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BIOGRAPHIES CHAIRS AND SPEAKERS R2

B R2-001

BIOGRAPHY R.W. HOLLAND

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

Ross W. Holland, Ph.D., Ed.D., FPS, FAIPM, FACPP, FASHP, has been actively involved in community pharmacy ownership or management for over 30 years of his professional life. He initially trained as a pharmacist at Sydney University, Australia. As his career progressed he gained postgraduate qualifications and experience in a broad range of related disciplines including clinical pharmacy, hospital pharmacy management, the vocational education of pharmacists and nurses, educational administration, and medical education. Immediately prior to his relocation to the United States of America three years ago Ross was Dean of the Australian College of Pharmacy Practice.

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 Ninnmo, to jointly create a systematic approach to implementation of new practices amongst health care practitioners, a system that is now employed in many countries.

In addition to in-country programs for health workers at all levels, Ross is currently designing, developing and implementing programs for medical and pharmacy professionals working internationally to improve reliable access to and rational use of medications and pharmaceutical and laboratory supplies for HIV/AIDS, malaria, tuberculosis, infectious diseases, and child and maternal health in over 50 countries worldwide.

Ross is a member of the Global Adherence Interdisciplinary Network (GAIN), formed as a review panel for the recently published WHO document Adherence to Long-Term Therapies: Evidence for Action.

B R2-002

BIOGRAPHY H. HERBORG

H. Herborg
Danish College of Pharmacy Practice,
Denmark

Hanne Herborg, MSc (Pharm)
Director, R&D

Hanne Herborg (HH) is head of the R&D division in Pharmakon, the Danish College of Pharmacy Practice. The division performs literature studies, needs assessments, programme development, training, consultancy, quality documentation and evaluation of new services for community pharmacy practice. HH has been responsible for controlled multi-centre trials of pharmacy based self-care counselling and of pharmaceutical care programmes for respectively asthma patients and elderly patients in Denmark. In recent years emphasis has been on developing an evidence database for community pharmacy, on implementation research and on a research programme for patient adherence in primary care.

Hanne Herborg was formerly researcher in social pharmacy at the Danish University of Pharmaceutical Sciences. She has in this context carried out a number of studies in areas of patient behaviour, patient information, pharmacy practice and educational issues. Ms. Herborg was the first chairman of the Pharmaceutical Care Network Europe and she is currently co-chair and member of FIPs Post Graduate Education Planning Committee on Pharmaceutical Care.

B R2-003

BIOGRAPHY A.S. ROBERTS

A.S. Roberts
University of Sydney,
Australia

Alison Roberts is a community pharmacist from Sydney, Australia. She is currently completing a PhD at the University of Sydney, investigating the implementation of cognitive services in community pharmacy. Her research focuses on facilitating practice change from an organisational perspective. As this area of research is internationally relevant, it forms part of a collaboration involving researchers from Australia, Denmark, Spain and Portugal; whose aim is to see greater uptake and delivery of community pharmacy-based services around the world.

Since completing her pharmacy degree in 1996, Alison has held a number of positions including manager of a community pharmacy, coordinator of the pre-registration training program for pharmacy graduates, and practitioner teacher at the University of Sydney. Since 2001, Alison has worked as a consultant for Pharmacist Advice, an innovative pharmacy banner group who pioneered the concept of 'forward pharmacy' in Australia.

Alison is also involved with professional organisations in pharmacy. A member of the board of the Pharmaceutical Society of Australia (PSA) since 2000, Alison also chaired the PSA NSW Young Pharmacists Group in 2001-2, and was a member of the FIP-YPG Steering Committee in 2003. Alison is also a member of the FIP Community Pharmacy Section's CPD Planning Committee.

Alison has presented various aspects of her research at conferences both in Australia and internationally. In 2003, she was invited as a chair of the Community Pharmacy Sections session entitled 'Coaching for Change' at the FIP Congress in Sydney and in 2004 was the keynote speaker together with Trine Hopp.

B R2-004

BIOGRAPHY M. SCHULZ

M. Dr. Schulz
ABDA,
Germany

Martin Schulz is Head of the Center for Drug Information and Pharmacy Practice (ZAPP) at ABDA - Federal Union of German Associations of Pharmacists, Berlin, Germany. In addition since March 2002, 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. Dr. Schulz is a lecturer in Clinical Pharmacy at the University of Frankfurt at Main. He has published 315 papers/articles/book chapters so far and presented over 200 talks, lectures, and posters throughout the world, and is coeditor of 6 books. He is a member of the German Pharmaceutical Society (DPhG), German Society for Clinical Pharmacy, DGPT, FIP, ASCPT, ESCP, ACCPharm, ACCPharmacol, and ASHP. Dr. Schulz serves on various committees and is the Vice-Director of the Commission on Drugs of German Pharmacists. From 1999 to 2001 he was Chairman of the Pharmaceutical Care Network Europe (PCNE). He his a member of the FIP BPP and CPS-CPD Programme Planning Committees.

B R2-005

BIOGRAPHY J. [illegible]

[illegible]
Queen's University Belfast
United Kingdom

[illegible]

[illegible]

Professor of Pharmacy Practice (198? present)
Dean of the Faculty of Science and Agriculture (2002 present), Queens University Belfast
Previous posts held (with dates)
1994 - 2001 Head of School, School of Pharmacy, The Queens University of Belfast
1995 - present: Co-Director of Antrim Area Hospital Academic Practice Unit
1992-1994: Reader in Pharmacy Practice, School of Pharmacy, The Queens University of Belfast
1991 - 1992: Visiting Professor in Clinical Pharmacy, Department of Pharmacy Practice, University of Houston, Houston, Texas 77030.
1990 - 1991: Senior Lecturer in Pharmacy Practice, School of Pharmacy, The Queen's University of Belfast
1981 - 1990: Lecturer in Biopharmacy, School of Pharmacy, The Queen's University of Belfast
1980-1981: Postdoctoral Research Fellow; College of Pharmacy, University of Iowa, USA
1979 - 1980: Lecturer in Pharmacology, School of Pharmacy, The Queen's University of Belfast

