for studying of metabolites, enantiomers as well as bioequivalence studies under fed or fasting states are also discussed. Special considerations in dealing with highly variable drugs, fixed dose combination products and the applicability of truncated metrics in establishing bioequivalence are presented.

The new BCS system and appropriateness of biowaivers based on solubility, permeability (API) and dissolution (dosage form) are presented and discussed with recommendations to extend biowaivers from Class I (highly soluble and highly permeable) to Class 2 (low solubility/high permeability) and Class 3 (high solubility/low permeability). Qualifications for biowaivers based on dose proportionality of formulations which are proportionally similar are discussed. In this presentation I shall discuss some pivotal points of the revised WHO guideline highlighting when it differs from the earlier version and how it compares to guidelines of other countries and regions.

BIO S3

BIOGRAPHY D.J.A. CROMMELIN

D.J.A. Crommelin
Dutch Top Institute Pharma Netherlands

Daan J.A. Crommelin, Ph.D.

Prof. Daan Crommmelin is presently scientific director of the Dutch Top Institute Pharma in Leiden. He is also professor at the Department of Pharmaceutics at Utrecht University. He is adjunct professor at the Department of Pharmaceutics and Pharmaceutical Chemistry at the University of Utah. Crommelin is Chief Scientific Officer of OctoPlus, a Leiden based company specialized in the development of pharmaceutical product formulations and advanced drug delivery systems. He published extensively and is on the editorial board of 10 peer reviewed journals in the pharmaceutical sciences. He presently chairs the Board of Pharmaceutical Sciences of the International Pharmaceutical Federation (F.I.P.) and is chair of the organizing committee of the Pharmaceutical Sciences World Conference 2007 in Amsterdam. He is president elect of the European Federation of Pharmaceutical Sciences (EUFEPS).

BIO S3

BIOGRAPHY L. ODA

L.M. Oda
ANBio Brazil

Leila Oda has been graduated in Chemistry in 1974, master and doctor in Microbiology and Immunology by the Federal University of Rio de Janeiro, having developed thesis on surface antigens characterization of microorganisms. She has made post-doctoral studies abroad, amongst them one in evaluation of risks of GMOs in the Center of Genetic Engineering and Biotechnology, Trieste, Italy. It was member of the Brazilian Biosafety Committee- CTNBio in the period of 1996-2000, being president of the Committee during two years. She is senior researcher of the Oswaldo Cruz Foundation- Fiocruz working on Biosafety programmes and researches, since 1982. She was responsible for the implantation of the Control of Quality of Vaccines in the National Institute of Quality Control in Health and of the Biosafety Nucleus of Fiocruz. She was consultant for the World Health Organization and to the Pan-American Health Organization in the subjects of quality control of vaccines and Biosafety during the period 1982-1986, co-ordinating the self-sufficiency Brazilian program in biological products at Fiocruz. She has published more than 100 articles on scientific magazines, books and books' chapters. She is at this moment FAO's ad hoc consultant for the subject of risks analysis of GMOs. She has made several consultation trips to Latin America and the Caribbean aiming the implantation of Biosafety systems in these countries. She is member of the Scientific Advisory Committee of the United Nations University for Latin America and the Caribbean and president of the Biotechnology Committee of India-Brazil Chamber. She established the National Biosafety Association- ANBio and she is the Chair of this scientific society since 1999.

ABS S3-1

BIOTECHNOLOGY DRUGS: HOW ARE THEY DIFFERENT FROM OTHER DRUGS?

A.R. Moreira
SPI USA Inc. United States of America

Classical pharmaceutical drugs are made up of small synthetic molecules which are produced by a prescribed method. On the other hand, biotechnology drugs are larger and heterogeneous molecules manufactured from living cells by very specific processing in a sterile environment. These drugs differ from pharmaceutical drugs in their size, complexity, structure and method of manufacture. Such products include therapeutic proteins and other products obtained by genetic engineering techniques, as well as cellular and gene therapy products.

Biotechnological drugs are derived from living organisms. They are difficult to quantify and often easily subject to damage by factors such as heat, light, and shear forces. They are also prone to contamination from many sources which can be difficult to detect and remove. They interact with the human body in many ways that can trigger an immune response.

This presentation will provide an overview of the key characteristics of biopharmaceutical drug products and of the corresponding manufacturing technologies. It will highlight the importance of the manufacturing process on the final product quality attributes and the scientific challenges associated with the development of these products under strict regulatory agency compliance requirements.

ABS S3-2

DELIVERY OF THERAPEUTIC BIOTECH PRODUCTS

D.J.A. Crommelin
Dutch Top Institute Pharma Netherlands

Pharmaceutical proteins are large, often physically and chemically unstable molecules. These characteristics lead to two special features typical for these molecules: 1) formulating proteins (assessment of quality, selection of dosage form, stability) is a complicated matter, 2) the predominant route of administration is the parenteral route.

Formulating pharmaceutical proteins is different from formulating low molecular weight drugs. Because the predominant route of administration is 'by the needle', with few exceptions all protein products have to be sterilized (filtration, no autoclaving) or manufactured under aseptic conditions. Secondly, pharmaceutical proteins are difficult to fully characterize by physico-chemical or other means. Even a set of sophisticated spectroscopic and chromatographic techniques fails to fully describe all structural details of the active protein. Moreover, proteins in an aqueous environment tend to lose their chemical and physical integrity on storage; this means that freeze drying under the proper conditions (e.g., presence of lyoprotectants) is the rule rather than the exception. Finally, the patient often receives not one protein molecule, but a mixture of (glyco)protein molecules, e.g. differing in glycosylation patterns.

In this presentation the consequences of these issues on the design of delivery systems for therapeutic proteins will be discussed and illustrated by evaluating current approaches.

ABS S3-3

GMO: GENETICALLY MODIFIED ORGANISMS AS SOURCE OF BIOTECH DRUGS

L.M. Oda
ANBio Brazil

Beginning in the early 1970s, advances on molecular biology and genetic engineering have led to enormous progress on the ability to understand of the bio-molecular route of human diseases. Paul Berg first produced the r-DNA in 1972 and this led the first transformation of Escherichia coli cells in 1973. It was founded the basis for genetic engineering technology or DNA recombinant technology. In 1982 was on the market the first biopharmaceutical product, a recombinant human protein, the insulin.

After more than two decades of the continuous global expansion, business formation and technological diversification, the r-DNA therapeutics sector includes hundreds of companies worldwide that are involved in discovery, development and marketing of r-DNA products.

Analyses of key trends relating to approved and pipeline products worldwide reveal that the current leading r-DNA therapeutics will continue to dominate the market.

With the possibility of the world's first transgenic plant-produced biopharmaceutical being approved for use this year, a vaccine against the Newcastle disease, worldwide attention is focusing on the futuristic breakthroughs that could dramatically alter the biopharm manufacturing landscape and drive sales past the $12 billion mark by 2012.

By using animal and plant platforms as bioreactors rather than established production technologies, which use GM bacteria, yeast, and cultured mammalian cells, the potential to provide large quantities of complex proteins in a more cost-effective manner has arrived.

A new study on Transgenic Animals and Plants in Pharmaceutical Research and Manufacturing, predicts that several such drugs will go to the market this year, and the market is expected to reach $225 million.

Further refining of such technology and the anticipated approval of other plant- and animal-derived drugs currently in clinical trials are expected to grow the market by 140% over the next six years.

Words like Molecular Farming, Plantibodies, Plantigens, PMP (Plant made Pharmaceutical), PMIP (Plant Made Industrial Protein products) and Edible vaccines will be more and more frequent in the pharmaceutical industry vocabulary.

Medical Molecular Farming is the growing and harvesting of genetically engineered crops of transgenic plants, to produce biopharmaceuticals. The purpose is to use these molecular crops as biological factories to generate drugs difficult or expensive to produce in any other way. Combining plant genetics, molecular biology and gene delivery, scientists take genes from other sources, such as microorganisms, and splice them into the plant's genome. During normal growth these genetically engineered plants synthesize recombinant proteins which can be Therapeutics, Vaccines, Blood substitutes, Enzymes or Diagnostics which are then extracted from the crop. These transgenic techniques are already being used to produce vaccines for some animal diseases, such as mink enteritis virus. Many others are at advanced stages, such as measles vaccine in Australian potatoes and drugs to fight cancer, heart disease, infant diabetes and Crohn's disease. Therapeutic Proteins, edible vaccines, 'plantigens' (plant substances which can cause production of human or animal antibodies) and 'plantibodies' (human or animal antibodies produced by transgenic plants) are already in Clinical trials.

The future is already here and producing biopharmaceuticals through newer methodologies which utilize the lower-cost genetic capabilities of plants and animals as opposed to the enormously expensive current methods of cell culture production. Over the next several years, as more and more of these drugs are approved worldwide, we should begin to see such transgenic manufacturing becoming an industry standard which will help to keep these high-tech drugs affordable.

Biographies - Natural Products research and development (S 4)

BIO S4-1

BIOGRAPHY S. BHOJRAJ
S. Bhojraj
JSS COLLEGE OF PHARMACY India

Bhojraj Suresh, M.Pharm., Ph.D., Principal, J.S.S. College of Pharmacy, Ootacamund, & President, Pharmacy Council of India, New Delhi

Dr B Suresh is the Principal & Professor of Pharmacology, J.S.S. College of Pharmacy, Ootacamund, India and presently the President, Pharmacy Council of India, New Delhi. He has received his M.Pharm in Pharmacology from Bangalore University, Bangalore & Ph.D. from Bharathiar University, Coimbatore, in 1993. He joined the college in 1982 as a Lecturer and then with his commitment and dedication was elevated as the Principal. His Research interest include revitalization of traditional medicines, antifungal drug research, pharmacological and toxicological validation of herbal drugs and their formulations and promoting concept of pharmacy practice in India. He has authored 4 books and has to his credit over 160 research papers since 1984 . He is the First Indian Academician to be awarded FAPA Ishidate Award – 2004 (International Award) for the valuable services rendered in the field of Pharmaceutical Education.

BIO S4-2

BIOGRAPHY T. HONDA
T.H. Honda
Hoshi University Japan

Dr. Honda, Professor of Organic Chemistry and Medicinal Chemistry, Faculty of Pharmaceutical Sciences, Hoshi University, Japan, was born in Tokyo on 18th February 1947. He was graduated in 1969 from Graduate Course of the School of Pharmacy, Tokyo University of Pharmacy and Life Science, and licensed Pharmacist at the same year. His postgraduate course was carried out at Pharmaceutical Institute, Tohoku University, and he obtained his Ph.D. degree in 1975 from Tohoku University based on 'Synthesis and Structure Determination of Corydalis species Plant'. After finishing his post-doctoral work from 1976-1979 at the University of British Columbia, Canada, he became a Lecturer at Pharmaceutical Institute, Tohoku University. In 1981, he moved to Hoshi University, and became a full professor in 1992.

His major research works are synthesis of biologically active compounds including natural products, development of new synthetic reactions and reagents, and development of new synthetic strategy for chiral compounds, etc. He received The PSJ Award for Young Scientists from The Pharmaceutical Society of Japan in 1989, and FIP Pharmaceutical Scientist Award 2004 in 2004.

BIO S4-3

BIOGRAPHY K. HOSTETTMANN
K.H. Hostettmann
School of Pharmaceutical Sciences Switzerland

Kurt Hostettmann studied chemistry at the University of Neuchâtel, Switzerland and was awarded his PhD at the same University. With a passion for plants, he continued his studies at Columbia University of New York. He was then given a post at the ETH in Zürich, at the same time teaching at the Universities of Neuchâtel and Fribourg. Since 1981, he has been a full professor at the University of Lausanne, Switzerland, and director of the Institute of Pharmacognosy and Phytochemistry. His teaching duties are directed at pharmacy students, both at the University of Lausanne and the University of Geneva. In 2004, his institute was transferred to the University of Geneva. His research interests include the active principles of plants used in traditional medicine and the quality control of medicinal plants and phytomedicines. He is author of more than 450 scientific publications and a dozen books, one of which has been translated into Japanese, Chinese, Indonesian and Spanish. He has also published four books destined for a larger public and has appeared in numerous television and radio interviews. Professor Hostettmann has received several international distinctions, the last of which were the award of the title of Honorary Professor at the Chinese Academy of Sciences in Shanghai in June 2002, the title of Doctor Honoris Causa at the University of Toulouse in France in 2003, the title of Honorary Professor at the University of Panama in December 2003 and since February 2005, the title of Honorary Professor at Shandong University of Jinan in China. In December 2005, Prof. Hostettmann was elected foreign corresponding member of the National Academy of Pharmacy of Paris.

BIO S4-4

BIOGRAPHY C.L. TAMAYO
L. Tamayo
Flora Inc United States of America

Dr. Carmen Tamayo was educated at the Central University of Venezuela and received her Medical Degree in 1986. Following four years of internship and practice in general internal medicine, she moved to Canada and pursued a degree in Public Health and Epidemiology. She graduated from the University of Toronto in June 1994.

Dr. Tamayo initiated her research career at the National Cancer Institute of Canada evaluating complementary therapies for cancer. She joined the University of Texas-Center for Alternative Medicine Research in Cancer a National Institutes of Health (NIH) funded center and participated in several complementary and alternative medicine (CAM) projects sponsored by the National Centre for Complementary and Alternative Medicine (NC-CAM). She also worked as a medical reviewer at the Centre for Evidence Based Medicine, Department of Clinical Epidemiology in Mc Master University and more recently was appointed as expert reviewer for the World Health Organization and other International committees, CAM and Phytotherapy journals.

She acted as a Clinical Trial Project Coordinator at the Bureau of Product Review and Assessment of Health Canada's Natural Health Products Directorate and collaborated in the development of a Clinical Trial's Framework to evaluate natural health products (NHPs) in Canada.

She currently serves as a medical and regulatory consultant to botanical, natural health products and pharmaceutical companies both in data management, clinical research and development as well as in clinical trial monitoring and auditing. She collaborates with research and academic programs at the University of Western Ontario and directs research and development projects at Flora Inc.

She is also co- chair of the Natural Health Product Special Interest Area Committee (NHP/SIAC) of the Drug Information Association (DIA) a forum that support and promote worldwide collaborative dialogue for scientific evidence-based research, knowledge management, and regulatory issues concerning research and development of NHPs including herbal medicines, nutritional supplements and functional foods.

Her major areas of interest are the development and analysis of research methodologies to evaluate traditional systems of medicine and the safety and efficacy of natural health products in general and herbal medicines in particular. She serves in various CAM-Research networks, is an editorial member of the Journal of Ethnopharmacology and is funding co-editor of an Internet based Canadian CAM journal, Journal of Integrative and Complementary Medicine (JICM) – An international forum for evidence-based practices established at the University of Western Ontario in London.

She is married to a Venezuelan physician and scientist, Dr. Guillermo Arreaza and has two boys, Alirio 17 and Rafael 12. She loves reading, traveling and family life and serves as a women's/youth leader and public educator in several Christian and non-profit organizations.