B R2-006

BIOGRAPHY J.W.F. VAN MIL

J.W.F. Van Mil
Van Mil Consultancy,
Netherlands

Professional career
Foppe van Mil (16 July 1950) is community pharmacist since January 1978 in a rural area of the Netherlands. Since 2001 he also is pharmacy consultant on PFR and Pharmaceutical Care.
Academic career
From 1993 till 2000 he worked at the University of Groningen. The investigation of the export of Dutch drugs to developing countries resulted in the report Dutch Drugs in developing countries. In January 2000 he concluded his PhD at the working group Social Pharmacy and Pharmacoepidemiology of the University Centre of Pharmacy in Groningen on the concept of Pharmaceutical Care. His supervisors were Prof. Th.F.J. Tromp, Prof L.T.W. de Jong-van den Berg and Prof. J.C. McElnay. He publishes regularly on pharmacy practice and pharmaceutical care. He left university at the end of 2000.
Excerpt other activities
In 1985 he founded Pharma Selecta, an independent and critical Dutch drug bulletin. In 1990, he started a literature database, PS-On Line. Since September 1994 he is member of the Committee for continuing professional education of the section Community Pharmacy of FIP. In July 1997 he published the book Pharmacists and Aids, an unknown territory, together with 8 colleagues. Between 1996 and 1999 he was Chairman of the Pharmaceutical Care Network Europe (PCNE), and currently he is the secretary of that association. Between 1995 and 2002 he co-organised national Symposia on Pharmaceutical Care in the Netherlands. He teaches in several national and international continuing education programs and is editor-in-Chief of Pharmacy, World & Science and FIP's International Pharmaceutical Journal.

B R2-007

BIOGRAPHY C. M. NIMMO

C.M. Nimmo
ASHP,
United States of America

Christine M. Nimmo, M.Ed., Ph.D., is an instructional designer whose particular areas of interest include 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 for the Accreditation Services Division of the American Society of Health-System Pharmacists. 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.

COMPLIANCE, ADHERENCE OR CONCORDANCE - WHO CARES?

R2-001

HOW TO DETECT NON-ADHERENCE AND IMPROVE ADHERENCE

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

We all know that adherence to treatment of chronic diseases is a worldwide problem. In developed countries this averages only 50%. Poor adherence severely compromises the effectiveness of treatments of diseases such as asthma, diabetes, cancer, depression, epilepsy, HIV/AIDS, hypertension, tuberculosis as well as the effective treatment of smoking and obesity. Both the World Health Organization and the International Pharmacy Federation have issued statements indicating the importance with which this topic is held at international level.

The impact of poor adherence to treatment has wide-reaching consequences in terms of patient safety, poor health outcomes and increased health care costs. What a difference it would make even if the average adherence rate could be increased from 50% to 60%!

Of immediate importance to community pharmacists are the answers to the questions: Where do we fit into this scenario? What approaches have been tried and tested? What does research tell us? What works? What doesnt?

Just as there are many reasons for non-adherence, so have many approaches been tried to improve adherence rates. The fact that there are so many proposed strategies of itself suggests that there is no one method that works for all patients all the time, but we should examine them to see what we can learn.

So where does adherence fit into our day to day practice? The World Health Organization suggests that the following competencies are needed: a patient-centred approach, partnering, quality improvement, information and communication technology and a public health perspective. We might call it pharmaceutical care.

R2-002

DETECTING NON-ADHERENCE IN DAILY PRACTICE

J.W.F. Van Mil
Van Mil Consultancy,
Netherlands

As part of the continuing education program of the Community Pharmacy Section, a brief overview will be given about the ways that non-adherence to pharmacotherapeutic treatment can be detected in practice.
Roughly spoken there are several approaches:
- Third party impressions (doctors, nurses, pharmacists, family)
- Patient report (verbal, diaries, questionnaires)
- Pill count (including returned medicines and MEMS)
- Calculations based on repeat patterns
- Monitoring plasma levels

Several methods will be discussed during the presentation, including their advantages and disadvantages for the (daily) practice of pharmacists.

BIOGRAPHIES CHAIRS AND SPEAKERS P1

B P1-001

BIOGRAPHY P.J. SCHNEIDER

P.J. Schneider
Ohio State University,
United States of America

Phillip J. Schneider is Clinical Professor and Director of the Latiolais Leadership Program at the Ohio State University, an inter professional program to optimized the medication use process and reduce adverse drug events. He earned a B.S. in Pharmacy from the University of Wisconsin and a Masters of Science from the Ohio State University. He also completed an ASHP accredited residency at the Ohio State University Medical Center. He developed a nationally recognized program for the reporting and analysis of adverse drug events that led to improvements in the medication use process at the Medical Center. During his 30 years of professional and academic service, he has published more than 100 articles and abstracts in professional and scientific journals, ten book chapters, edited seven books and given more than 300 contributed or invited presentations in eleven countries and the US. He is a past president of the American Society of Health-System Pharmacists (ASHP), Past President of the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.), having served for ten years as Editor in Chief of Nutrition in Clinical Practice, one of its official publications, and is past Secretary and newsletter editor of the Hospital Pharmacy Section, chairman of the Congress Planning Committee, and member of the Board of Pharmacy Practice and Executive Committee of the International Pharmaceutical Federation His faculty rank is Clinical Professor in the Division of Pharmacy Practice and Administration at the College of Pharmacy at the Ohio State University.

B P1-002

BIOGRAPHY A.M. TAHA

A.M. Taha
Medical Union Pharmaceuticals,
Egypt

1) B. Pharm.Sci. Cairo University, Egypt. June 1959.
2) Ph.D., University of Connecticut, Storrs, CT, U.S.A ; June 1966.
3) Research Chemist. Parke-Davis Co., Detroit, Michigan, U.S.A.; 1966-67
4) Professor & Chairman of Pharmaceutical Chemistry, Assiut University, Egypt 1972-1980
5) Visiting Professor, Institut fur Pharmazeutische Chemie, Munster W. Germany.(Alexander von Humboldt Stftung Grant).
6) Professor of Medical Chemistry. College of Medicine & Allied Sciences, King Abd Al-Aziz University, Saudi Arabia. 1980-1991.
7) Vice President (Marketing) Medical Union Pharmaceuticals, Egypt (1992-date).
Other : Visiting Professor, Khartoum University, Sudan; Research Grants from NIH (USA), KACST (Saudi Arabia); Research consultant many pharmaceutical firms over 25 years.
Publications : 83 full papers in the field of pharmaceutical chemistry, Supervision of 20 M.Sc. & Ph.D. theses.
Member : Am Chem Soc, Am Pharm Assoc, Egypt Pharm Society, Egypt Pharmacy Synd, Egypt Peer Review Boards & Pharmacopoeia Comm.
Languages : Arabic (mother tongue), English (fluent), German (fairly good).

B P1-003

BIOGRAPHY H.V. HOGERZEIL

H.V. Hogerzeil
World Health Organization

Hans V. Hogerzeil qualified as a medical doctor from Leiden University in the Netherlands and received a PhD in public health in 1984. For five years he was a mission doctor in India and Ghana and in 1985 he joined the WHO Action Programme of Essential Drugs, first in the Regional Office for the Eastern Mediterranean in Alexandria, and later in Geneva. As a staff member of WHO he has advised many developing countries especially in Africa and Asia on the development of their national drug policy, essential drugs list and essential drugs programme. As Secretary of the Expert Committee on the Selection and Use of Essential Medicines he has initiated the recent changes in procedures for updating the Model List of Essential Medicines, which stronger emphasis on evidence-based selections. He established the web-based WHO Essential Medicines Library and is one of the editors of the WHO Model Formulary 2006.

Dr Hogerzeil is the editor of several WHO books on essential medicines policies and has published over 40 scientific papers. He teaches every year at international courses all over the world. In 1996 he was invited to become a Fellow of the Royal College of Physicians in Edinburgh and in 1998 he received an honorary Doctorate of Science from the Robert Gordon University in Aberdeen, Scotland. He is married with four children.

B P1-005

BIOGRAPHY E.A.M. OMBAKA

E.M.A. Ombaka
Ecumenical Pharmaceutical Network,
Kenya

Dr. Eva M A Ombaka trained as a pharmacist at University of Aston in Birmingham, UK where she also did her PhD research in Pharmaceutical Microbiology. Her 30-year carrier in pharmacy has span from hospital practice, academia, and manufacture. In the last fourteen years she has been involved in pharmaceutical policy development, capacity building for people in practice and in advocacy. She is currently the coordinator of the Ecumenical Pharmaceutical Network (EPN) that brings church-related health services around the world to address pharmaceutical issues together. She is an honorary pharmaceutical adviser to the World Council of Churches. She is also involved in the work of Sustainable Healthcare Enterprises Foundation (SHEF) that is pioneering the franchising of community-based pharmaceutical services to enable access to essential medicines and other basic health services.
Dr. Ombaka is a Tanzanian but is currently working and living in Nairobi, Kenya.

ACCESS TO MEDICINES

P1-001

ACCESS TO ESSENTIAL MEDICINES: A GLOBAL PERSPECTIVE

H.V. Hogerzeil
World Health Organization

About one-third of the world's population still has no access to essential medicines. This situation has become more visible, and perceived as more urgent, by the serious lack of access to antiretrovirals and other essential medicines in the prevention and care of HIV/AIDS. At the same time, efforts to improve the situation for AIDS, tuberculosis and malaria will also help to improve the general policy and infrastructure for essential medicines.

The WHO Access Frame work recognizes four core components for achieving equitable access: rational selection, affordable prices, sustainable financing and reliable health systems. All of these components are essential in ensuring access.

The WHO prequalification project is steadily expanding, covering an increasing number of essential medicines for HIV/AIDS, TB and malaria. The transparent quality requirements for prequalification, the confidential dossier assessments and international inspections have been very supportive to national regulatory agencies and to the pharmaceutical industry.

WHO and Health Action International have jointly developed a standard protocol for medicine price surveys. Retail prices have been collected in several developing countries, of branded product, most prescribed generic and cheapest generic in the public, NGO and private sector. Prices are compared with global references and also with indicators of local purchasing power.

WHO is also collecting information on best practices in medicine supply management, both in the public as well as in the private not-for-profit sector, and on interventions to promote rational prescribing. These are now ready for global use and national scale-up

P1-002

THE HUMAN REQUIREMENT FOR PHARMACISTS, TECHNICIANS AND ASSOCIATED PERSONNEL - HOW CAN THE TARGETS BE ACHIEVED?

E.M.A. Ombaka
Ecumenical Pharmaceutical Network,
Kenya

The shortage of pharmaceutical staff arises from insufficient training opportunities; unhelpful practices; and economic factors leading to brain-drain, workforce deterioration and imbalance in manpower distribution.

Better workforce planning is the option available for increasing numbers. This means defining and training pharmaceutical staff to match the job specifications. Emphasis should be placed in training greater numbers of technicians and assistants to whom the technical and clerical aspects of the work can be delegated. Training opportunities for advancement and a carrier path must be in place. Review of the pharmacy curriculum so as to equip the graduate with the tools to work in their reality, may be necessary. Pharmacists must look at issue such as social sciences, public health and management for their greater participation in policy development, leadership and supervisory activities.

Clear job separation addresses turf protection practises and the underutilization of the pharmacist. This should be supported by enforced laws and regulations that define and uphold the roles and responsibilities of each professional. Professional bodies must take the lead in proposing solutions and spearheading implementation of developments appropriate to the circumstances.

In addressing economic factors, countries must strive to provide adequate compensation, improve working conditions and facilitate continuous education for all the staff. Exchange programmes and ethical approaches to recruiting from developing countries as well as partnerships that foster the sharing of the trained staff and use of modern technology should be explored.

BIOGRAPHIES CHAIRS AND SPEAKERS P2

B P2-001

BIOGRAPHY H.V. HOGERZEIL
H.V. Hogerzeil
World Health Organization

Hans V. Hogerzeil qualified as a medical doctor from Leiden University in the Netherlands and received a PhD in public health in 1984. For five years he was a mission doctor in India and Ghana and in 1985 he joined the WHO Action Programme of Essential Drugs, first in the Regional Office for the Eastern Mediterranean in Alexandria, and later in Geneva. As a staff member of WHO he has advised many developing countries especially in Africa and Asia on the development of their national drug policy, essential drugs list and essential drugs programme. As Secretary of the Expert Committee on the Selection and Use of Essential Medicines he has initiated the recent changes in procedures for updating the Model List of Essential Medicines, which stronger emphasis on evidence-based selections. He established the web-based WHO Essential Medicines Library and is one of the editors of the WHO Model Formulary 2006.

Dr Hogerzeil is the editor of several WHO books on essential medicines policies and has published over 40 scientific papers. He teaches every year at international courses all over the world. In 1996 he was invited to become a Fellow of the Royal College of Physicians in Edinburgh and in 1998 he received an honorary Doctorate of Science from the Robert Gordon University in Aberdeen, Scotland. He is married with four children.

B P2-002

BIOGRAPHY E. 'T HOEN
E. T Hoen
Medecins Sans Frontieres,
France

Ellen t Hoen is Director of Policy Advocacy and Research of the Campaign for Access to Essential Medicines of Mdecins Sans Frontires.

In 1981 she was one of the co-founders of DES Action the Netherlands where she worked as a coordinator until 1990. From 1990 until 1996 she was a project coordinator at the European office of the consumer network Health Action International. From 1996 until 1999 she was the coordinator of the International Society of Drug Bulletins (ISDB) and consultant to the editorial board of the independent French pharmaceutical journal La revue Prescrire and Prescrire International.

She worked as a drug policy consultant for a number of institutions, including the World Health Organization.

She graduated from Social Work Academy and has a Masters Degree in Law from the University of Amsterdam.