Abstracts - Natural Products research and development (S 4)

ABS S4-1

DEVELOPMENT OF STANDARDIZED HERBAL FORMULATIONS

S. Bhojraj
JSS COLLEGE OF PHARMACY India

Herbal medicine is still the mainstay of about 75-80% of the world population, mainly in the developing countries for primary health care. This is primarily because of the general belief that herbal drugs are without any side effects besides being cheap and locally available. According to the World Health Organization (WHO), the use of herbal remedies throughout the world exceeds that of the conventional drugs by two to three times. Many conventional drugs also originated from plant sources. Some of the examples include aspirin (willow bark), digoxin (from foxglove), quinine (from cinchona bark) and morphine (from the opium poppy). Herbal products are increasingly being sought out not only as medicinal products but also nutraceuticals and cosmetics. The world market for these products is growing at a rate of 15% per annum. India's share is little less than 2% of the world market in spite of the fact that India has one of the 12 mega biodiversities in the world. There are several reasons for this. One of the major reasons is that these products are not backed by rigorous scientific studies to establish their safety, efficacy and standards. There is thus, a need to initiate activities in this direction to take India to the world leadership. The lack of consistent quality control and manufacturing standards is a major problem. It is inherently difficult to control all the factors that affect a plant's chemical composition. The key to a healthy future of the herbal industry, however, is standardization: standardization of herbs according to marker compounds, standardization of active constituents from batch to batch, standardization of testing methods across the industry to confirm these active compounds, and standardization of dosages to limit consumer confusion. It is a proven fact that a large percentage of herbal products sold in the market do not contain the content of actives as claimed on the label. Manufacturers knowingly or unknowingly add either substandard or inadequate herbal ingredient to the finished product or completely omit the herb from the recipe due to high costs or non-availability in the market. This is because the herbal products in the market today have not been subjected to drug approval process to demonstrate their safety and effectiveness. Many herbal products fall between the far ends of regulatory range. Unlicensed preparations are thought to account for over 80 per cent of herbal sales. Thousand years of traditional use should provide us with valuable guidelines to the selection, preparation and application of herbal formulations. To be accepted as viable alternative to modern medicine, the same vigorous methods of scientific and clinical validation must be applied to prove the safety and effectiveness of these products. It is essential to establish internationally recognized guidelines for assessing their quality. The World Health Assembly in its resolutions WHA31.33(1978), WHA40.30(1987) and WHA42.43(1989) has emphasized the need to ensure the quality of medicinal plant products by using modern quality control techniques and applying suitable standards.
Further, a smart herbal recipe with proven efficacy is no good if presented in an unstable or unattractive or otherwise inferior dosage form. Herbal products for a global market have to be formulated as per modern pharmaceutical principles of stability and speed of release. Products need to be packaged in sound and consumer friendly packaging that will act as effective barrier against the elements. Another challenge for the formulation scientist is to deliver the fruits of traditional knowledge to the modern man to suit his present lifestyle. The formulation development has to follow various stages such as,
1.Preformulation a Assessment of the physicochemical parameters of the extract/extracts - b. Selection of the suitable excipients for the developmental work.
2. Formulation development
3. Evaluation of the developed formulation for various physicochemical parameters and phytoconstituents.
4 Stability studies as per the ICH guidelines.
There is thus, a need to initiate activities in this direction to take India to the world leadership. With this in view the TIFAC Centre of Relevance and Excellence (CORE) was established at J.S.S. College of Pharmacy, Ootacamund, which is one of the leading institutions in India and well equipped. This centre will continue to provide support not only for standardization of herbal products but also a broad base for the discovery of bioactive leads from active fractions and active formulations with the object of discovering new drugs

ABS S4-2

NATURAL PRODUCTS AS THE GENEROUS GIFTS FROM NATURE IN MEDICINAL CHEMISTRY

T.H. Honda
Hoshi University Japan

Throughout the history of medicinal chemistry we find that the study of natural products frequently has provided the impetus for great advances. For example, one of the famous non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, was developed based on the structure of salicin, a constituent of Salix alba. In recent years, it is believed that aspirin inhibits the synthesis of prostaglandin G2 (PGG2) by transfer of its acetyl moiety to the hydroxyl group of serine presented in PG synthase to show its biological activity. These results clearly indicated that the natural products always provide great opportunities to develop new medicines. However, natural products themselves are not always the best drugs, and so-called 'man-design drugs' derived by chemical modifications of the structures of natural products, sometimes give better results in terms of bioavailabilities and biological activities. Many examples of the modern drugs based on natural products will be introduced and some progress of our works in medicinal chemistry will be discussed and presented.

ABS S4-3

SEARCH FOR NEW LEAD COMPOUNDS AND DRUGS FROM HIGHER PLANTS

K.H. Hostettmann
School of Pharmaceutical Sciences Switzerland

Despite tremendous progress in the development of new drugs using biotechnology, genetics and genomics, the plant kingdom remains an almost unexploited reservoir of new molecules to be discovered. In the field of cancer therapy, Taxus constituents play a major role to treat breast, ovarian and lung cancers and alkaloids issued from the Chinese plant Camptotheca acuminata (Nyssaceae) are used worldwide to fight colon, ovarian and bronchial cancers. Galanthamine, an alkaloid with acetylcholinesterase inhibitory properties, initially isolated from Galanthus species (Amaryllidaceae) is used to slow down the progression of Alzheimer's disease. Huperzine A, from the Chinese club moss Huperzia serrata (Lycopodiaceae) is in advanced clinical trials for the same indication. Many drugs and lead compounds which could become drugs will still come from plants.

The approach used to find bioactive plant constituents will be presented. It includes the selection of the plants to be investigated, the preparation of extracts and their biological and chemical screening. Hyphenated techniques such as the coupling of HPLC with UV spectroscopy, mass spectrometry and NMR are essential for the rapid identification of compounds of interest. The whole approach will be illustrated by the search for new antifungal agents against Candida albicans and new inhibitors of acetylcholinesterase which could find application in the treatment of Alzheimer's disease. Other examples of plant constituents with a potential to treat problems related to aging will also be presented.

ABS S4-4

NATURAL HEALTH PRODUCTS: QUALITY CONTROL AND CLINICAL DEVELOPMENT ISSUES

L. Tamayo
Flora Inc United States of America

Natural Health Products (NHPs) encompasses a variety of products from traditional herbal medicines to nutritional supplements, to foods, to cosmetics and botanical drug products. In fact NHPs can be regulated as conventional foods, spices, food additives, dietary supplements and functional foods. It can also be regulated as drugs, over-the-counter drugs, biologics and devices. In addition, several factors, including the desired marketing claims, formulation, safety and risk/benefit issues can dictate which regulatory route(s) are appropriate for a particular product. WHO estimates that of the 35000–70000 species of plants that are used for medicinal purposes around the world, some 5000 have been submitted to biomedical scrutiny. Much work has been done in recent years to increase credibility and acceptance of herbal medicines and scientific evidence of efficacy is beginning to emerge from randomized controlled trials in which herbs compare favorably with placebo.
Government and non-government institutions around the world are spending a great amount of resources to facilitate research in this area and to increase the evidence about the value of NHPs and herbal medicines in human health. In addition NHPs researchers and industry are steadily working to comply with new regulations addressing quality issues, good manufacturing practices and science-based research. Despite the efforts there are several issues that need to be considered when developing a research and development (R&D) program for complex herbal products and both the research community and the NHP industry still face a number of challenges. These challenges are multiple and vary according to the type of product (i.e.: single vs combination), the history of use (i.e. new vs traditional) and the 'intended use' (i.e nutritional supplement vs drug).
Good 'development' practices (GXPs) are paramount in biomedical research. Reliable standardization and good laboratory practices, (GLPs), good manufacturing practices (GMPs), analytical methods, bioassays and well-designed clinical studies are essential for cost-effective development of these products and should follow established guidelines and international initiatives. Studies should be carried out and evaluated with the same basic scientific criteria applied to single chemical entities but the uniqueness and plethora of putative synergistic, antagonistic and interacting activities of herbal medicines should be taken into consideration when evaluating products with therapeutic effects.
This session will address several of these issues and challenges. It will provide information about the main phases of botanical R&D and its implications. It will focus on quality control and clinical research and will summarize regulatory requirements in several jurisdictions. A summary of major herbal medicines trials conducted to date in the United States and issues related to study design, selection of appropriate outcome measurements and reporting will be presented.
Clinical development of NHPs must simultaneously encourage risk taking among researchers and industry and empower others to make right decisions. This session will focus on some of the necessary tools to create this balancing act
Session Objectives:
- To recognize and assess the impact of natural health product's research and development in human health
- To address issues related to quality control, pharmacological activity and clinical evaluation of botanicals
- To identify the major requirements sponsors of botanicals products should follow when submitting applications to regulatory agencies to evaluate the safety and efficacy of botanicals.

BIO S5

BIOGRAPHY R.L. WILLIAMS

R.L.W. Williams
U.S. Pharmacopeia United States of America

Roger L. Williams, M.D., has been the executive vice president and chief executive officer of the United States Pharmacopeia (USP) since April 2000. Working with a staff of nearly 400, Dr. Williams provides strategic leadership for USP at the direction of USP's Board of Trustees. Dr. Williams also serves as chair of the Council of Experts, USP's scientific body, which continuously revises the United States Pharmacopeia and National Formulary.

Since joining USP, Dr. Williams has led a re-engineering effort designed to assure that USP's products and services meet the needs of its constituencies. These constituencies include practitioners and patients/consumers who seek safe, effective, and good quality therapeutic products as well as pharmaceutical manufacturers, compounding professionals, and many other stakeholders. Dr. Williams has reorganized the structure of the Council of Experts, brought focus to its science-based decisions, and has aligned USP's efforts with other pharmacopeias throughout the world. He has established stakeholder forums that promote communication with and input from pharmaceutical and dietary supplement manufacturers, compounding professionals, patient safety advocates, and USP's membership. He is USP's lead representative for international activities and outreach efforts to the many professional groups and societies who share USP's public health mission. The strength of USP's public programs has allowed USP to expand its public health mission both nationally and internationally. For instance, USP will soon be establishing a site in India and will also be publishing the USP-NF in Spanish.

Dr. Williams received his undergraduate degree at Oberlin College and his medical degree and training in internal medicine at the University of Chicago. He served in the United States Army, both in Korea and at Walter Reed Army Institute of Research, where he conducted anti-malarial drug research. After completing a fellowship in clinical pharmacology at the University of California, San Francisco, in 1974, he continued as a faculty member until 1989. He joined the Food and Drug Administration in 1990 as the director of the Office of Generic Drugs in the Center for Drug Evaluation and Research, moving to associate director in the Center in 1993 and deputy center director for pharmaceutical science in 1995. In this capacity, he had oversight for the Center's Office of New Drug Chemistry, Office of Generic Drugs, Office of Clinical Pharmacology and Biopharmaceutics, and Office of Research and Testing.

Dr. Williams is a member of the medical honor societies Phi Beta Kappa and Alpha Omega Alpha. He is a fellow of the American Association of Pharmaceutical Scientists, an expert member of the International Pharmacy Federation (FIP) Board of Pharmaceutical Sciences, and represents USP at the World Health Organization. He has authored or co-authored approximately 175 reports in the areas of clinical pharmacology, patient safety, biopharmaceutics, and pharmaceutical chemistry, and has published books on clinical pharmacology and regulatory science. He retains an adjunct appointment at UCSF, serves on the Board of Overseers for the University's School of Pharmacy, is a member of Pharmaceutical Foundation Advisory Council of the College of Pharmacy at the University of Texas at Austin, and serves on the Board of Directors for the American Society for Clinical Pharmacology and Therapeutics. Dr. Williams is a board-certified internist and clinical pharmacologist.

ABS S5

IMMUNOGENICITY

D.J.A. Crommelin
Dutch Top Institute Pharma Netherlands

The group of therapeutics proteins produced via recombinant or hybridoma technology ('biologicals') is growing fast. These (glyco)proteins differ in a number of aspects from low molecular weight drugs (1). They are all macromolecules folding their amino acid/sugar strands in complex secondary, tertiary and sometimes quaternary structures. These structures are mostly stabilized by relatively weak physical forces. Moreover, the amino acids forming the primary structure can be chemically degraded e.g. through oxidation, deamidation and/or racemization. Therefore, the structure of these large molecules tends to be less well defined than low molecular weight products in spite of the availability of a large 'toolbox' of analytical techniques (2) and extensive purification protocols.

Many biologicals are similar to endogenous proteins and therefore considered self-proteins. However, in practice antibodies are often formed. These antibodies may neutralize the therapeutic effect of the biological and even interfere with essential functions of the body. The antibodies appearing in the blood of the patients can be considered biomarker molecules.

In this lecture the possible causes for the formation of antibodies after administration of biologicals will be discussed. In addition, the challenges assessing the presence of antibodies will be addressed and finally the current attempts to predict antibody formation will be presented

ABS S5

PHARMACEUTICAL EQUIVALENCE OF BIOTECHNOLOGICAL PRODUCTS (BIOGENERICS)

R.L.W. Williams
U.S. Pharmacopeia United States of America

For a biotechnological product, equivalence experiments to document either pharmaceutical equivalence or bioequivalence—and hence therapeutic equivalence--rely on a broad spectrum of marketplace surveillance, clinical safety and efficacy, pharmacodynamic, pharmacokinetic, non-clinical (animal), a biologic potency test, and physicochemical procedures. With the exception of a subset of the physicochemical procedures and the biologic potency test, which are used in the product specification for batch release, all of these procedures are characterization studies (see ICH Q6B) that assess the quality not only of the proposed biotechnology product but also allow equivalence comparisons with a first entry reference product. These comparisons support a judgment of therapeutic equivalence and hence interchangeability. Manufacturing and regulatory scientists must decide which measurements should be used for making comparisons, depending on the nature of a product (e.g., peptides, nonglycosylated proteins, glycosylated proteins, or monoclonal antibodies), the private and/or public historical data already available, and other factors. For intra- or inter-manufacturer changes, a broad array of procedures may be required to demonstrate equivalence. Despite some unresolved questions, well evolved statistical procedures are available to document equivalence. From a compendial standpoint, the scientific challenge to assure continuing consistency (equivalence) of a biotechnological product batch to batch is a metrologic one, in which commonly accepted approaches to measure the strength, quality, and purity of a medicine in terms of mass or mole (SI units) are inadequate. This puts emphasis on the use of the USP Biologic Potency test, which is undergoing substantial revision based on deliberations of the USP Council of Experts. The presentation will provide an update on the scientific underpinning of this work and indicate its importance to modern compendial monographs for biotechnologic products. USP believes it is critical for first (manufacturer), second (purchasers), and third (governmental) bodies to be able to test biotechnologic products in the marketplace, using independently tested physicial reference standards when needed, to assure the public health. This is particularly critical in light of the fact that many high-value pharmaceutical products that are targeted for counterfeiting and diversion are biotechnology products, and the availability of high quality public standards can help significantly in combating this serious global problem.