B P2-003

BIOGRAPHY E. EGHAN
E. Eghan
Management Sciences for Health,
Ghana

Kwesi Eghan is the Field Project Manager/ Snr. Technical Advisor for the Management Sciences for Healths Strategies for Enhancing Access to Medicines (SEAM) Project in Ghana. He has over 15 years experience in pharmaceutical service industry and health insurance management. As Head, health operations for Ghana Healthcare Company Ltd he was responsible for the development of the reimbursable drug list, design and implementation of the reimbursement systems for the health insurance organization. He was a primary facilitator in the development of the National Health Insurance Policy Framework and the Health Insurance Act of Ghana. He has also worked as country representative for 8 years for the Swiss multinational Sandoz (now Novartis).With SEAM he has lead the local effort of design, development and implementation of the essential medicines franchise network, the pooled procurement for the catholic pharmaceutical services, conducting of training for drug retail outlets and implemented a needs assessment exercise of private health care providers in rural and peri-urban Ghana. In addition to his pharmacy degree Mr. Kwesi Eghan has a masters degree in Business Administration with a major in Finance.

B P2-004

BIOGRAPHY H.E. BALE, JR.
H.E. Bale, Jr.
IFPMA,
Switzerland

Dr. Harvey E. Bale, Jr. is the Director-General of the International Federation of Pharmaceutical Manufacturers and Associations, IFPMA. Previously he was Senior Vice President for International Affairs with the Pharmaceutical Research and Manufacturers of America. Prior to that he was International Manager at Hewlett-Packard. He also served 12 years in the Office of the U.S. Trade Representative. In 1980 he was on special White House assignment to the Middle East Camp David negotiations. In 1986 he received the Distinguished Service Award from President of the United States Ronald Reagan. In 1996-1997 he taught a post-graduate course on intellectual property and technology strategy at Georgetown University. Dr. Bale received a Ph.D. in economics from University of Maryland and a B.A. from Temple University.

THE PRICE OF MEDICINES

P2-001

THE PRICE OF MEDICINES WORLDWIDE - HOW PRICES ARE DETERMINED

M.A. Ewen
Health Action International Europe,
Netherlands

Data collected using the WHO/HAI price survey methodology show medicines are unaffordable for many people. In Kenya, the lowest paid government employee has to work 20 days to pay for a months course of originator brand ranitidine for ulcer treatment, and 7 days for the generic, when purchased from a private retail pharmacy. It isnt just an African problem. For the same treatment, in the Philippines it takes 13 days salary to pay for the originator brand and 7 days for the generic. In Peru, the figures are 8 days (brand) and 2 days (generic). In addition to showing price, availability and affordability data, the presentation will show how the manufacturer's selling price, taxes, fees, wholesale and pharmacy mark-ups, and other component costs can contribute to a deadly serious situation for millions of people.

P2-002

THE AFFORDABILITY OF MEDICINES INTELLECTUAL PROPERTY AND PATENTS

E. T Hoen
Medecins Sans Frontieres,
France

The magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease or alleviate suffering. The reasons for the lack of access to essential medicines are manifold: logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, prohibitive prices and lack of financing for health care.
In many cases, however, high drug prices are the main barrier to needed treatments. Prohibitive drug prices are often the result of strong intellectual property protection. Governments in developing countries that attempt to bring the price of medicines down have come under pressure from industrialised countries and the multinational pharmaceutical industry. The 1995 World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS or 'Agreement') sets out minimum standards for the protection of intellectual property, including patents on pharmaceuticals. These standards derive from wealthy Western nations and are not necessarily appropriate for developing countries. MSF has witnessed the effects of patents on the prices and availability of medicines, in particular newer medicines, and has documented the patent practices in the countries where it works. In addition to their impact on prices, patents may also hamper the development and availability of recommended formulations. New approaches are needed to ensure that in the future affordable versions of new essential medicines will rapidly be available for people in developing countries.

P2-003

THE FINANCING OF PERSONAL MEDICINES: GOVERNMENT VERSUS INSURANCE

E. Eghan
Management Sciences for Health,
Ghana

Whilst the global percentage of people with no access to essential medicines has dropped from 50 percent in 1975 to about one third, today the absolute number of people hasnt changed and remains at about 1.7 billion.In low income countries, the share of pharmaceuticals consumed fell from 3.9% of the world population in 1985 to 2.9% in 1999.In Africa, almost half of the population, lack access to essential medicines. Efforts to improve access continue to face major challenges in a rapidly changing national and international policy environment. The key barriers to affordable medicines include an unreliable medicine supply, irrational use of medicines, unfair health financing mechanisms-leaving households responsible for the cost of essential medicines, unaffordable medicine prices, poor quality of medicines, and lack of new medicines.
In some sub-Saharan African countries such as Ghana, well intended Government policies such as 'cash and carry' system had failed.For instance ,the number of days the lowest paid worker has to workpay for standard recommended course of therapy for tracer conditions is observed to be highly disproportionate to incomes in most developing countries.Presently, there is significant increase in the final price to the patient as a result of government imposed taxes and tariffs as well as trade mark ups leading to a high out of pocket cost for the acquisition of personal medicines-in some cases 100-200% higher than manufacturers prices. Implementing healthcare financing mechanisms such as insurance, especially to cover the purchase of medicines, amidst all its challenges, will be the way forward for most developing countries

P2-004

DIFFERENTIAL PRICING OF MEDICINES - INDUSTRY PERSPECTIVE

H.E. Bale, Jr.
IFPMA,
Switzerland

Price variations have a significant impact on the availability of medicines in different markets: (1) Countries that are charged the lower prices would be unable to purchase at a higher price. In other words, consumers in a much greater number of markets have access to new medicines. (2) Patients consume a larger total volume of medicines, so a larger proportion of the global patient population base has access to new products. International price variations for pharmaceuticals can also help provide companies with the cash flow and resources to finance R&D budgets, as they facilitate simultaneous launch of new products in many markets. For example, the most recently launched products are available in 50 to 65 countries worldwide in just 1-3 years after their approval, compared to 5-10 years needed to achieve the same result for drugs developed a decade ago. Consequently, price variations allow the burden of R&D costs to be spread across a larger consumer base. This contributes to minimizing the financial risk of R&D investment on one hand, and improves the diffusion of innovative pharmaceuticals among populations at different income levels, including poor populations where medicines are frequently offered at zero-profit prices even often below generic prices for drugs used against serious pandemic disease threats (e.g., AIDS).