BIO S6-0

BIOGRAPHY C.N. COLE

N. Cole
GE Healthcare United States of America

Cole is the Director Pharmacy Standards for GE Healthcare, a Fellow of the APhA and a pioneer in Nuclear Pharmacy specialty practice. He received his BS from the Massachusetts College of Pharmacy and MS in Nuclear Pharmacy from the University of Southern California. He served as a Captain in the Army where he developed a Nuclear Pharmacy Training program and in 1976 co-founded RadPharm serving as Chief Nuclear Pharmacist and Director of Regulatory Affairs until 1982. He practiced hospital nuclear pharmacy, was Vice President of Cadema Medical and managed traditional and PET pharmacies for Amersham Health. Cole has been an adjunct professor and preceptor for multiple Nuclear Pharmacy clerkship programs and is co-chair elect for the Radioligic Pharmacy Section of the International Pharmacy Federation (FIP). He chaired the Nuclear Group of the Specialized Pharmaceutical Services Section in 1991 and has served on and chaired multiple committees for the APhA Nuclear Pharmacy Section. While an APPM officer he was Vice Chairman of the Policy Committee and served on the Awards Committee. He has been a speaker and moderator at numerous APhA and FIP annual meetings and a speaker and moderator at the 9th and 10th European Radiopharmaceutical Symposia. He is a Fellow of the American Pharmacist Association and the recipient of the William H. Briner Award for excellence in Nuclear Pharmacy

BIO S6-1

BIOGRAPHY E. SAVIO

E. Savio
Faculty of Chemistry Uruguay

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2.- Education

Degree	Year	University
PhD.	1994	UDELAR and PEDECIBA
Pharmacist.	1988.	UDELAR.
Bachelor in Chemistry	1986	UDELAR

UDELAR – Universidad de la República – Uruguay PEDECIBA – Programa de Investigaciones Básicas – PNUD)
3.- Employment history in the University
Present Positions 98- Professor of Radiochemistry - 04 - Director of Hospital Pharmacy Diploma
Previous Positions
94-98 Associated Professor of Pharmacology. 95-98 Associated Professor of Radiochemistry
91-94 Assistant of Radiochemistry 88-90 Research contracts on Radiopharmacy Projects
90-93 Fellowship for Ph.D. studies.
4- Other relevant information
91-06 Director of the National Pharmaceutical Journal (Revista de la Asociación de Química y Farmacia del Uruguay).
04-06 Member of the National Technical Group on behalf of Faculty of Chemistry, which is carrying out Good Pharmacy Practice Project, National Coordinator.
94 - 04 Participation in national and international courses of Radiopharmacy, Hospital Radiopharmacy and Interne Dosimetry.
01-03 President of the Nuclear Medicine and Biology Society of Uruguay
00-01 Member of the organization of the Pharmaceutical Congress of the Americas, supported by AAPS (American Association of Pharmaceutical Scientist) and other organizations (OPS, FePAFAR, FeFaS, FFCC, FIP, Canadian Society for Pharmaceutical Sciences, Food and Drug Administration, American Pharmaceutical Association, American Association of Colleges of Pharmacy)
00 President of the 'VI Congreso de la Federación Farmacéutica' (VI FEFAS Congress), VI Encuentro Nacional de Químicos Farmacéuticos Hospitalarios y II Jornadas Nacionales de Farmacia Comunitaria
97-98 Member of the Council of PEDECIBA (National Programme for the Development of Sciences)
93- President of the I Congreso de la Federación Farmacéutica Sudamericana (I FEFAS Congress) y II Encuentro de Ciencias Farmacéuticas del Cono Sur.
92-94 President of the National Pharmacist Association
02-05 Expert of the International Agency of Atomic Agency (IAEA)
05- Expert mission to develop Hospital Radiopharmacy in Colombia- September, National Instituto of Cancer.
04- Consultans meeting to elaborate the document 'How to operate Radiopharmacy Units', with Dres. Chianelli (Italy, Jeong (Corea), Blonsic (United Kingdom), Saw (Singapore), March, Vienna, Austria.
03- Expert mission to evaluate Radiopharmacy activities in Colombia. 28 Febreaury - 3 March 2002.
02 - Expert mission to evaluate Project Arcal LII. San Pablo, Instituto de Pesquisas Nucleares, Brazil. 10 to 14 September 2002
86-00 Member of the Faculty of Chemistry Council on behalf of pharmacist students (1986-88), pharmacists (1988-90), teachers (1998-00)

BIO S6-2

BIOGRAPHY N.G. HARTMAN

N.G. Hartman
Addenbrooke's Hospital United Kingdom

Obtained a B.Pharm, followed by a M.Sc in medicinal sciences (nuclear medicine). Completed Ph.D in clinical oncology and radiotherapeutics at Cambridge University. Post-doctoral fellowship in nuclear pharmacy at the University of Kentucky, followed by being radiopharmacist at hospitals in Vancouver, Montreal and Ottawa. Currently head of radiopharmacy and consultant radiopharmaceutical scientist at Addenbrooke's Hospital in Cambridge (United Kingdom) and affiliated lecturer in radiology at Cambridge University.

BIO S6-3

BIOGRAPHY S.M. SHAW

S.M. Shaw
Purdue University United States of America

Stanley Shaw is a Professor Ermeritus of Nuclear Pharmacy and in the Division of Nuclear Pharmacy in the Department of Industrial and Physical Pharmacy within the School of Pharmacy at Purdue University, West Lafayette, IN 47907, USA. He joined the faculty at Purdue after receiving his Ph.D. from Purdue University in 1962. During the first 20-25 years on the faculty he was heavily involved in research as well as contributed to instruction in graduate and undergraduate courses. In 1972, he initiated a series of courses leading to specialization in the practice of nuclear pharmacy. His involvement in this area changed his focus to the emphasis of excellence in teaching of undergraduate students. As a result, he has been recognized three times by the students as the outstanding teacher in the School of Pharmacy, received the Purdue Charles B. Murphy Award for outstanding undergraduate teaching and the American Association of Colleges of Pharmacy Distinguished Pharmacy Educator award.

Stanley Shaw has been active in national professional organizations devoted to the practice of pharmacy. He has been recognized for his leadership and service by receiving the status of fellow in two national organizations. For his devotion and efforts in developing nuclear pharmacy he received the American Pharmaceutical Association (APhA) Distinguished Achievement Award in Nuclear Pharmacy Practice in 1998 and the APhA Daniel B. Smith Practice Excellent Award for the year 2000.

BIO S6-4

BIOGRAPHY A.Y. ÖZER
A.Y. Ozer
Univ. Turkey

- Graduated from Hacettepe Univ, Fac. Pharmacy in 1975,
- Started to Dep. Galenical Pharmacy as Assistant in 1976,
- Got her Ph. D. In Galenical Pharmacy field in 1981,
- Got her Assoc. Prof., Degree in 1988,
- Got her Full Prof. Degree in 1994,
- Appointed as the Head of Radiopharmacy Dep in 1994 and Head since then,
- Went to Holland/Utrecht Univ/ Prof. Dr. D. J. A. Crommelin on sabatical,
- Appointed to the member of Executive Committee of the Fac. Pharmacy in between 1991-1997.
- Carried out Apprenticeship Program of Fac. Pharm,
- Carried out foundadion of Posion Control Center and Drug Information Center of Fac. Pharm. In between 1981-1988.

- Carried out the Head of Medical Device Lisencing Commision at the Min. Of Health in between 2000-2003

- Carrying out the membership of Radiopharmacy Lisencing Commision at the Min. of Health since 2000,

- Carring out the membership of Main Lisencing Commision at the Min. Of Health since 2002,

- She has many publications including research and review articles, oral and poster peresentations, book and book chapters.

- She has two awards in science and several poster awards.

She is married and has one daughter.

BIO S6-5

BIOGRAPHY E.P. VANEGAS ESCAMILLA
E.P. Vanegas Escamilla
INSTITUTO NACIONAL DE CANCEROLOGIA Colombia

Egdda Patricia Vanegas Escamilla

She is a pharmacits formed at Universidad NAcional de Colombia in 1998, and specialized in Public Health managament at The Rosario University in Bogotà. She has worked at some hospitals in Bogotà, also she has worked as teacher atThe national university of Colombia. Since 2000, is the Pharmacy Services chief's of The National Institute of cancer in Bogotà, during the time that she was worked there the service has implemented new activities like the stablismentf of a centralized iv oncology admixtures pharmacy and the develop of a radiopharmacy centralized with the nuclear medicine service.

BIO S6-6

BIOGRAPHY K.D. WEATHERMAN
K.D. Weatherman
Purdue University United States of America

Kara Duncan Weatherman is an Assistant Professor of Nuclear Pharmacy at Purdue University. She received her Pharm.D. degree from Purdue in 1994 and practiced as a nuclear pharmacist until she began her educational career at Purdue University in 1998. Her primary educational focus involves the development and implementation of new training methodologies for nuclear pharmacy education, including a broader focus on the impact USP 797 plays in nuclear pharmacy practice. She was recently named a Fellow of the American Pharmacists Association and is a member of the Indiana Pharmacists Alliance, the British Nuclear Medicine Society, the European Association of Nuclear Medicine and the International Pharmaceutical Federation.

BIO S6-7

BIOGRAPHY H.S. BALTER
H.S. Balter
Nuclear Research Center Uruguay

Director of Nuclear Research Center (C.I.N.), Faculty of Sciences, Montevideo, Uruguay
e-Mail: jbalter@cin.edu.uy

ACADEMIC FORMATION
Chemist Pharmacist, Faculty of Chemistry, University of the Republic Oriental of Uruguay, 1984.
Doctor in Chemistry, Faculty of Chemistry, University of the Republic Oriental of Uruguay, 1999.
Thesis on: "Interactions protein - carbohydrate: study of Tn structures"
Specialization in Radiopharmacy

UNIVERSITY COURSES
• Basic Course on Methodology of Radioisotopes, Nuclear Research Center (CIN), Faculty of Sciences; 1981 to now.
• Advanced Course on Radioinmunoassay, CIN, Faculty of Sciences. Dictated by Dr. Eduardo Charreau, IBYME, Argentina. Participation in practical classes; february 1991.
• Radioisotopic labelling of molecules of biological interest. Postgraduate course, PEDECIBA Chemistry, CIN, Faculty of Sciences, 24 -l 28 july 1995. Co-direction of the course.
• Basic course on Radioimmunoassay, C.I.N, Faculty of Sciences, 1992 to 2001.
• Data processing and quality control in RIA, C.I.N. 1992 to 1997.
• First national course on screening of neonatal hypothyroidism. CIN, Facultad de Ciencias, Faculty of Medicine, Faculty of Chemistry and BPS. Theoric and practical classes, colaboration in the coordination of the course, december 1993.
• Profundization in Radioimmunochemistry, CIN, Faculty of Sciences, 2001 and 2003.

TEACHING POSITION
Associate Profesor of Radiopharmacy, full time (G 4), CIN, Faculty of Sciences.
Head of Departament of Radiopharmacy, CIN, Faculty of Sciences.

BIO S6-8

BIOGRAPHY M. TERÁN
M.A. Terán Gretter
Faculty of Chemistry Uruguay

Titles:

Pharmacist degree: Faculty of Chemistry , Montevideo Uruguay 1996

PhD: Faculty of Chemistry , Montevideo Uruguay 2005

Actual position:

Assistant Profesor of the Radiochemistry Department of the Faculty of Chemistry, Montevideo-Uruguay.

Lines of investigation:

Radiotracers in pharmaceutical development, proteins labelling and kits formulations, biological effects and internal dosimetry.

Dr.Teran is Chief Scientific Investigator of the Coordinated Research Project IAEA

'Development and Quality control of hospital prepared radiopharmaceuticals for infection imaging for use in HIV/AIDS positive patients' and collaborator in the IAEA Project 'Standardisation and Quality control of in-house prepared radiopharmaceuticals for Nuclear Oncology: RADIOPHARMACEUTICALS FOR TUMOUR IMAGING AND THERAPY'. She is also Coordinator of the National Internal Monitoring Programme for workers exposed to radiation.

BIO S6-9

BIOGRAPHY A. REY
A. Rey
Faculty of Chemistry Uruguay

PERSONAL DATA
Date of birth: April 10, 1965, Montevideo, Uruguay
Title: PhD in Chemistry, Pharmaceutical Chemist
E-mail arey@fq.edu.uy

EDUCATION AND TRAINING

Degree	Year	Institution	Field
Diploma	1988	UDELAR (*)	Pharmaceutical Chemistry
Ph.D.	1999	UDELAR	Tc Coordination Chemistry

(*) Universidad de la República, Montevideo, Uruguay

EMPLOYMENT HISTORY
Present position from: october 2000
Associate Professor of Radiochemistry, Faculty of Chemistry, UDELAR, Uruguay

RESEARCH DIRECTION
2004-2006
" Desing and biological evaluation of 99mTc labelled RGD peptides as potential radiopharmaceuticals for imaging tumoral neoangeogenesis"
Supported by "Comisión Honoraria de Lucha contra el Cáncer", (National Cancer Institute) Uruguay.
2003-2006
"Design and evaluation of potential 99mTc radiopharmaceuticals based on the Tc-carbonyl and Tc-nitrido approaches", part of the Coordinated Research Programme "Development of Tc99m based small bio molecules using novel Tc99m cores"
Supported by International Atomic Energy Agency.

TEACHING
Direction of a Master Degree Student with the topic "Aplication of novel cores in the labelling of biomolecules with potential application in Nuclear Medicine
Starting in September 2003

ABS S6-00

THE PHARMACIST IN A CENTRALIZED NUCLEAR PHARMACY; NORTH AMERICAN EXPERIENCE

N. Cole
GE Healthcare United States of America

Nuclear Pharmacy Practice is widespread in the North America with more than several hundred centralized nuclear pharmacies currently providing service. They are in organizations from large manufacturers to individual independent operations and are all dedicated to serve the Nuclear Medicine Community. This presentation touches on the basic concepts of the specialty and addresses issues germane to Nuclear Pharmacy Practice. Small Nuclear Pharmacies can have workloads of 200 Rx per day whereas the largest Pharmacy may dispense as many as 1200 Rx per day. Regardless of size, the Pharmacist's responsibilities encompass all activities that transpire in the pharmacy. The responsibilities include regulatory, fiduciary, personnel management, radiation safety, compounding and dispensing, inventory control and radiopharmaceutical consultation.

A major aspect of the centralized nuclear pharmacy concept is the ready availability of radiopharmaceuticals compounded and dispensed, tailored to a patient's individual requirements. Radioactive decay dictates that they must be prepare and delivered in a timely fashion. The most common isotope used in Nuclear Pharmacy is Tc-99m with a half-life of only 6 hours. To this end a responsive distribution system is necessary to assure rapid delivery of the unit dose such that the dose is available for injection at or near the calibration time. The parameters of adequate space, equipment, aseptic control policies, radiation dosimetry issues and cost are all significant factors in developing appropriate standards for service and profitability and will be considered. Nuclear Pharmacies dispense 70% to 80 % of the radiopharmaceuticals administered each year and the practice of Nuclear Pharmacy is growing rapidly. Nuclear Pharmacy is a dynamic, growing, innovative, exciting and satisfying specialty area of pharmacy that enjoys global interest and representation.

ABS S6-01

NUCLEAR PHARMACY: BACKGROUND AND HISTORY OF THE DEVELOPMENT AND CURRENT STATUS (EUROPE)

N.G. Hartman
Addenbrooke's Hospital United Kingdom

Iodine-131 treatment was introduced in Europe in the 1940s just after the war soon after the USA. The UK and France were the first countries to implement radioiodine therapy, since they had the first European reactors, but this was soon repeated in other states (Norway being the first of the smaller states to have a reactor in 1951). In the 1950s and 1960s most European countries developed nuclear research centres in which radiopharmaceuticals were produced at very small cost. At first these productions of 'tracers' were only loosely regulated, since these agents were not considered as pharmaceuticals. The first appearance of radiopharmaceutical monographs was in the Nordic Pharmacopoeia (Scandinavian countries), followed by entries in the European Pharmacopoeia (Ph.Eur.) later in the 1960s.

Denmark was the first country to ensure quality control through market authorisations for radiopharmaceuticals, and this was followed by the same in the UK. A national Isotope Pharmacy was established in Denmark in the early 1970s to inspect nuclear medicine departments, and granted permission to prepare radiopharmaceuticals.In 1988 an EU directive on Radiopharmaceuticals decided that all radiopharmaceuticals had to be approved by authorities before the end of 1992, and this revolutionised the production of these agents, and also ensured that from 1992 all radiopharmaceuticals are considered as pharmaceuticals in Europe.

The practise of radiopharmacy still varies considerably in Europe, but there is a strong movement towards the application of the highest level of barrier/aseptic technology and quality assurance in the preparation of radiopharmaceuticals in the 21st century.

ABS S6-02

PRACTICE OF NUCLEAR PHARMACY: THE DEVELOPMENT AND CURRENT STATUS IN THE USA.

S.M. Shaw
Purdue University United States of America

Nuclear pharmacy services were first offered in large medical centers. The first pharmacy services are commonly attributed to a radioisotope laboratory in Chicago in the early 1950's. Not many years later Captain William (Bill) Briner provided pharmacy services at the National Institutes of Health (NIH) and established the NIH Radiopharmacy. Captain Briner and Dr. John E. Christian at Purdue University encouraged pharmacists to become involved with radiopharmaceuticals, but with limited success.

Modern nuclear pharmacy practice was stimulated by the development of the technetium generator and ligands labeled with technetium generator and ligands labeled with technetium and the advent of non-radioactive reagent kits. The evolution of nuclear pharmacy in the USA was also influenced by a study that illustrated the financial advantage of shared nuclear pharmacy services for several nuclear medicine facilities. The development of a stand-alone nuclear pharmacy separate from hospital nuclear medicine and recognized as a pharmacy by state pharmacy regulators as well as by regulators of radioactivity was a critical step in the creation of commercial centralized nuclear pharmacies that are common today. As a result of these events 70-80%of radiopharmaceutical doses are dispensed by commercial centralized nuclear pharmacies in the USA. In addition to these traditional commercial centralized nuclear pharmacies, commercial centralized PET nuclear pharmacies (facilities) are increasing as a result of the clinical utilitiy of 18F-FDG in nuclear medicine.

ABS S6-03

RADIOPHARMACY EXPERIENCE IN TURKEY

A.Y. Ozer
Univ. Turkey

Radiopharmacy covers the professional principles and practices of pharmacology and nuclear radiation in the preparation, dispensing and control of radiopharmaceuticals used either in producing scans used for imaging., metabolic and functional studies of internal parts of the body for diagostic purposes or in the treatment of patients with several diseases. Radiopharmacy and education activities have started in 1993 in Turkey officially. In this presentation, the current status of radiopharmacy has been discussed.

ABS S6-04

PRODUCTS AND APPLICATIONS IN NUCLEAR MEDICINE

K.D. Weatherman
Purdue University United States of America

This session will discuss the most common products dispensed by nuclear pharmacists. The clinical use and applications of each of the products will be covered to allow practitioners to understand the importance of each of the agents in patient care.

ABS S6-05

SERVICES PROVIDED BY PHARMACIST: CENTRALIZED RADIOPHARMACY

E.P. Vanegas Escamilla
INSTITUTO NACIONAL DE CANCEROLOGIA Colombia

The operation at a nuclear pharmacy, it is not much different than of a traditional pharmacy, in a prescription, the nuclear physician solicits a radiopharmaceutical product, and the pharmacist have to prepare and dispense that prescription. There are few differences : in the traditional pharmacy the dose is expressed in weight units while in the radiopharmacy its expressed in millicurie activity units.

In the same way, the concept of centralized radiopharmaceutical preparations, become used in the early of 1970´s. The centralized radiopharmacy is a unit that makes and dispense doses of radiopharmaceutical products. Some hospitals can have pharmacists with the knowledge, abilities and training in the radioactive material, others hospitals can not have the adequate infrastructure, procedures and the staff to support the doses in a cost effective manner and it can justifies the develop of the centralized radiopharmacy. In some countries or regions due to the particular reality it can be a generalized practice.

In the implementation, it should be considered, the design of areas , personal, quality assurance, equipment and the procedures communes to the centralized iv admixtures pharmacy where admixtures are compounded and or prepared, also should meet all the considerations to handle radioactive products.

ABS S6-06

QUALITY CONTROL

K.D. Weatherman
Purdue University United States of America

Each product compounded by a nuclear pharmacist must be tested prior to dispensing for patient use. Quality control testing is done to assure the safety and efficacy of the final product. The rationale behind quality control testing will be discussed, as will the most common quality control procedures used by nuclear pharmacists in daily practice.

ABS S6-07

REGULATIONS AND EDUCATION: INTERNATIONAL ATOMIC ENERGY AGENCY GUIDELINES

E. Savio
Faculty of Chemistry Uruguay

The International Atomic Energy Agency (IAEA) is the world's center of cooperation in the nuclear field. It was set up as the world's 'Atoms for peace' organization in 1957 within the United Nations family. The Agency works with its Member States and multiple partners worldwide (such as WHO) to promote safe, secure and peaceful nuclear technologies. Science and Technology are one of the three main pillars – or areas or work- underpin the IAEA's mission, as well as 'Safety & Security' and 'Safeguards & verification'.
Within this scope over the last decade many successful programmes by the IAEA have significantly enhanced the capabilities of many Member States in the field of Nuclear Medicine and Nuclear Pharmacy. However due to heterogeneous growth the development of these two areas in the world, the operating standards of practice differ considerably from country to country and regional to region. For this reason on March of 2004 a group of experts on Nuclear Pharmacy were invited, coming from all the regions of the world, in order to develop an 'Operational Guidance on Hospital Radiopharmacy: a safe and effective approach'. This guidance is a result of international professionals assisting the IAEA, in the process of standardization and harmonization.
As the purpose is to provide guidance at an International level on hospital nuclear pharmacy practice, this presentation will include many aspects related to training, facilities, equipment, operations and quality systems for application at clinical practice level. Taking into account routine clinical practice, therefore it provides many practical points that could help new or more developed Nuclear Pharmacies as well. Therefore a pharmacist in charge of the Nuclear Pharmacist, with a specialization on Radiopharmacy, would find this guidance a supplementary and/or and aid establishing meeting international requeriments. The new centres or pharmacist with little background in the area will find specific information essential for setting up the provision of the service, while the more developed centers will find numerous updated protocols and suggestions on improving operational performance
The guidance is certaintly of interest to anyone working in the Nuclear Medicine area. The key compilers/authors are Uday Bonsle, Marco chanelli, Jae Ming Jeong, Eduardo Savio and Muang Muang Saw, being the technical officer responsible for the preparation of this publication Dr. Kishor Solanski (Nuclear Medicine Section, Human Health Division, IAEA). A process of revision by other contributors and reviewers has taken during last year and its final edition and distribution will be done during this year.

ABS S6-08

NUCLEAR PHARMACY: REGULATIONS AND EDUCATION (EUROPE)

N.G. Hartman
Addenbrooke's Hospital United Kingdom

The European Union (EU) is a conglomerate of a growing number of sovereign states, and this is reflected in the variety of regulations and training programmes that exists. As the union consolidated various functions/rules, training and regulatory affairs have been harmonised. European laws are tabled in Bruxelles, and it is the prerogative of individual countries to implement these. The European Pharmacopoeia (since 1964) form the central convention to harmonise laws on manufacture and distribution of medicinal products, and several radiopharmaceutical monographs are included. The European Association of Nuclear Medicine (EANM; founded in 1985) proposed Guidelines for Radiopharmacy in 2003, and published current Good Radiopharmacy Practise guidelines in 2005.

Training of radiopharmacists/radiopharmaceutical scientists reflect the complexity of the EU members and their individual histories. Most of the training in the past was individual grandfathering within recognised groups. The Institut National des Sciences et Techniques Nucléaires (Saclay, France) currently provides jointly with the EANM an intensive postgraduate modular course to teach radiopharmaceutical production, EU regulations and directives, and related topics such as radiopharmacology, biopharmacy, etc. The University of London and the Technische Hochschule Aachen both provide, amongst others, graduate course over several years in topics such as radiopharmaceutics, PET radiochemistry and radiation safety. Online learning has been promoted by the VirRAD virtual-learning community.

ABS S6-09

REGULATION AND EDUCATION IN THE USA

S. M. Shaw
Purdue University United States of America

Nuclear pharmacy is a highly regulated specialty. Federal agencies and state agencies are involved in the regulation of nuclear pharmacies and nuclear pharmacists. Because radiopharmaceuticals are prescription drugs the Food and Drug Administration (FDA) is involved as well as the Nuclear Regulatory Commission (NRC) because the agents are radioactive. Since radiopharmaceuticals and radioactivity are transported, the Department of Transportation (DOT) has regulations that must be followed when shipping radioactivity and radiopharmaceuticals. The Occupational Safety and Health Administration (OSHA) is a federal agency that is concerned about the working environment for personnel in a nuclear pharmacy while the Environmental Protection Agency (EPA) has regulations to protect the environment from toxic material and radioactivity is considered as toxic.

A nuclear pharmacy must be licensed by a state board of pharmacy or a similar agency if it is operating as an independent pharmacy in the same manner as a traditional retail pharmacy. The pharmacists must be registered (licensed) by the state board of pharmacy. Many pharmacists are Board Certified Nuclear Pharmacists, but this is not a requirement to practice nuclear pharmacy. The nuclear pharmacy must be licensed by the NRC or in many states by a regulatory agency within the state that operates under a formal agreement with the NRC (an Agreement State). Over half of the states in the USA are Agreement States.

The FDA regulates the manufacture, sale and distribution of new drugs in interstate commerce to assure that the drugs are safe and effective for their intended use. The FDA has legislative authority under the Federal Food, Drug and Cosmetic Act to regulate drugs for human use. Radiopharmaceuticals, radioactive drugs, are stated to be new drugs under the law. A nuclear pharmacy, excluding PET, does not need to register as a drug establishment with the FDA if 1) it operates in conformance with applicable local laws regulating the practice of pharmacy, 2) is regularly engaged in dispensing prescription drugs upon the prescription of practitioners licensed to administer prescription drugs to patients and 3) does not manufacture, propagate, compound, or process drugs or devices for sale other than in the regular course of business of dispensing or selling at retail. Simply stated, the nuclear pharmacy operates under the laws of the state as a licensed pharmacy.Nuclear pharmacy education is driven by the regulatory agencies and the practice site in the USA. The most common practice site is the commercial centralized nuclear pharmacy. Thus, the greater number of educational programs are directed toward training pharmacists either pursuing the first professional degree or wishing to enter nuclear pharmacy after practicing in some other area of pharamcy. A small number of schools of pharmacy have educational programs in nuclear pharmacy for first professional degree students. Several short courses are available for pharmacy graduates that wish to enter the field later in their professional career. Only two residency programs are available to train nuclear pharmacists. Very few pharmacists enter nuclear pharmacy through advanced degree programs such as the M.S. degree.

ABS S6-10

PRESENT AND FUTURE RADIOPHARAMCEUTICALS FOR THERAPY

H.S. Balter
Nuclear Research Center Uruguay

Targeted therapy with radiopharmaceuticals is an essential mode of treatment of many cancer patients either alone or in conjunction with other modalities like surgery and chemotherapy. It has several advantages over external beam therapy including the possibility of delivering doses more selectively to the tumour and treating widespread multiple metastasis.

Examples of radionuclides in use are I-131, Y-90, Re-188 and Sm-153 which have applications in thyroid cancer therapy, pain palliation therapy for bone metastases, radiosynovectomy and others. The research of new radionuclides like Lu-177, Cu-67 and alpha emitters such as At-211 is advancing due their promising physical and chemical properties. Besides the radionuclide characteristics, the other key factor is the search of molecules that bind to specific characteristics of cancer cells, such as receptors or surface antigens. The significant progress in various related scientific fields such as target, radio-peptide-chemistry (i.e. Somatostatine analogs), bifunctional complexing agents (i.e. DOTA), monoclonal antibodies (i.e antiCD20, antiCEA, antiEGFr), as well as the production of a number of new radionuclides, besides to an improved knowledge of tumor antigen binding, has made possible to expand this field of research. These achievements can be exploited for development of more effective therapeutic radiopharmaceuticals.

The identification of the ideal targeted radiopharmaceutical for each potential clinical application is a difficult task because of the multitude of variables that must be considered, some related to the radioisotope, and others to the biological carrier. A rational scheme of research include: choice of target, ligand, radionuclide and labelling strategies, radiochemical purity analysis, stability evaluation, in-vitro receptor binding, cellular processing and metabolism, in-vivo biodistribution and dosimetry.

ABS S6-11

CONTRIBUTIONS OF RADIOPHARMACEUTICALS TO DOSAGE FORMULATION DEVELOPMENT

M.A. Terán Gretter
Faculty of Chemistry Uruguay

Development of new drug formulations requires the performance of extensive studies, both in the laboratory, and in vivo, in animals and in volunteers. In vitro studies can be very expensive but costs are even higher when in vivo stages are reached. Methodology that can generate relevant means important savings in economic, human and time terms. Gamma scintigraphy provides rapid, complementary information that often cannot be obtained by other methodologies. It has been successfully used during development stages of feasibility studies and in determining specific parameters of the final product. The

information obtained by scintigraphy gives support during investigation and development, and also complements the development of registration dossiers and marketing publicity. The incorporation of a radiopharmaceutical into a drug formulation allows determination of

the biodistribution kinetics and the release sites. It is very important to choose the proper radionuclide, often 99mTc (technetium), as this has optimal characteristics of half-life and energy, allowing images to obtain with high efficiency and low doses. Many studies to validate the methodology mentioned above have already been undertaken , but, in general

within these studies, radiopharmaceuticals are only rarely used as drug surrogates. Radiopharmaceuticals were primarily developed for diagnostic purposes in nuclear medicine, most of them being intended for intravenous administration. In order to optimise the usage of radiopharmaceuticals in the development of pharmaceutical drug-delivery systems, the behaviour of these tracers following administration by other routes must be validated. Stability and in vitro studies of different radiopharmaceuticals have been previously reported by our group, with the aim of creating a database of radiotracers or model drugs with known physicochemical properties to be used as in pharmaceutical dosage development, particularly of tablet formulations. Provided that the tablet formulation can be radiolabelled with a suitable gamma emitter without altering its characteristics, imaging with a gamma camera can be used to monitor in vivo transit and dispersion of the tablet, and give some indication of deposition and absorption of the drug. The aim of our work was to assess in vivo and in vitro behaviour of tablet formulations using scintigraphic studies, to examine the way in which radiopharmaceuticals model the release of drugs, using four different tracers with different physicochemical characteristics. Based on this assessment, the correlation between in vitro and in vivo behaviour could be investigated. The characterised radiopharmaceuticals were 99mTc-diethylenetriamine-

pentaacetic acid (99mTc-DTPA), 99mTc-ethyl cysteinate dimer (99mTc-ECD), 99mTc-methylene diphosphonate (99mTc-MDP) and 99mTc-sestamibi (99mTc-MIBI). They were incorporated into the tablets during wet granulation. Disintegration and dissolution profiles were assessed in vitro in dissolution vessels and in vivo by scintigraphic imaging in healthy volunteers.