BIOGRAPHIES CHAIRS AND SPEAKERS P3

B P3-001

BIOGRAPHY E.K. TERSALMI

E.K. Tersalmi
Apple pharmacy,
Finland

-Graduated from Helsinki University -82 MSc in Pharm.
-Further education in social pharmacy and pharmacology
Working history:
-Pharmaceutical Learning Center 82-83, pharmacist
-The Association of Finnish Pharmacies 83-96, pharmacist, director for pharmaceutical affairs
-Eisbo centrum apotek, pharmacist 96 - 98
-Apple pharmacy; Virikkala, Sinnin, Routio, pharmacy owner 99 →
Other activities:
-The Association of Finnish Pharmacists, board member 79-81. Member of working groups in quality issues, pharmacy education and health promotion, nordic co-operation etc.
-The Association of Finnish Pharmacies, vice president 00-01, board member 02 → . Member of working groups in pharmacy education, quality work, health promotion and education, development of pharmacy practice, nordic and international co-operation
-WHO EuroPharm Forum, task force manager (smoking cessation) 96 →
vice president 01-02
President 02-04
board member 05->
-Member of FIP Community Pharmacy section since 1984, member of Executive Committee 03->.
-Publications:articles in national pharmaceutical journals and other publications, WHO research report on Pharmacists against smoking 2001.
-Presentations: Presentations in international and national congresses about strategies, practices, quality issues, health promotion etc concerning community pharmacy and pharmacists.
Marital status:
Married, 2 daughters 11 and 17 years old.
Personal interests:
My personal aim is to further develop evidence based pharmacy practice and to promote professionalism in pharmacy. My hobbies are gardening in the summer cottage and reading both professional and nonprofessional literature.

B P3-002

BIOGRAPHY O.K. ROSTOM

O.K. Rostom
EIPICO,
Egypt

Pharmacist graduated in 1974 from faculty of Pharmacy, Alexanderia, Egypt. Holder of a MBA degree from the university of Bradford, U.K. Highly experienced in the sales, marketing and distribution of pharmaceutical products across the Middle East. Worked throughout my career for several multinational pharmaceutical companies (mainly GlaxoSmithKline), and am now heading the commercial department for Egyptian International Pharmaceutical Industries CO. (EIPICO-the leading pharmaceutical company in Egypt).

B P3-003

BIOGRAPHY L. EMERSON

L.E. Emerson
The Pharmacy Guild of Australia,
Australia

Director - Programs and Professional Development, The Pharmacy Guild of Australia National Secretariat, Australia

Graduating from the Australian National University in 1989, and a Master of Science from Flinders Medical School in 1998, Lance has a background in primary health care, and has worked for various State Health Departments in health service development and implementation. He has worked for the Pharmacy Guild of Australia for the past 10 years, and his area of responsibility is overseeing all matters relating to rural pharmacy, research and development, Aboriginal issues, and remunerated professional pharmacy services. He was instrumental in lobbying for, securing and overseeing many new initiatives, such as the Home Medicines Review program. Lance is currently undertaking a PhD (part time) with the Faculty of Pharmacy, University of Sydney.

B P3-004

BIOGRAPHY P. TROEIN

P. Troein
IMS HEALTH,
United Kingdom

Per Troein
VP Strategic Alliances IMS Health

Per Troein is responsible for supplier and government relationships, strategic planning, and statistical office in IMS Europe, Middle East & Africa. During the last few years one of Europes top priorities has been developing partnership relationships with key suppliers and to further develop the understanding of the trade dynamics. Key for this strategy has been to secure industry best privacy compliance and developing services back to data sources.

Prior to joining IMS, Per worked for Pharmacia starting his career with line responsibility building a Medical Device business based in U.S. His last 6 years where spent in strategic development including several major mergers and acquisitions.

Per started his career with Ericsson and progressed through the company with increasing responsibilities in operations and development.

He holds an MSc in engineering from Lunds Institute of Technology and an MBA from INSEAD.

SELECTION, SUPPLY AND DISTRIBUTION OF MEDICINES

P3-001

PROBLEMS ASSOCIATED WITH THE SUPPLY AND DISTRIBUTION OF MEDICINES IN A DEVELOPED COUNTRY IMPROVING MEDICATION ACCESS FOR AUSTRALIAN ABORIGINAL COMMUNITIES.

L.E. Emerson
The Pharmacy Guild of Australia,
Australia

Many developed countries are presently focused on quality use and rational use of medicines, however a more critical and often unrecognised problem is the adequate supply and distribution of medicines, particularly due to cultural, geographic or financial barriers.

Whilst Australia is one of the top 20 richest countries in the world (GDP per capita), it has made poor progress in addressing the needs of Aboriginal Australians, whose life expectancy is significantly poorer than the majority of the 20 poorest countries in the world.

Cultural barriers often deny Aboriginal people access to mainstream health services. These barriers are exacerbated in remote Australia, where huge distances and transport problems limit access to health services. Furthermore, due to the extreme poverty experienced by most Aboriginal people, affordability of medicines is also a barrier. Lack of access to medicines is illustrated by the fact that Government expenditure on medicines for Aboriginal people is only 33% of that for non-Aboriginal people.

Whilst these barriers are routinely encountered by many developing countries, in developed countries they are perhaps most noticeable in Australia. To improve medicines access, The Pharmacy Guild, along with the National Aboriginal Community Controlled Health Organisation and the Australian Government, have implemented a scheme which has revolutionised medicines access for Aboriginal people, particularly in remote Australia. This presentation will describe this scheme, as well as a range of innovative government remunerated services provided by pharmacists to facilitate quality medication use by Aboriginal people.

P3-002

DRUG DISTRIBUTION; THE DIFFERENT MODELS

P. Trocin
IMS HEALTH,
United Kingdom

Throughout the world, drug distribution models are changing. Drugs are reaching patients through many different routes and not all involve either the full line wholesaler or the community pharmacists. There are many different reasons for this. Many of them are economic. Payers try to reduce cost or entrepreneurs try to earn a greater margin. Many are also driven by patient convenience or medical specialisation

In the dispensing process there are 5 key trends to highlight:

The increase of mail order, especially in US. What are the reasons and how does the service compare with a community pharmacy?

Direct to patient as in Italy where both wholesalers and community pharmacies are by-passed.

Increase of hospital out-patient dispensing in many countries

Parallel trade within Europe and re-importation into US

Supplying pharmacies through short-line wholesalers, direct distribution and Pfizers initiative of Direct To Pharmacy delivery

In this changing environment has patient care been improved? Does the System deliver overall cost savings? What are the patients views? There is not one answer to these important questions. It is certainly so that there are many positive elements in the changes but also that there is much that the traditional community pharmacist can learn.