ABS S6-12

NEW LABELLING STRATEGIES IN THE DEVELOPMENT OF DIAGNOSTIC RADIOPHARMACEUTICALS

A. Rey
Faculty of Chemistry Uruguay

A radiopharmaceutical can be defined as a chemical substance that contains radioactive atoms within its structure and is suitable for administration in humans either for diagnosis or treatment of disease. The introduction of the radionuclide within the radiopharmaceutical is the so-called 'labelling'.

99mTc is the preferred radionuclide due to its ideal nuclear properties (t1/2= 6 h, Eγ = 140 KeV) that allow high efficiency imaging with low irradiation of the patient. Technetium belongs to group 7 of the periodic table and is located in the second row of the transition metals. Its chemistry is dominated by the formation of metal-donor complexes by combination with atoms or functional groups which are capable of donating electron pairs. 99mTc-labelling usually consists in the formation of co-ordination compounds between the radionuclide and an appropriate ligand. While our source of technetium is the 99Mo/99mTc generator systems, which provides the radionuclide as sodium pertechnetate (Tc (VII)), most radiopharmaceuticals contain the metal in reduced forms (Tc(V), Tc(III) or Tc(I)). Most labelling procedures require as a first step the reduction of pertechnetate. Although this might seem rather simple, the development of target-specific compounds using a non-physiological metal as technetium required a great deal of chemical effort. More and more complex labelling strategies were developed in order to follow the evolution of Radiopharmacy and Nuclear Medicine. First generation radiopharmaceuticals were simple 99mTc-labelled species (complexes, particles, cells) that could measure basic physiological functions by means of non-substrate specific mechanisms. Remarkable examples are 99mTc_DTPA (dietilenetetraminepentaacetic acid) for studies of renal functionality or 99mTc-labelled colloids for imaging the reticuloendothelial system. Labelling consisted only in the reduction of pertechnetate in presence of the ligand. Side reactions or impurities were almost negligible. Chemical structure of these first radiopharmaceuticals was unknown.

The development of the second generation 99mTc radiopharmaceuticals (agents designed to study the perfusion in heart, brain or kidneys) was based on both the ability for structural characterization of technetium compounds and the introduction of non-coordinating functional groups that could direct the 'in vivo' localization. Structure-biodistribution relationships were established and permitted the optimization of uptake and clearance. Most interesting examples are 99mTc-ECD (ethylenecysteinedimer) and 99mTc-MIBI (methoxyisobutylisonitrile). Labelling methods required to obtain these type of tracers in high yield and radiochemical purity were more complex, usually multistep and making use of intermediate ligands such as gluceptepnate, tartrate, EDTA (ethylenediaminetetraacetic acid). Modern Nuclear Medicine, focused on the study of biochemical processes 'in vivo' by means of non-invasive procedures, requires the labelling of biochemically relevant ligands. The third generation radiopharmaceuticals are consequently compounds that imitate biochemical substrates like enzymes or receptor ligands. The design of such agents required the development of new labelling strategies yielding pure and stable compounds of preserved bioactivity. Two approaches have been used for this purpose: integrate approach and pendent approach. The integrate approach incorporates technetium as an integral part of the biomolecule and mimics its three dimensional configuration. Labelling of steroids is the most remarkable example of this methodology. The pendent approach, on the other hand, makes use of the so-called biofunctional chelating agents (BFCA), a moiety that connects the biomolecule with a chelating unit for technetium through a linker. The linker is generally an hydrocarbon chain whose lenght and lipophilicity determines the pharmacokinetics of the resulting product. Some examples of BFCA are N2S2 (diaminedithiols), NS3 (mercaptoacetyltriglycine derivatives), N4 (propilenaminooxime derivatives) or HYNIC (hydrazine nicotinamide). Recently introduced 99mTc moieties as the Tc (I)-tricarbonyl and Tc(V)-nitrido or the Tc(III) 4 + 1 complexes open new possibilities for the labelling of small biomolecules. Our group has worked during the past few years in the design, preparation and evaluation of potential third generation 99mTc radiopharmaceuticals using novel labelling strategies. The 3+1 oxotechnetium (V) complexes, formed by simultaneous coordination of a tridentate SNS ligand and a monodentate thiol yield neutral lipophilic complexes that can incorporate a variety of different pharmacophores. The monodentate ligand 1-(2-methoxyphenyl)-4-(2-mercaptoethyl)-piperazine was designed by attaching a thiol group to the 1-(2-methoxyphenyl)piperazine moiety (a fragment of the true 5-HT1A antagonist WAY 100635) using an ethylene group as spacer. A group of 3+1 complexes were prepared, their structure was determined and their biological behaviour both 'in vivo' and 'in vitro' was studied. The same design approach was also applied to the preparation of potential markers of hypoxia using a nitroaromatic group as pharmacophore. Electrochemical behaviour, 'in vitro' cytotoxicity and uptake in mice bearing induced tumours were the main points studied in this area.

99mTc-tricarbonyl complexes are under intense investigation with the aim to produce 99mTc- labelled small biomolecules. Their high stability due to the d6 configuration of the metal is their main advantage. Our group has applied this strategy to the preparation of radiopharmaceuticals containing the p-nitrobenzyl bioreductive pharmacophore, with potential application in oncology and cardiology.

Other field of increasing interest is the labelling of small peptides. The peptide RGD-YK [c(Arg-Gly-Asp-D-Tyr-Lys)] which contains the RGD sequence, binding to αvβ3-integrin receptors expressed during neoangeogenesis in tumours and surrounding blood vessels, was selected in order to study the influence of the labelling strategy on the overall properties of the 99mTc derivative. Tc(I) tricarboyl, Tc(V) nitrido and Tc(III) 4 +1 complexes were used for labelling by means of a pendent approach. Different chelators were chemically combined to the basic peptidic structure. Lipophilicity, protein binding, 'in vitro' and 'in vivo' stability, biodistribution in mice and uptake in tumour models were studied and compared with the same peptide labelled by the traditional HYNIC methodology.

In conclusion, the clinical needs of Nuclear Medicine for specific tracers require the development of novel 99mTc labelling strategies yielding pure, stable and biologically active molecules. Many parameters influence the overall biodistribution of the final products and consequently further research on Tc chemistry is still required to fully satisfy these needs.

ACKNOWLEDGEMENTS: IAEA, CISC, PEDECIBA-QUÍMICA

ABS S6-13

RADIOPHARMACEUTICALS FOR APOPTOSIS AND NECROSIS DETECTION

E. Savio
Faculty of Chemistry Uruguay

Apoptosis or programmed cell death plays an important role in embryogenesis and homeostasis, and abnormal induction or inhibition of apoptosis has been related to several diseases such as neurodegenerative diseases, cardiomyopathy, myocarditis, cerebral and myocardial ischemia, infectious diseases, cancer development and tumour response to treatment, viral or toxin-induced hepatitis, and organ and bone-marrow transplant rejection,. As a consequence, in vivo imaging of apoptosis has potentially numerous valuable applications, as can be seen in the rapidly growing body of literature in the subject.

As already mentioned, apoptosis is a characteristic of tumours. The therapeutic response and the overall disease free survival depends on the cell death in a particular malignancy undergoing a particular treatment protocol. The present criteria of evaluation of response in tumours include regression of tumour size which appears to be inadequate. Detection and quantification of apoptosis in vivo are of significant clinical value for diagnosis and assessment of therapeutic efficacy. Apoptotic cell status of any tumour before and after therapy is important for patient management. A general and persistent feature characterizing cells undergoing apoptosis is the rapid exposure of phosphatidylserine, a membrane-bound phospholipid, by transport from the inner to the outer leaflet of the plasma membrane. This phenomenon occurs early in the apoptotic process, before membrane bleb formation and DNA fragmentation, forming an attractive target for visualization of apoptosis. Annexin V, a 36 Kda human protein, binds with high affinity to phosphatidylserine. Added to conventional imaging, the application of Annexin V imaging in guiding chemotherapy/radiotherapy might enhance the possibility of individualized therapy, influence clinical decision making and aid in time of surgery. Overall patient survival and quality of life can be further improved.

Annexin V has been prepared in our University, in an association work of the Radiochemistry Laboratory with the Molecular Biology Laboratory, through recombinant technology. The suitable DE3 E. coli strain was transformed with the pET22b::AnxV construction and grown until A600=0.7, induced with IPTG (isopropylthiogalactopiranoside) 0.1nM final concentration and finally grown for 5 hours.

Labelling Annexin V with a suitable radionuclide such as 99mTc, enables to carry out a non invasive study and therefore detects tissues/organs where apoptotic processs are present. As direct labelling of the protein is not suitable, different bifunctional chelating agent used for complexation of 99mTc has been used. One the most promising agent is a derivative Annexin V, in which the protein is modified with hydrazinonicotinamide side chain (Hynic-Annexin V) and with the simple addition of a reducting agent and pertechnetate in the presence of a coligand (tricine), the radiopharmaceutical can be prepared with a radiochemical purity higher than 90%.

On the other hand necrosis implies a broad spectrum of morphological changes that follows the cellular death in the tissue, derived mainly of progressive action of enzymes on cells which suffer a kind of lesion such as trauma, bacterial infection or acute hypoxia. Two processes take place at the same time: enzymatic cell digestion and protein denaturalization. In the patient, most necrotic cells are finally processed by a phagocytic process.

In mammals, D-glucaric acid (glucarate, GLA) is a 6-carbon dicarboxylic acid sugar and a natural catabolite of glucuronic acid metabolism (1,2). All mammals excrete

glucaric acid as a physiologic end product. GLA can be readily radiolabeled with sodium pertechnetate, resulting in 99mTc-GLA. Experimental studies have shown the favorable targeting potential of 99mTc-GLA of severe ischemia or early necrosis of the heart and brain, as well as tumour agent.. In acutely injured cells, it is believed that 99mTc-GLA is associated with disruption of the cell and nuclear membranes, allowing free intracellular diffusion and electrochemical binding of the negatively charged GLA complex to positively charged histones. This intracellular distribution is driven by the avidity of GLA to the nuclear protein and cytoplasmic proteins with a positive charge. In rat models with isoproterenol-induced myocardial infarction, 99mTc-GLA uptake in the infarcted hearts was found 6 times more than in normal rats. 99mTc-GLA has been proposed as a specific necrotic marker in the very early stages of myocyte injury but not as an apoptotic marker. As an infarct-avid agent, the early distribution in necrotic myocardium and rapid blood-pool clearance of 99mTc-GLA suggest important diagnostic potential in early detection of acute myocardial infarction and identification of successful acute revascularization.

99mTc-GLA was evaluated by our group in an animal model of induced mammary adenocarcinomas with nitrosomethylurea (NMU). NMU induces spontaneously tumour when given to young female Wistar rats, being an alkylating agent, which does not requered metabolic activation to initiate tumour formation. NMU decomposes spontaneously to shield a methyl-diazonium ion believed to be the ultimate carcinogenic. The study was carried out in wistar rats during 50 – 55 days, injecting through the tale vein 5 mg of NMU in acetic acid (0.3%) each 100 g weight in three times (at week 0, 4 and 8). When tumour was palpable (week 9) scintigraphic images were acquired in a Sophia Camera DSX at 1, 2, 4 and 6 hs post-injection of 99mTc-GLA weekly. First human studies are now being carried out.

In conclusion, radiopharmaceuticals for detection of apoptotic and necrotic processes will be shown in this presentation, explaining which are the main differences and requeriments for both agents as tracers of different, but related, phisiologycal/pathological pathways of cell death.

BIO S7

BIOGRAPHY A.N.O. DODOO

N.O. Dodoo
University of Ghana Medical School Ghana

Dr Alexander Nii Oto Dodoo is the Coordinator of the Ghana National Centre for Pharmacovigilance and the Acting Director of the Centre for Tropical Clinical Pharmacology & Therapeutics at the University of Ghana Medical School. He undertook his pharmacy degree in Kumasi, Ghana and postgraduate degrees (M.Sc. and Ph.D.) from the Chelsea Department of Pharmacy, King's College London. Dr Dodoo worked as a Senior Scientist at Roche Discovery Welwyn, the UK Division of F. Hoffman La Roche Pharmaceuticals of Switzerland from 1996-1998 and moved later into community pharmacy practice as a locum in July 1999.

Dr Dodoo joined the University of Ghana Medical School as a Research Fellow in January 2000 and was involved in the setting up and running of the National Centre for Pharmacovigilance in Ghana. This Centre was the first of its kind in West Africa and made Ghana the 65th member of the WHO Programme for International Drug Monitoring.

Dr Dodoo is a member of the WHO Global Advisory Committee on Vaccine Safety, the CIOMS/WHO core group on drug development in resource-poor countries as well as the CIOMS/WHO working group on AEFI. He is a member of the Consortium Safety Panel for Intermittent Preventive Treatment of Malaria in Infants and serves on the Data and Safety Monitoring Board for HIV/AIDS trials in Africa. Dr Dodoo is a member of the Pharmaceutical Society of Ghana, the Royal Pharmaceutical Society of Great Britain, the International Society of Pharmacovigilance and a Life Member of the Society of Pharmacovigilance in India. He includes writing, travelling, trying exotic cuisine and wines and listening to good music among his hobbies.