BIOGRAPHIES CHAIRS AND SPEAKERS P4

B P4-001

BIOGRAPHY K.W. JOHNSON

K.W. Johnson
Management Sciences for Health,
United States of America

As Director of MSH's SEAM Program and Deputy Director for Program Administration, Information, and Communications, Keith W. Johnson is responsible for a variety of developing country initiatives that focus on increased access to essential medicines and other health commodities. He is also responsible for program development and implementation relating to the creation, application, and dissemination of information resources necessary for making appropriate drug access and use decisions, including the development and publication of Managing Drug Supply. Mr. Johnson received his undergraduate training at the University of Nebraska (Pharmacy), his graduate training at the University of Minnesota (Social and Administrative Pharmacy and Educational Psychology), and his postgraduate training at Harvard University's Center for Community Health and Medical Care. Prior to his current position at MSH, he worked at the United States Pharmacopeia (USP) in several capacities, with his last position being that of Vice President of Information Development and Director of the New and Off-label Use Division. In addition, from 1993-2000 he served as Director of the USP Rational Pharmaceutical Management (RPM) project, focusing on drug information and rational use initiatives in developing countries. Mr. Johnson has taught at the University of Minnesota College of Pharmacy and currently teaches at the Georgetown University School of Medicine.

B P4-002

BIOGRAPHY B. CUDDY

B. Cuddy
European Medicines Agency,
United Kingdom

Brendan Cuddy obtained his degree in Chemistry from Trinity College, Dublin in Ireland. In 2000 he obtained a Masters degree from the National University of Ireland in Quality and Operations Management. In 2002 he obtained a postgraduate diploma in Pharmaceutical Manufacturing Technology from Trinity College, Dublin in Ireland which satisfies the educational requirements of Article 49 of Directive 2001/83/EC & Article 45 of Directive 2001/82 for Qualified Person.
In October 2002 he joined the European Medicines Agency as Scientific Administrator. He is responsible for, inter alia, co-ordination of GMP and GLP inspection, regulatory procedures relating to defective products and quality problems. He currently acts as the EMEA liaison point with the EU Medicines Enforcement Group.

B P4-003

BIOGRAPHY TH.F.J. TROMP

Th.F.J. Tromp
FIP,
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-;

Vice and (immediate past) president of the Community Pharmacy Section (CPS) of FIP, 1991-200;

Chairman of the Board of Pharmaceutical Practice (BPF), 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.

B P4-004

BIOGRAPHY M. NDOMONDO-SIGNONDA

M. Ndomondo-Signda
Ministry of Health,
Tanzania

Margareth Ndomondo-Signda is a pharmacist with a Masters Degree in Pharmaceutical Services and Medicines Control from the University of Bradford, UK. From 1998 she worked as the Registrar of the Pharmacy Board of Tanzania for five years, before being appointed as the Director General for the Tanzania Food and Drugs Authority in 2003. She has vast experience not only in medicines regulation but also in policy development, implementation, monitoring, and evaluation.

THE WORLD WIDE PROBLEM OF COUNTERFEIT MEDICINES

P4-001

COUNTERACTING COUNTERFEITING: STRATEGIES FOR IMPROVING THE INTEGRITY OF THE MEDICINAL MARKETPLACE IN TANZANIA

M. Ndomondo-Sigonda
Ministry of Health,
Tanzania

The business of medicinal product counterfeiting is intended to make money, with profits subject to economies of scale, i.e., the larger the production run, the lower unit costs; and the greater the market distribution, the greater the income. The largest potential market penetration for counterfeit products is high volume product diversion into the legitimate supply system. Lower volume and therefore less profitable counterfeit market entries are through petty traders further down the distribution system.

With limited resources available, TFDA priorities for counteracting counterfeiting had to be set. Since the greatest economic incentive is the large scale distribution of counterfeit products, TFDA has focused inspection and testing resources at major Ports-of-Entry (POE) and the Medical Stores Department. This accounts for most of the medicinal products used in the country. In addition, some resources go for inspection and testing of consumer drug outlets.

Results have been encouraging. Some counterfeit products at retail outlets, likely arising from petty traders, have been found but large-scale entry of such products into Tanzania has been controlled through stakeholder education programs, introduction of a quality assurance program, strengthening post-marketing surveillance, product confiscation, and effective control at POE.

Much remains to be done to reduce the inflow of counterfeit products through Tanzanias porous borders. Regional cooperation through the East African Community (EAC) and Southern African Development Community (SADC), including an alert system, would help focus our limited resources on high yield targets.

P4-002

FIP'S ACTIONS AGAINST COUNTERFEIT

Th.F.J. Tromp
FIP,
Netherlands

In Barcelona (1999) FIP launched its first statement on counterfeit medicines. A couple of years later (Sydney 2003) FIP updated this statement and published it.

Publication of statements is considered not to be sufficient to combat counterfeit. The Board of Pharmaceutical Practice (BPP) decided in 2003 to initiate a working group on implementation of this statement. A special budget was set aside to support this group.

The working group created a number of recommendations to be presented to the BPP. They were about actions towards member associations, the creation of a website, actions to be taken by individual pharmacists and actions to be taken in cooperation with pharmaceutical industries. These recommendations were mainly adopted by the BPP. A number of these recommendations will be discussed.

On one hand FIP wants to provide a number of examples of counterfeit actions to the members in order to facilitate early detection, but at the other hand there is the problem of accountability in case these examples are not strongly evident.
Or in other words, the criminal acts behind the counterfeits are not bound by rules and regulations, but combating pharmacists are highly bound by rules and regulations. This might be an interesting element to be discussed at the end of the lecture. A number of examples, websites (including FIPs website), and pharmacists activities will be shown.

Counterfeit is considered a very serious problem to be combated by FIP. Because of its importance the FIP Bureau has taken over the responsibility for these actions. This means that the 'highest' body within FIP is directing the appropriate actions.

BIOGRAPHIES CHAIRS AND SPEAKERS P5

B P5-001

BIOGRAPHY H.R. MANASSE

H.R. Manasse
ASHP,
United States of America

Henri R. Manasse, Jr. serves as Executive Vice President and Chief Executive Officer of the American Society of Health-System Pharmacists (ASHP)--a 30,000-member national professional association that represents pharmacists practicing in hospitals, health maintenance organizations, long-term care facilities, home care and other components of health care systems.

Dr. Manasse received his Bachelor of Science degree in pharmacy from the University of Illinois at the Medical Center, a Master of Arts degree in educational psychology from Loyola University of Chicago, and the Doctorate in Pharmacy Administration from the University of Minnesota. He is also the recipient of Honorary Doctor of Science degrees from several universities.

Prior to his appointment with ASHP, Dr. Manasse was Vice President for Health Sciences, The University of Iowa, and Chairman of the Board of the University of Iowa Health System.

He has held a variety of positions including dean, professor of pharmacy administration, and health professions education at the College of Pharmacy, University of Illinois at Chicago, and serves as Senior Policy Fellow with the Center on Drugs and Public Policy, University of Maryland.