BIO S7

BIOGRAPHY G.G. DE OLIVEIRA

G. De Oliveira
National Agency of Sanitary Surveillance Brazil

* MD, PhD (Pharmacology);
* Consultant of ANVISA President;
* Specialized in Internal Medicine, Cardiology, Lung Diseases, Intensive Care Medicine;
* Post-doctoral Fellowships in Clinical Pharmacology at Harvard Medical School, University of Rochester, FDA and NIH(USA);
* Fellow of the American College of Clinical Pharmacology;
* Fellow of the National Academy of Pharmacy (Brazil);
* Researcher of National Council of Scientific Deveopment (Brazil);
* Professor of Clinical Pharmacology of the Faculty of Medicine of Brasilia

BIO S7

BIOGRAPHY G. LEUFKENS

G. Leufkens
Utrecht University Netherlands

Dr Leufkens obtained his PharmD and PhD degree from Utrecht University. In 1998 he was appointed as full professor and Chair of the Department of Pharmacoepidemiology and Pharmacotherapy at the same university. This is one of the leading groups in pharmacoepidemiology (output >;50 publications per year in peer reviewed press, highly visible profile, resource for innovative methodologies). From 2003-2005 he has been the Scientific Director of the Utrecht Institute for Pharmaceutical Sciences (UIPS). Since the beginning of 2006 he is Dean of Pharmaceutical Sciences of the Faculty of Science in Utrecht. Moreover, Dr Leufkens is scientific director of the SIR Pharma Policy Institute in Leiden and active at several (inter)national platforms on pharmacoepidemiology (e.g. Past-President of ISPE) , pharmacovigilance, risk assessment, pharma policy, orphan drugs and scenario planning. He is (co) author of >: 230 papers in peer reviewed journals, book chapters and research reports.

ABS S7

PRACTICAL ASPECTS OF PHARMACOVIGILENCE

G. Leufkens
Utrecht University Netherlands

Pharmacovigilence aims to bridge clinical pharmacology, medicine, epidemiology, molecular sciences and public health. There is increasing awareness about the limitations of pre-marketing research in drug therapy. The occurrence of unknown, rare adverse effects, the 'real world' of pharmacotherapy with conditions not reflected by the controlled clinical trial environment and the erratic nature of all the different market forces, fuel the need for ongoing monitoring and surveillance in order to fill the gap with the pre-marketing picture. There is ample evidence that drug safety is correlated both with patient factors (disease severity, co-morbidity, metabolism, genetics) and utilization factors (quality of diagnosis, inappropriate prescribing, concomitant use of other drugs, non-compliance and other patterns of interrupted drug usage). With the introduction of new drug therapies in upcoming years, there will be a clear need for comparative risk/benefit evaluation after the drug has been used widely in daily practice. The term risk management has been introduced to umbrella the pharmacovigilence activities starting with risk detection, identification, assessment and management. An important part of risk management is patient typing, integrating reports on ADRs, bioinformatics, clinical medicine and epidemiology.

BIO S8

BIOGRAPHY S. KEITEL
S. Keitel
Federal Institute for Drugs and Med. Dev Germany

Dr. Susanne Keitel is a licensed pharmacist and holds a Ph.D. in pharmaceutical technology. Her working experience includes 10 years in pharmaceutical development in the pharmaceutical industry, five of which as Department Head 'Pharmaceutical Development/Oral Dosage Forms' at Schering AG, Berlin. From Oct. 1997 to June 2005, Dr. Keitel held the position of Division Head Pharmaceutical Quality at the Federal Institute for Drugs and Medical Devices (BfArM), Germany. In additions,whe served as Acting Head of the division European Procedures.

As of July 2005, Dr. Keitel is now Head of EU and International Affairs at BfArM. She is vice-chair of the Joint CHMP/CVMP Quality Working Party and a member of the EMEA Paediatric Working Party, the Notice to Applicants Group and has been rapporteur for the ICH stability guidelines. At present, she is EU-topic leader of the Expert Working Group 'Pharmaceutical Development' (ICH Q8). Furthermore, Dr. Keitel chairs the Special Interest Group 'Quality of Pharmaceuticals' of FIP as well as the Expert Group 'Drug Regulatory Affairs' of APV.

BIO S8

BIOGRAPHY A.S.R. RAW
A.S.R. Raw
Food and Drug Administration United States of America

Andre Raw received his B.S. degree in chemistry from the Massachusetts Institute of Technology (1988) and his Ph.D. degree in organic chemistry from the University of California at Berkeley (1993). Dr. Raw was a post-doctoral research fellow with Alfred G. Gilman at the University of Texas Southwestern Medical Center where his research interests focused on protein biochemistry and x-ray crystallography. In 2000, he joined the FDA as a chemistry reviewer. Currently he is in the Office of Science and Regulatory Policy for the Office of Generic Drugs, where he is actively involved in the review and resolution of complex scientific and regulatory issues related to drug applications, citizen petitions, and industry correspondence.

BIO S8

BIOGRAPHY P.A. PAULUS
P.A. Paulus
Boehringer Ingelheim GmbH Germany

Name: Friedemann Paulus
Year of birth: 1947
Nationality: German
Profession: Pharmacist

2000 until current date:
Head of Corporate Group GMP Compliance at Boehringer Ingelheim GmbH
Main functions:
- Alignment of BI companies concerning GMP compliance and quality systems
- System owner of corporate GMP and EHS audits
- Support for the preparation of authorities' audits

1996 – 2000: Head of GMP audits at Boehringer Ingelheim Germany
Main functions:
- System owner of self inspections of pharmaceutical and bio – pharmaceutical production sites
- System owner of supplier qualification
- Preparation of sites for authorities' inspections (7 USA FDA inspections)

1987 – 1996: Head of Corporate Group 'Production Americas' at BI GmbH
Main functions:
- Production strategies within North and South American Pharmaceutical Operations
- Project leader of 'Production Alliance Argentina – Brazil'
- Project participant of 'Production Alliance Canada – USA – Mexico'
- Development of a KPI system for BI operations worldwide

1979 – 1986: Head of Operations Boehringer Ingelheim Columbia

1976 – 1979: Head of Pharmaceutical Production Boehringer Ingelheim Brazil

1973 – 1976: Boehringer Ingelheim Germany

- Co-ordination of third party manufacturers in Asia

ABS S8

QUESTION-BASED REVIEW FOR CMC EVALUATIONS OF ANDAS

A.S.R. Raw
Food and Drug Administration United States of America

The Office of Generic Drugs (OGD) is developing a question-based review (QbR) for the Chemistry, Manufacturing, and Controls (CMC) evaluation of an Abbreviated New Drug Application (ANDA) that is focused on critical pharmaceutical quality attributes. The QbR will transform the CMC review into a modern, science and risk-based pharmaceutical quality assessment that incorporates and implements the concepts and principles of the FDA's Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach and Process Analytical Technology initiatives. The main objectives of this enhanced review system are to 1) assure product quality through design and performance-based specifications, 2) facilitate continuous improvement and reduce CMC supplements through risk assessment, 3) enhance the quality of reviews through standardized review questions, and 4) reduce CMC review time when sponsors submit a quality overall summary that addresses the QbR.

ABS S8

GMP INSPECTIONS: HOW TO MEET THE CHALLENGES

P.A. Paulus
Boehringer Ingelheim GmbH Germany

Pharmaceutical supply chains have become complex in recent years. Bulk may be produced in country A, packaging is performed in country B, the product itself may be delivered to a series of different countries all over the world. Authorities of countries which have granted marketing authorisations are increasingly inspecting manufacturing sites. Inspectors of most of the internationally inspecting countries are well prepared and quite demanding.

Passing authorities' GMP inspections is the Ticket for Business in different countries. Preparation for those inspections should, therefore, be handled like a project which requires special skills and sufficient resources.

This speech focuses on how to prepare an operation efficiently for inspections like the US FDA, the EMEA of the European Community, the Brazilian ANVISA and others. It highlights critical topics concerning GMPs as well as the human factor – of both sides: the auditees' and the auditors'.

ABS S8

GOOD DISTRIBUTION PRACTICES - PACKAGING, STORAGE, AND DISTRIBUTION

S.P. Phanouvong
United States Pharmacopeia United States of America

Topic: FIP Special Interest Group on Quality Pharmaceuticals
Session: Quality Issues
Souly Phanouvong, PharmD, PhD, Manager, Drug Quality Assurance and Policy Development, and Nancy L. Blum, MPH, MA, Vice-President-International Affairs and Director, USP Drug Quality and Information Program, U. S. Pharmacopeia,
Title of Presentation: Good Distribution Practices - Packaging, Storage, and Distribution
Abstract:
In quality assurance, by definition good distribution practices ensure that the quality of pharmaceutical products is maintained throughout every step of the distribution process. That is, the products are adequately labeled and packaged and are consistently stored, transported, and handled under the conditions required by the marketing authorization or product specifications. Many challenges affect, in part or in whole, the distribution processes about which all interested parties involved—manufacturers, importers, distributors and wholesalers, retailers, and health professionals—should be aware. These quality assurance practices should cover not only the finished pharmaceutical dosage forms, but also the starting materials and exipients. Any negligence, fraudulence, or attempt to circumvent legislation or regulatory systems in the course of product labeling, packaging, storage, and distribution practices, could lead to compromised products, contamination, personal injury, or loss of life. Distribution systems with inadequate regulatory protection or poor authority enforcement are especially susceptible to these risks. This presentation discusses key principles and practical guidelines to which each business involved in the packaging, storage, and distribution of medicines—and their quality control systems, in particular—should comply to ensure that the correct pharmaceutical product reaches the end user with safety and assured quality.
Learning Objectives:
- Define what is meant by good distribution practices.
- Articulate basic principles of proper labelling, packaging, storage, and distribution of pharmaceuticals.
- Recognize the impact of each process malpractice.
- Describe interventions that governments, the pharmaceutical industry, and health care providers can take to improve labeling, packaging, storage, and distribution practices.
Keywords: practices, packaging, storage, distribution, guidelines.
Related Web page: www.uspdqi.org
Presenting author's disclosure statement:
I wish to disclose that I have no financial interest or other relationship with the manufactures of commercial products, suppliers of commercial services, or commercial supporters.

BIO G01-0

BIOGRAPHY K. HAKKARAINEN

K.M.E. Hakkarainen
IPSF Netherlands

Ms Katja Hakkarainen was the President of the International Pharmaceutical Students' Federation in 2005-06. She started in the IPSF Executive as the IPSF Chairperson of Student Exchange in 2003-04. During her terms in the IPSF Executive, Ms Hakkarainen served IPSF as the Permanent Officer in The Hague, The Netherlands, in 2003-04 and in 2005-06. In 2004-05 she was the Co-ordinator of the IPSF-FIP booklet 'Counselling, Concordance and Communication – Innovative Education for Pharmacists' that was launched at the FIP Congress in Cairo, Egypt, in 2005. Between 2004 and 2006 Ms Hakkarainen has been in the organising committee of two IPSF Patient Counselling Events in Finland and the Patient Counselling Events of the 51st and 52nd IPSF Congresses in Bonn, Germany and Cairns, Australia. In 2006 she has co-ordinated the translation processes of the booklet into Portuguese, Chinese and Japanese. As the IPSF President she has been actively involved in several educational activities of IPSF, including the Moving On II research on students' learning experiences, Moving On III research on students' migratory intentions and several public health projects on diabetes, HIV/AIDS, tobacco and tuberculosis. Ms Hakkarainen has attended IPSF events and meetings in 20 countries, represented IPSF at the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) and taken part in three FIP Congresses. Ms Hakkarainen will start her 5th year in pharmacy at the University of Helsinki, Finland, in September 2006, specialising in social pharmacy. She has worked in a community pharmacy since 2000 and practiced pharmacy as a bachelor of pharmacy since 2004.

BIO G01-0

BIOGRAPHY C. ANDERSON

C.W. Anderson
University of Nottingham United Kingdom

Claire Anderson is Professor of Social Pharmacy and Director of the Centre for Pharmacy Health and Society at the School of Pharmacy, University of Nottingham, UK. She is President of the Academic Section of International Pharmaceutical Federation (FIP) and on the board of the College of Pharmacy Practice. Her major research interest is about the role of community pharmacists in improving the health of the public. Claire Anderson has published over 60 refereed papers and numerous conference abstracts. Perhaps the most important piece of research she has produced is the strategic research for Pharmacy HealthLink and the Royal Pharmaceutical Society of Great Britain, investigating the broader public health role of pharmacy. She has also been Nottingham's principal investigator in a high profile, collaborative research project that has the potential to radically restructure the role of community pharmacists. The Community Pharmacy Medicines Management Project, a Department of Health funded multi-centre, randomised controlled trial, has evaluated the role of pharmacists in advising patients and prescribers concerning appropriate treatment for coronary heart disease. Her team along with reserachers at The univeristy of Sheffiled are evaluating supplementary prescribing by nurses and pharmacists for the Department of Health, this is a major study which will inform both policy and practice in this area.

BIO G01-1

BIOGRAPHY E.K.D. DIEDRICHSEN

E.K.D. Diedrichsen
Massachusetts General Hospital United States of America

Ellen Diedrichsen served as the Chairperson of Pharmacy Education for the International Pharmaceutical Students' Federation in 2005-06. She earned a PharmD at the University of Nebraska - Medical Center, USA, and completed a pharmacy practice residency at Massachusetts General Hospital in Boston, Massachusetts, USA. Ms Diedrichsen is currently a pharmacist at Massachusetts General Hospital.

BIO G01-2

BIOGRAPHY T.F. CHEN

F. Chen
The University of Sydney Australia

Dr Timothy F Chen

B Pharm, DipHPharm, PhD, MPS

Dr Tim Chen is a Senior Lecturer in Pharmacy Practice at The University of Sydney, Faculty of Pharmacy. He is an experienced researcher and educator. His doctoral research involved the first major Australian study evaluating the role of the pharmacist in conducting Home Medicines Review (HMR) and interprofessional collaboration with medical practitioners. This research and his subsequent studies in HMR have helped inform a national model for practice which has been taken up by the Australian Commonwealth Government. In recognition for his contribution to the advancement of Pharmacy Practice, he was awarded the Young Australian Pharmacist of the Year Excellence Medal, (2001). Dr Chen currently serves on a number of peak national pharmacy advisory boards. He is the principal author for two process-based case studies books for pharmacists and pharmacy students, in Medication Review (2002) and Pharmacist Only and Pharmacy Medicines (2003). He leads an active research team which includes PhDs, Masters and Honours candidates.

BIO G01-3

BIOGRAPHY J.L. MARRIOTT

J.L. Marriott
Monash University Australia

Jennifer graduated with a Bachelor of Pharmacy degree from the Victorian College of Pharmacy, Australia in 1971.

She worked for 5 years as manager of a community pharmacy then as locum pharmacist in both hospital and community settings for several years before commencing as a senior clinical pharmacist at a tertiary care hospital where she remained for 15 years. During this time Jennifer was responsible for Clinical Ward pharmacy, Drug Use Evaluation and Clinical education.

Jennifer was awarded her Doctor of Philosophy at Monash University, Faculty of Medicine in 2000.

In 1999 she was appointed to the position of Lecturer (now Senior Lecturer) in Clinical Pharmacy, Department of Pharmacy Practice, Victorian College of Pharmacy, Monash University, where she developed the Course in Clinical Pharmacy. Her teaching responsibilities include unit co-ordination and teaching Clinical Pharmacy to third and fourth year undergraduate students.

Her research interests include: New Professional roles for pharmacists, Preceptor Education, Community Liaison Pharmacy, Electronic Decision support, Palliative Care, and the effect of cultural and linguistic difficulties on medication use.

Jennifer is currently President–Elect of the Academic section of the International Pharmaceutical Federation (FIP).