Dr. Manasse currently serves on the Board of Directors of the National Patient Safety Foundation, and represents ASHP at the National Quality Forum, where he co-chairs the Safe Practices Steering Committee. He chairs the Sentinel Event Alert Advisory Group at the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and was recently appointed to the Drug Safety and Risk Management Advisory Committee of the United States Food and Drug Administration (FDA).

B P5-002

BIOGRAPHY M.G. DUKES

M.G. Dukes
University of Oslo,
Norway

World-renowned expert on health planning and pharmaceuticals policy, regulation and legislation. Dr. Dukes is a Medical Doctor and Lawyer.

Graham Dukes has worked with EHG since 1990. Having held senior positions with national regulatory authorities, WHO, and WB, he has a distinguished professional record. Graham Dukes has peerless experience in the areas of drug policy, legislation, regulation, utilization studies, information services, adverse reaction monitoring, medical risk management and professional training. He has assisted numerous countries in the development of new polices, reorganization of regulatory systems, the design of new pharmaceutical legislation and supply structures. An acclaimed team leader, he is acknowledged as an outstanding writer in his field. Remarkably, Graham Dukes is fluent in English, French, Dutch, Norwegian and German, with a basic knowledge of Russian.

B P5-003

BIOGRAPHY L.Z. BENET

L.Z. Benet
Institute for OneWorld Health,
United States of America

Dr. Benet, a member of the Board for Institute for OneWorld Health, Professor and former (1978-98) Chairman, Department of Biopharmaceutical Sciences, UCSF and Chairman of the Board, AvMax, Inc., has received honorary doctorates from Uppsala University (Pharm.D., 1987), Leiden University (Ph.D., 1995), University of Illinois at Chicago (D.Sc., 1997), the Philadelphia College of Pharmacy and Science (D.Sc., 1997) and Long Island University (D.Sc., 1999). During 1986, Dr. Benet was a founder and first President of the American Association of Pharmaceutical Scientists (AAPS). In 1989 he received the first AAPS Distinguished Pharmaceutical Scientist Award; in 1991, the Volwiler Research Achievement Award of the American Association of Colleges of Pharmacy (AACP) and served as President of AACP in 1993-94; in 1995, the Rawls-Palmer Award of the American Society for Clinical Pharmacology and Therapeutics; in 2000, the American Pharmaceutical Association Higuchi Research Prize and the AAPS Wurster Award in Pharmaceutics; in 2001 the FIP Host-Madsen Medal; in 2003 he was listed as one of 250 most highly cited pharmacologists worldwide; and in 2004, he was awarded the FIP Pharmaceutical Sciences World Congress Research Achievement Award and the Controlled Release Societys Career Achievement in Oral Drug Delivery Award. He is a Past Chair of the FIP Board of Pharmaceutical Science and chaired the organizing committee for the FIP Millennial World Congress of Pharmaceutical Sciences. His research interests, more than 460 publications and 10 patents are in the areas of pharmacokinetics, biopharmaceutics, drug delivery and pharmacodynamics.

THINKING THE UNTHINKABLE

P5-001

DO THE PRICES OF MEDICINES HAVE TO ESCALATE?

M.G. Dukes
University of Oslo,
Norway

The prices of medicines are commonly bewildering: in some markets the prices of individual medicines rise almost annually; in others cost increases are frequent, but mainly due to replacement with newer items; in some, where one is sufficiently insistent, prices are constant or fall. There is much elasticity and generally a wide margin of profit available for bargaining - if only the purchaser knew just how wide or narrow it was! In any type of country procurement agencies can best function in collaboration with experts in drug choice and prescribing so that the therapeutic and social value of a drug is taken into consideration when a price is negotiated; the example of the Australian Pharmaceutical Benefits Scheme is instructive in this respect, while some other schemes attempt to take into account the manufacturer's essential expenses (e.g. research and development as opposed to marketing and administration costs). These and other approaches seem to show that one can do a great deal to keep pharmaceutical prices in check while allowing industry ample room for growth and development. An important issue is the technical and professional independence of the cost assessment and price regulation body; where it is under strong political pressure from the principal manufacturers it is not likely to achieve optimal results on the community's behalf.

P5-002

THE DEVELOPMENT OF MEDICINES FOR NEGLECTED AND ORPHAN DISEASES

L.Z. Benet
Institute for OneWorld Health,
United States of America

Infectious diseases in poor countries kill more than 12 million people each year and threaten hundreds of millions more. The Global Forum for Health Research reports that 90% of the $70 billion spent worldwide annually on health research and development by the public and private sectors is directed toward 10% of the global disease burden. This means that the vast majority of the global disease burden is neglected. Of 1,393 new drugs approved worldwide from 1975 to 1990, just 13 drugs were targeted at infectious diseases that primarily affect the developing world, according to Médecins Sans Frontières. The World Health Organization affirms that almost all neglected diseases can be controlled using low-cost technologies that are safe, rapidly effective, and easy to administer in resource-poor settings. Many foundations, private-public partnerships, government institutes, and non-governmental organizations focus on neglected diseases, but they cannot do it alone. Incentives to stimulate R&D on the scale necessary to meet the needs of developing countries are lacking. The economics and traditional structure of drug development are shifting in ways that can lead to viable markets for new, affordable drugs in the developing world, as well as for orphan diseases in developed countries, if biopharmaceutical companies considered innovative collaborations with nonprofits. Private and public sectors can achieve a win-win situation by targeting developing world diseases. As examples of such an innovative approach, OneWorld Healths programs in visceral leishmaniasis, diarrheal disease, malaria, schistosomiasis and Chagas disease will be highlighted.

BIOGRAPHIES CHAIRS AND SPEAKERS S1

B S1-001

BIOGRAPHY K.K. MIDHA

K.K. Midha
Pharmalytics Inc.,
Canada

Dr. Midha is Chair of the Board of Directors and primary founder of Pharmalytics Inc., a not-for-profit research institute at the University of Saskatchewan, Saskatoon, Canada, and an Adjunct Professor of the Colleges of Pharmacy and Medicine. The study of drugs which act on the CNS is a major thrust of the research activities of Pharmalytics.