BIO G01-4

BIOGRAPHY S. BELL

J.S. Bell
The University of Sydney Australia

Simon Bell completed his pharmacy degree at the University of Sydney in 2000, and registered as a pharmacist in Australia in 2001. His PhD study involved the development and evaluation of new models of multidisciplinary collaboration in mental health care.

Simon is an Executive Councillor of the Pharmaceutical Society of Australia (NSW Branch), Chairperson of the Pharmaceutical Society of Australia (NSW Branch) Futures Taskforce and a past Chairperson of the NSW Young Pharmacists. Simon has acted as an advisor on pharmacy practice for the World Health Organization, Australian Consumers Association and several pharmaceutical companies.

In 2003, Simon was elected President of the International Pharmaceutical Students' Federation (IPSF). During his term as President Simon worked from the IPSF and International Pharmaceutical Federation (FIP) secretariat in The Hague, The Netherlands.

Simon has spoken about pharmacy practice and pharmacy education at conferences and universities in more than 30 countries worldwide, and been a chief investigator or co-investigator on five successful grant applications. Simon was Young Australian Pharmacist of the Year in 2004.

ABS G01-1

MOVING ON II STUDY: STUDENTS' LEARNING EXPERIENCES

E.K.D. Diedrichsen
Massachusetts General Hospital United States of America

A questionnaire-based research project was conducted by the International Pharmaceutical Students' Federation (IPSF) to determine pharmacy students' experiences and aspirations around the globe. More specifically the project aimed to discern how the type of academic proagramme and personal influences affected students' perception of their programme and their plans for the future.

ABS G01-2

LEARNING FOR PRACTICE: HOME MEDICINES REVIEWS

F. Chen
The University of Sydney Australia

The profession of pharmacy has undergone significant advances over the past two decades, especially with respect to the development of professional pharmaceutical services. These new professional services include medication review for ambulatory patients; disease state management services for patients with chronic conditions such as diabetes and asthma; and screening and monitoring services. Correspondingly, pharmacists have had to learn new skills in order to provide such services to clients. The aim of this paper is to discuss the multiplicity of learning and teaching approaches to help prepare pharmacists for the provision of medication review services for ambulatory patients, known as Home Medicines Review in Australia. It will also describe why pharmacists must take a life long approach to learning, if they are to deliver professional services in an increasingly competitive healthcare environment. This paper will be divided into two broad sections, although not mutually exclusive. One section will focus on the educational aspects of undergraduate/graduate university-based training in medication review, such as case-based and/or problem based learning in small tutorial groups; the principles of evidence-based practice; the role of the pharmacists as a 'medicines expert' within the multidisciplinary health sector; inter-professional communication (verbal and written) and experiential learning. The second section will focus on programmes for registered pharmacists who wish to provide medication review services and the professional support and requirements, offered to those currently undertaking reviews. In addition to provision of pharmacotherapeutic updates, examples will include tailored, interactive continuing professional education; practice support offered by professional organizations; the use of technology to support activities; and the integration of professional services into the routine activities of pharmacists. The latter is of particular practical importance. In summary, the provision of professional pharmaceutical services such as medication review, requires a variety of learning and teaching approaches. These approaches must be central to university-based training and relevant to contemporary pharmacy practice, as the professional roles of pharmacists expand.

ABS G01-3

VIRTUAL PATIENTS IN PHARMACY EDUCATION

J.L. Marriott
Monash University Australia

This presentation will outline the use of virtual patients and simulated patients within the Bachelor of Pharmacy degree and Pre-Registration Program. Virtual patients are computer-generated, standardised patients that can be used for a variety of purposes; this presentation will focus on their use to develop a case-based assignment. Simulated patients are real people, who are not necessarily patients, but who are taught to act the role of patients for a variety of purposes; this presentation will focus on their use to teach and assess communication skills. It will also compare the use of virtual patients with simulated patients.

The Case-based Assessment program is a specially designed computer program that contains a database of 200 virtual patients created from information contained in databases of medication, medical conditions and allergies, supplemented by additional information such as a name, age and smoking history. The databases can be regularly updated to accommodate new or deleted medications or to add new scenarios. A range of clinical scenarios based on respiratory, dermatological or other conditions are able to be randomly allocated to each patient based on pre-determined criteria such as age, medical condition or smoking history. The student is required to assess the applied scenario and determine appropriate treatment with consideration of patient characteristics and present their case to a small group for both tutor and peer assessment using a criterion referenced marking guide.

Simulated patients are used to assess communication skills in undergraduate and pre-registration students using a variety of clinical scenarios. The simulated patient may assume a variety of moods from shy or embarrassed to aggressive or rushed. The student must draw upon their communication skills to deal with the variety of patient types as well as the variety of problems. Simulated patients can be used to assess history –taking or counselling skills depending on the scenario.

ABS G01-4

MENTAL HEALTH PATIENTS AS PROVIDERS OF PHARMACY EDUCATION

J.S. Bell
The University of Sydney Australia

The World Health Organization has estimated that 450 million people worldwide suffer from a mental illness. People with mental illnesses have expressed their dissatisfaction with information about medications provided by their health professionals. Lack of education and sub-optimal attitudes toward people with mental illnesses have been cited as barriers to pharmacists' provision of medication counselling. Institutions offering education to students studying to become health professionals have typically not been accountable to recipients of health care.

A consumer educator is a person who has previously received mental health care and works to inform and educate professionals, students and the wider community about the effects of mental illnesses. Utilising consumer educators as providers of undergraduate and postgraduate pharmacy education may be associated with positive outcomes for students, pharmacists and consumers alike. Promoting interpersonal contact with people with mental illnesses can improve students' attitudes toward people with schizophrenia and severe depression. Consumers have reported that speaking about their illness has assisted in their recovery. This presentation will outline the research evidence for involving consumers as providers of mental health pharmacy education.

Biographies - Managing Change in Pharmacy Practice (G 02)

BIO G02-1

BIOGRAPHY A.O. ARANCIBIA

O. Arancibia
Universidad de Chile Chile

Graduated as pharmaceutical chemist at the University of Chile. Postgraduate training at the universities of Pavia, Italy, and California, San Francisco. Professor of the Faculty of Pharmaceutical Sciences and Technology, University of Chile .

Researh interest in biopharmaceutics, pharmacokinetics and pharmaceutical technology Doctor Honoris causa of the University of Auvergne, France. FIP Scientific Award 2000.President of the Pharmaceutical Forum of the Americas.

BIO G02-2

BIOGRAPHY M. SCHULZ

M. Schulz
ABDA Germany

Curriculum vitae

Professor Martin Schulz, PhD

Martin Schulz, PhD (born 1959, married, 3 boys), is an Adjunct Professor at Johann Wolfgang Goethe University, Department of Pharmacology, Frankfurt at Main, Germany. In his main job, he is Head of the Centre for Drug Information and Pharmacy Practice (ZAPP) of the ABDA - Federal Union of German Associations of Pharmacists, Berlin. In addition, Dr. Schulz is Director Pharmacy of the German Institute for Drug Use Evaluation (DAPI). He graduated as a pharmacist from the University of Hamburg, Germany, in 1983. From 1983-1984, he was a hospital pharmacist, and studied Medicine at the University of Hamburg from 1984-1986. In 1988, he obtained his Ph.D. in Pharmacology from the University of Hamburg. In 1989, he was named 'Expert in Pharmacology DGPT' by the German Society for Experimental and Clinical Pharmacology and Toxicology (DGPT). He specialized as a Drug Information Pharmacist in 1993. Evaluation and implementation of the pharmaceutical support (pharmacy practice, pharmaceutical care); Promotion of an effective and safe self-medication; Pharmacoepidemiology and -economics; Drug information and drug supply and -usage etc. are some of the areas where Dr. Schulz has expertise. Main interests: Outcomes research; Quality and effectiveness of interventions (in particular medicines); Drug information and regulation; Health-/pharmacoeconomics. He has nearly 350 publications to his name and has also delivered 215 lectures, seminars and has written some books as well. Dr. Schulz is a member in various committees and commissions like BfArM, Bonn; BMG, Berlin; FIP, The Hague, and serves on various advisory/expert committees.

BIO G02-3

BIOGRAPHY R.W. HOLLAND

R.W. Holland
PharmEd Consultants United States of America

Ross W. Holland, Ph.D., Ed.D., FPS, FASHP, FAIPM, FACPP, has been actively involved in community pharmacy ownership or management for almost 40 years. In addition he has been involved in clinical pharmacy, hospital pharmacy management, the vocational education of pharmacists and nurses, educational administration and medical education.

Over the years Ross has been involved in many areas of practice change relating to the implementation of pharmacy services. His doctoral studies in the faculty of medicine at the University of New South Wales, Australia, revolved around practice change for pharmacists. This lead to working with a colleague with similar interests, Dr Christine Nimmo, to jointly create a systematic approach to implementation of new practices amongst health care practitioners, a system that is now employed in many countries. Together they have written extensively about practice change in both community and hospital pharmacy.

Prior to his relocation to the United States of America four years ago Ross was Dean of the Australian College of Pharmacy Practice. Until recently Ross was actively involved in education and training as Senior Manager, Capacity Building for Performance Improvement at Management Sciences for Health, a not-for-profit international organization providing support and training in practice change for pharmacy supply chain management systems in developing countries. In that role he was designing, developing and implementing programs for medical and pharmacy professionals working to improve reliable access to and rational use of medications, laboratory and related supplies for HIV/AIDS, malaria, tuberculosis, infectious diseases and child and maternal health in over 50 countries worldwide.

Dr Holland is currently working as an independent education consultant

BIO G02-4

BIOGRAPHY C.M. NIMMO

C.M. Nimmo
American Society of Health-System Pharma United States of America

Christine M. Nimmo, Ph.D., is an instructional designer whose particular areas of interest include pharmacy residency training and continuing education programs that teach clinical problem solving skills. Her B.S. in English, M.Ed. in curriculum development, and Ph.D. in instructional design were all earned at the University of Maryland, College Park. She is currently Manager, Standards Development and Training in the Accreditation Services Division of the American Society of Health System Pharmacists. Current projects include the development of standardized criteria for use by pharmacy residency accreditation surveyors and of a surveyor training program. Recent projects include leading the task and learning analysis for the Medication-Use System Safety Strategy (MS3), leading the development of a customization of the Residency Learning System (RLS) for use in community practice residencies, and international training for use of the Holland-Nimmo Practice Change System, a change model that addresses how to maximize the possibility that an individual pharmacist will make a significant change in practice model. She is the primary editor and author of Staff Development for Pharmacy Practice, a text addressing all tasks associated with a systematic approach to training staff,and has contributed chapters to A Practical Guide to Pharmaceutical Care and Medication Safety: A Guide for Health Care Facilities.

BIO G02-5

BIOGRAPHY TH.F.J. TROMP

Th.F.J. Tromp
QIPC/Flevowijk pharmacy Netherlands

- Graduated at Groningen University in 1973;
- Community pharmacist in Kampen in 1980 (until today), a staff of 3 pharmacists and approx 10 assistants and supporting team members. Taking care of approx 12.000 patients;
- PhD Thesis in 1983;
- President of the Royal Dutch Association for the Advancement of Pharmacy (KNMP), 1988-1993. Active in many committees covering e.g. quality, ethics, pharmaceutical care and care protocols;
- Professor in Pharmaceutical Care, University of Groningen, 1991-2002;

- Member and president of the executive committee of the European Association for Faculties of Pharmacy and chairman of the Task Force for the development of a curriculum for Pharmaceutical Care in the European Faculties, 1997-2002;

- (Founding) member of the Pharmaceutical Care Network Europe (PCNE);

- Member of the Dutch delegation of the Pharmaceutical Group in Europe (PGEU), 1988-1998;

- (Founding) member of and delegate to the EuroPharm Forum (EPF), 1992-today;

- Vice and (immediate past) president of the Community Pharmacy Section (CPS) of FIP, 1991-2000;

- Chairman of the Board of Pharmaceutical Practice (BPP) of FIP, 2002-..;

- Member of FIP Bureau, 2002-..;

- Founder and director of the Quality Institute for Pharmaceutical Care (QIPC),1997-..., to support pharmacists to develop and implement Pharmaceutical Care in their pharmacies.

BIO G02-6

BIOGRAPHY E. SAVIO

E. Savio
Faculty of Chemistry Uruguay

1.- Personal data: Date of birth: 22/11/61
Work address Facultad de Química Gral. Flores 2124. CP.11.800. Montevideo. Uruguay
2.- Education

Degree	Year	University
PhD.	1994	UDELAR and PEDECIBA
Pharmacist	1988.	UDELAR.
Bachelor in Chemistry	1986	UDELAR

UDELAR – Universidad de la República – Uruguay PEDECIBA – Programa de Investigaciones Básicas – PNUD)
3.- Employment history in the University
Present Positions 98- Professor of Radiochemistry - 04 - Director of Hospital Pharmacy Diploma
Previous Positions
94-98 Associated Professor of Pharmacology. 95-98 Associated Professor of Radiochemistry
91-94 Assistant of Radiochemistry 88-90 Research contracts on Radiopharmacy Projects
90-93 Fellowship for Ph.D. studies.
4- Other relevant information
91-06 Director of the National Pharmaceutical Journal (Revista de la Asociación de Química y Farmacia del Uruguay).
04-06 Member of the National Technical Group on behalf of Faculty of Chemistry, which is carrying out Good Pharmacy Practice Project. National Coordinator.
94 - 04 Participation in national and international courses of Radiopharmacy, Hospital Radiopharmacy and Interne Dosimetry.
01-03 President of the Nuclear Medicine and Biology Society of Uruguay
00-01 Member of the organization of the Pharmaceutical Congress of the Americas, supported by AAPS (American Association of Pharmaceutical Scientist) and other organizations (OPS, FePAFAR, FeFaS, FFCC, FIP, Canadian Society for Pharmaceutical Sciences, Food and Drug Administration, American Pharmaceutical Association, American Association of Colleges of Pharmacy)
00 President of the 'VI Congreso de la Federación Farmacéutica' (VI FEFAS Congress), VI Encuentro National de Químicos Farmacéuticos Hospitalarios y II Jornadas Nacionales de Farmacia Comunitaria
97-98 Member of the Council of PEDECIBA (National Programme for the Development of Sciences)
93- President of the I Congreso de la Federación Farmacéutica Sudamericana (I FEFAS Congress) y II Encuentro de Ciencias Farmacéuticas del Cono Sur.
92-94 President of the National Pharmacist Association
02-05 Expert of the International Agency of Atomic Agency (IAEA)
05- Expert mission to develop Hospital Radiopharmacy in Colombia- September. National Institute of Cancer.
04- Consultans meeting to elaborate the document 'How to operate Radiopharmacy Units', with Drs. Chianelli (Italy, Jeong (Corea), Bhonsle (United Kingdom), Saw (Singapore). March, Vienna, Austria.
03- Expert mission to evaluate Radiopharmacy activities in Colombia. 28 Febreaury - 3 March 2002.
02 - Expert mission to evaluate Project Arcal LII. Sao Pablo, Instituto de Pesquisas Nucleares, Brazil. 10 to 14 September 2002
86-00 Member of the Faculty of Chemistry Council on behalf of pharmacist students (1986-88), pharmacists (1988-90), teachers (1998-00)

ABS G02-1

INTRODUCTION

O. Arancibia
Universidad de Chile Chile

The Pharmaceutical Forun of the Americas seeks to strengthen all aspectos of imprioving health and the quality of life of the citizens of the member countries in the region of the Americas. The main objective is to improve the health by the development and enhancement of pharmacy practice. The Forum and Fip has been working together to support practice changes in pharmacy which has been applied in developed countries and are important in developing countries as well.

ABS G02-2

FROM PRODUCT ORIENTATION TO PATIENT ORIENTATION – A CHALLENGE FOR THE PROFESSION

M. Schulz
ABDA Germany

Seen in the long term, community pharmacy practice will only survive if this 'supply chain' will demonstrate an added value for the benefit of both, the individual patient and the society. Taking responsibility for both, (positive) patient and pharmacoeconomic outcomes in daily practice is challenging the profession. Hence, probably the most important shift in the recent history of pharmacy is from the product supply to patient-centred services The changes occurring in community pharmacy practice as the profession attempts the transition from product to service orientation are well documented in the literature. There is agreement amongst all stakeholders and community pharmacists about change: it is hard and generally more complex than initially anticipated. The impact of factors affecting change has largely been limited to discussion of barriers and constraints, rather than to focus on the factors that facilitate change (Roberts A, PhD thesis, U Sydney 2006).

As there is an steadily increasing body of evidence in the area of pharmaceutical care or cognitive pharmaceutical services and (community) pharmacy practice research, the current challenge for the profession is understanding and facilitating practice change. In this respect, both internal and organisational factors have to be addressed carefully and simultaneously. Therefore, we should learn from both positive and disappointing examples of community pharmacy practice which will be presented and discussed during the talk.

ABS G02-3

BEHAVIOUR CHANGE

R.W. Holland
PharmEd Consultants United States of America

Pharmacy practice continues to change at an ever increasing rate. Since the introduction of the concept of pharmaceutical care over a decade ago many exciting developments have occurred – medication reviews in nursing facilities, the community pharmacy and even in patients' homes, disease state management programs in the community, collaborative practice, and increased emphasis on medication safety issues – to name a few areas where changes have occurred and continue to occur.

These changes in practice all require changes in behaviour if they are to be successful – changes at the professional association level, and in community pharmacy managers, pharmacists, and pharmacy technicians and assistants. But changing behaviour whether at the association, community pharmacy or personal level is not easy and should be approached, planned and implemented in a systematic fashion.

In this presentation a simple framework will be presented that has been shown to be an effective tool in promoting change in behaviour.

ABS G02-4

CHANGING BEHAVIOUR

C.M. Nimmo
American Society of Health-System Pharma United States of America

Pharmacy practice continues to change at an ever increasing rate. Since the introduction of the concept of pharmaceutical care over a decade ago many exciting developments have occurred – medication reviews in nursing facilities, the community pharmacy and even in patients' homes, disease state management programs in the community, collaborative practice, and increased emphasis on medication safety issues – to name a few areas where changes have occurred and continue to occur.

These changes in practice all require changes in behaviour if they are to be successful – changes at the professional association level, and in community pharmacy managers, pharmacists, and pharmacy technicians and assistants. But changing behaviour whether at the association, community pharmacy or personal level is not easy and should be approached, planned and implemented in a systematic fashion.

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ABS G02-5

TOOLBOX FOR PROFESSIONAL MANAGEMENT

Th.F.J. Tromp
QIPC/Flevowijk pharmacy Netherlands

Dr Th(Dick)FJ Tromp,

Quality Institute for Pharmaceutical Care and Flevowijk Pharmacy, NL

Chairman of Board of Pharmaceutical Practice, FIP

Managing change needs a professional approach.

Pharmacists are, by nature, not a professional in changing his/her practice. Pharmacists tend to 'do' things without considering proper preparation and securing it to daily practice. They also do not consider the fact that a reactive practice (responsive to prescriptions, requests and questions) needs another attitude and behavior than a pro-active practice(taking an initiative without an external trigger).

It will be explained that one can divide change into four phases: enabling, promoting, willing and doing. The doing phase consists also of securing a changed activity.

EuroPharm Forum (the regional WHO FIP Forum in Europe) developed a toolbox, based upon the above mentioned system.

The content of this toolbox is produced as a CD-Rom instrument and is made available to all stakeholders, connected to EuroPharm Forum.

This instrument will be presented to the audience, the various entrances and links will be explained and questions and remarks will be answered in an interactive format.

ABS G02-6

MANAGING CHANGE IN PHARMACY PRACTICE - CASE FINLAND

E.K. Teräsalmi
Apple-pharmacy-Omena-apteekki Finland

Finnish community pharmacies have gone through complete changing process from product oriented traditional pharmacy practice to customer oriented modern pharmacy practice.

The process has taken about 30 years and has included several parallel processes which have supported the development. The process is still going on with new challenges.

In the presentation the overall process will be described and the subprograms will be presented. The main factors in the success of the changing process have been: Strong leadership with clear view of the desirable future, professional strategy, national implementation, good coaching and vide continuing education. All important partners in the community pharmacy have been of the same opinion of the basic strategy and about the actions needed. All processes have been well documented and evaluated together with pharmacy practice researchers.

ABS G02-7

MANAGING CHANGE IN PHARMACY PRACTICE: CASE URUGUAY

E. Savio Quevedo
Universidad de Republica Uruguay

Last year Uruguay was selected by the Pharmaceutical Forum of the Americas and FIP to implement Good Pharmacy Practice, as well as Thailand, with the support of FIP Foundation for Education. A National Technical Group (NTG) consisting of representatives from The Ministry of Public Health, PAHO, the School of Medicine and the School of Pharmacy (within the Faculty of Chemistry) of the University of the Republic and from the pharmaceutical association has been formed in the year 2004 and is involved in the process of drafting new regulations and designing changes in the pharmacy sector. As an important and previous activity, the Pharmaceutical Forum of the Americas initiated a pharmaceutical care project for hypertensive patients, which was received with great enthusiasm and was seen as the future for the professional profession and the pharmacy sector, contributing to the health of the population.
The Government is in the process of designing a reform of the health care sector, including a reform of the financial structure to be implemented over the next years. The pharmacy sector is included in the reform. The present pharmacy law dates back to 1986. More than half of the sales of medicines (55%) to the primary care sector are sold by out-patient dispensaries at private polyclinics and hospitals, owned mainly by associations of physicians. This contributes to a system where the community pharmacies tend to be quite small and dependent on sales of other products.
Although there are regulations about prescription medicines, prescriptions are not used very much. The population goes to the pharmacy and receives advice as well as drugs from the stock available. The population considers a pharmacy to be a reliable place. Nor the public nor the health professionals know what the pharmacists input could be or what could be expected. A pharmacist is not generally known as a professional by the population. Any person behind the counter may be considered as a pharmacist, whether trained or not. With this background, a project strategy was developed which took into account international experiences and our environmental conditions, in order to move foward three task forces were the responsible of educational, professional and regulatory aspects of the project. A Secretariat and project manager were on charge of the coordination of all the activities.
The professional task force elaborated three standards for pharmacy practice: Good Drug Dispensing Practice, Selfcare and a Glossary of GPP related concepts have been prepared and approved in a National Assembly of the Pharmaceutical Association. A fourth document related to Rational Use of Drugs is being prepared. These documents are addressed to community pharmacists and intended to be used as resources/training materials for individual pharmacists about GPP and to promote its implementation. Based upon the FIP's Policy Statement on Good Pharmacy Education Practice the educational task force proposed a change in the curriculum of pharmacist carreer, a proposal to shift the focus of pharmacy education, both at pre-graduate and postgraduate levels to a patient-centred approach placing a stronger emphasis on pharmacotherapy, pharmaceutical care and patient communication skills. Finally, the regulatory aspects task force is working on a new framework which would enable pharmaceutical care activities to be carried out, biologic fluids measurements, and an update in facilities and pharmacists responsabilities within the pharmacy. Several education courses are being implemented all over the country, as CPD, in order to change mindset of our colleagues, pharmacist assistants and pharmacy owners.
The GPP project itself, its background and its origin has been made widely known, within national health authorities and associations as well within the national offices of WHO and in the Regional Forums of collaboration between WHO and FIP
We can conclude that implementing GPP in a country is such a multifactorial process, that the NTG is just in the beggining of a very long road. The project has worked as an important catalyst for moving and chaging a broad range of situations that are still inappropiate but better, if we consider the patient in the focus of our attention. An increased awareness by authorities and practicing pharmacists for the need to improve knowledge and quality in drug management, distribution and the rational use of drugs as well as within the role of the pharmacist in health promotion and disease prevention has been achieved.

BIO G04-0

BIOGRAPHY R.J. MOLES

R.J. Moles
The University of Sydney Australia

Rebekah Moles is a young Australian Pharmacist working in the Faculty of Pharmacy at the University of Sydney. She has recently completed her PhD thesis which explored pharmacy services in Private Hospitals. She is currently the Vice President of Australasia in the Hospital Pharmacy Section, a National Councillor on the Society of Hospital Pharmacists of Australia and an active member of the Pharmaceutical Society of Australia's NSW Branch of Young Pharmacists.

BIO G04-0

BIOGRAPHY L.M. MCDEVITT

L. McDevitt
Massachusetts College of Pharmacy United States of America

Lisa McDevitt currently works as an Assistant Professor of Pharmacy Practice at the Massachusetts College of Pharmacy and Health Sciences. She also serves as the clinical pharmacist for the transplant surgery service at Tufts-New England Medical Center in Boston. She received her Pharm.D. from the University of Nebraska Medical Center in Omaha. She has completed a Pharmacy Practice Residency at Thomas Jefferson University Hospital in Philadelphia and a Specialty Residency in Organ Transplantation at the University of Utah Health Sciences Center in Salt Lake City.

Dr. McDevitt's teaching, research, and patient care activities focus on the care of liver and kidney transplant donors and recipients. She has presented posters at various meetings including the American Transplant Congress, ASN's Renal Week, the ASHP Midyear Clinical Meeting, and the ACCP Annual Meeting. She has published various articles and serves as a peer reviewer for several pharmacy journals. In addition, Dr. McDevitt has been an invited speaker at national pharmacy congresses in Mexico and Peru, where she discussed clinical pharmacy and the role of a pharmacist on the transplant team.

In addition to her work in transplant, Dr. McDevitt has an active interest in international pharmacy issues. She has worked with the International Pharmaceutical Federation (FIP) in various capacities and currently serves as the Steering Committee Chair of FIP's Young Pharmacists Group.

BIO G04-1

BIOGRAPHY A. LEWIS

A. Lewis
Royal Pharmaceutical Society United Kingdom

ANN LEWIS
OBE, LLB., Hon.DSc., FRPharmS., MCPP., MHSM., Barrister.
Appointed Secretary and Registrar of the Royal Pharmaceutical Society of Great Britain in October 1998.
Studied Pharmacy in Liverpool and registered in 1965. Graduated in Law as an external student of London University in 1973. Called to the Bar, Grays Inn 1980. Founder Member of the College of Pharmacy Practice. Appointed as a Fellow of the Royal Pharmaceutical Society in December 1993. Elected as a Member, Institute of Health Service Management, in 1994.
Worked briefly in Community Pharmacy before joining the hospital service. Career mainly in hospital pharmacy, including Director of Pharmaceutical Services, Countess of Chester Hospital NHS Trust from 1992 to 1996. Particular interests include pharmacy management, application and development of computers, the development of prescribing policies both in hospital and community, the development of postgraduate education and training, extending the scope of pharmacy services.
After leaving hospital service became Joint Director, Centre for Pharmacy Postgraduate Education (CPPE), Pharmacy Department, University of Manchester from 1996 to 1998, President, Royal Pharmaceutical Society of Great Britain 1994-96.
Member, Medicines Commission 1993 - 2001
Member and former Vice Chairman, Standing Pharmaceutical Advisory Committee - Department of Health.
Chairman, Consultative Working Group for the Development of Training Standards for Pharmacy Support Staff 1992 to 1998.
Member, Joint Formulary Committee, British National Formulary 1995 to 1998.

Member of the Council of the School of Pharmacy, University of London - January 2001 -.

Other interests include travel, gardening, theatre, riding, cars, fly fishing and conversation.

BIO G04-2

BIOGRAPHY M.J.A. ROUSE

M.J.A. Rouse
ACPE United States of America

Michael J. Rouse ('Mike') was born in Harare, Zimbabwe. He graduated with an Honours Degree in Pharmacy from the University of Zimbabwe in 1977. Mike has worked in hospital and community pharmacy and, before moving to the USA, was the chief executive of Zimbabwe's largest group of community pharmacies. In April 2001, Mike joined the Accreditation Council for Pharmacy Education (ACPE) in Chicago, where he is primarily working on strategic initiatives and special projects. He recently coordinated the revision of ACPE's PharmD Accreditation Standards. Mike was the primary author of a widely published and endorsed 2002 White Paper on Pharmacy Technicians. Other focus areas are international trends and developments in quality assurance of pharmacy education, and continuing professional development (CPD); the latter being the subject of two recent publications in the American Journal of Health-System Pharmacy (AJHP) and the Journal of the American Pharmacists Association (JAPhA). Mike is actively involved in discussions in the USA regarding possible national implementation of the CPD model for pharmacist's lifelong learning, and he consults widely on this subject.
In 2001, Mike established the International Forum for Quality Assurance of Pharmacy Education, which now has approximately 250 members from more than 60 countries, regional and international organizations. Mike has convened five international meetings of this body. Through the Forum, Mike is coordinating the development of global 'core principles' for quality assurance of pharmacy education.
Mike is a past-president of the Pharmaceutical Society of Zimbabwe and the National Pharmaceutical Council of Zimbabwe. In Zimbabwe, he was a member of many professional committees, was a part-time lecturer to pharmacy students, pharmacy technicians and nurses, and was actively involved in the revision of pharmacy legislation. He has been a speaker at numerous national, regional and international congresses.
As founder president of the Zimbabwe Pharmacy Students' Association, Mike attended an IPSF congress in Mexico in 1977, and since that time has been interested in developing international contacts. He has achieved this through active involvement in the International Pharmaceutical Federation (FIP) and the Commonwealth Pharmaceutical Association. By special invitation, he served on the Executive Committee of FIP's Community Pharmacy Section, and chaired their working group on Good Pharmacy Practice in Developing Countries. The reports and manuals that resulted from his work have been successfully used in a number of countries.
In 1996, Mike was elected to FIP's Board of Directors (the 'Bureau'), on which he served for the maximum eight years. He was also a member of FIP's Board of Pharmaceutical Practice (BPP) for eight years, and served on several BPP working groups, including one that developed FIP's Policy Statement on Continuing Professional Development (CPD) for Pharmacists, adopted in 2002. Mike currently serves as a Director of FIP's Foundation for Education & Research.
A visionary and innovator at heart, one of Mike's main interests has been the development and use of information technology to enhance professional and customer services, and he pioneered several initiatives in this regard while in Zimbabwe. He is married with three children and now lives in Chicago, Illinois.