Dr. Midha has served on the Editorial Boards of numerous prestigious Journals and has authored/co-authored 300 scientific articles/book chapters. He is a Fellow of many professional associations. He has received numerous awards such as: Indian Drug Manufacturers Association and the Eighth Pharmaceutical Analysis Convention (IDMA-APA PAC 2004)Eminent International Scientist Award (2004); Pharmaceutical Sciences World Congress Research Achievement Award (2004); Member of Honor in the Romanian Academy of Medical Sciences (2003); Queens Golden Jubilee Medal (2003); Member of President's Circle, National Academy of Science, National Academy of Engineering and Institute of Medicine, USA (1999 to present); recipient of Canada's highest award, the Order of Canada (1995); Kolthoff Gold Medal Award from American Pharmaceutical Association (1989); AAPS Research Achievement Award in Analysis and Pharmaceutical Quality (1992); Heinz Lehmann Award for Outstanding Achievement Award in Neuropsychopharmacology from Canadian College of Neuropsycho-pharmacology (1993); Distinguished Researcher Award from University of Saskatchewan (1994).

Dr. Midha is Vice-President of the International Pharmaceutical Federation (FIP), (1998 to present) and served as Chairman of the Board of Pharmaceutical Sciences of FIP (1988-1996).

B S1-002

BIOGRAPHY V. P. SHAH

V.P. Shah
United States of America

Vinod P. Shah, Ph. D.

Dr. Shah started his professional career at FDA in 1975. At present he is a Senior Research Scientist at FDA. Over the last decade, he has developed Regulatory Guidances for Pharmaceutical Industry in areas of dissolution, bioanalytical method validation, scale-up and post approval changes, topical dermatological drug products, biopharmaceutics classification system, bioavailability and bioequivalence for oral drug products.

Dr Shah is the Scientific Secretary and a member of the Executive Council of International Pharmaceutical Federation (FIP), 2003-2007. He is also an Expert Member of FIP/Board of Pharmaceutical Science (BPS) and Chair of FIP/BPS/Special Interest Group on Bioavailability and Bioequivalence. Dr. Shah is an Adjunct Professor at University of Kentucky, Lexington KY (2001 -) and USP Biopharmaceutics Expert Committee Member (2002 - 2005). In 2002 he was named Member of Honor of the Romanian Academy of Medical Sciences. In 2003 he was named Honorary Member of The Indian Pharmaceutical Association.

Dr. Shah has published over 200 scientific papers and is a co-editor of two books. He has organized over 50 national/international workshops and conferences. He has received several Awards including FDA's Award of Merit, FDAs Scientific Achievement Award and American Association of Pharmaceutical Scientists (AAPS) Distinguished Service Award. Dr. Shah is a Fellow of AAPS, and was AAPS President in 2003.

B S1-003

BIOGRAPHY M. ROWLAND

M. Rowland
University of Manchester,
United Kingdom

Malcolm Rowland is Professor Emeritus (2005-; Professor 1975-2005), School of Pharmacy and Pharmaceutical Sciences, and former director, Centre for Applied Pharmacokinetic Research (1996-2000), University of Manchester. He is VP FIP, and was President, European Federation of Pharmaceutical Sciences (1996-2000). He received his degree in Pharmacy and PhD, University of London, and was on faculty, School of Pharmacy, University of California San Francisco (1967-75).
Awarded honorary doctorate degrees from Universities of Poitiers (France) and Uppsala (Sweden), and Honorary Membership of Royal College of Physicians (London). Awards including the 1994 AAPS Research Achievement Award in Pharmacokinetics, Pharmacodynamics and Drug Metabolism, and the Millennial Pharmaceutical Scientist Award (FIP BPS, 2000). Made a fellow of the Academy of Medical Sciences, American College of Clinical Pharmacology (Hon), the Royal Pharmaceutical Society of Great Britain, AAPS, and the Institute of Mathematics. In 2002 he was cited among the top 100 most cited pharmacologists worldwide by the Institute of Scientific Information.
His main research interest is physiologically based pharmacokinetics and its application to drug discovery and development. Author of over 250 scientific articles, and co-author of the textbook - Clinical Pharmacokinetics: Concepts and Applications. An editor of Journal of Pharmacokinetics and Pharmacodynamics and has established European and U.S.A. workshops in pharmacokinetics.

B S1-004

BIOGRAPHY N.S. SHAH

N.S. Shah
Hoffmann Larcoche inc.
United States of America

BNavnit H. Shah Ph.D
Hoffmann-La Roche Inc.
Nutley, NJ 07110

Navnit H. Shah is a Distinguished Research Leader in the Pharmaceutical R&D Department at Hoffmann-La Roche Inc. Nutley, N.J. He is heading the oral dosage form development group. He has received his B.S. in Chemistry and Pharmacy from the Bombay University in India and M.S. and a Ph.D. in Pharmaceutics from St. Johns University in New York. Dr. Shah has accumulated over 25 years of experience on the research and development of oral dosage forms and published and presented over 50 papers in the field of development of controlled release drug delivery, oral absorption improvement of poorly soluble drugs, powder technology and solid dosage forms technology. He is the holder of 14 patent in drug delivery systems encompassing controlled release and oral absorption improvement area. Dr shah has been invited speakwer at national and international conferences. He is a member of the American Association of Pharmaceutical Scientists and Controlled Release Society. He is AAPS fellow and served AAPS in various capacities.He is also an adjunct associate professor at the University of Rhode Island and responsible for mentoring two Ph.D. students.

B S1-005

BIOGRAPHY A.A. SAKR

A.A. Sakr
University of Cincinnati,
United States of America

Adel Sakr, Ph.D., is professor of Industrial Pharmacy and Pharmaceutics and is the Director of the Industrial Pharmacy graduate program at the College of Pharmacy, University of Cincinnati Medical Center, Cincinnati, Ohio. He received his Ph.D. in Industrial Pharmacy from the University of Strathclyde, Glasgow, U.K. He has held leading academic and industrial positions in Egypt, England, Germany, Puerto Rico and the United States. Dr. Sakrs primary areas of interest include the design and optimization of extended release tablet formulations and manufacturing processes. He has published more than 140 full research papers in leading national and international pharmaceutical journals. In addition, Dr. Sakr has presented more than 340 original and/or invited workshop/symposium/podium/poster presentations to national and international meetings. Dr. Sakr is a member of Rho Chi Pharmaceutical Honor Society, the Controlled Release Society, American Pharmaceutical Association, American Association of Colleges of Pharmacy, International Federation of Pharmacy, Society of Cosmetic Chemists and American Association of Pharmaceutical Scientists. He is on the editorial boards of Pharmaceutical Development and Technology, Die Pharmazie, and Die Pharmazeutische Industrie. Dr. Sakr is an elected Fellow of the American Association of Pharmaceutical Scientists and Graduate Fellow of the University of Cincinnati. He is the recipient of the Distinguished Faculty Achievement Award of the University of Cincinnati. Dr. Sakr has been awarded DOCTOR HONORIS CAUSA from Gr. T. Popa University of Medicine and Pharmacy, Iasi, Romania

B S1-006

BIOGRAPHY H.E. JUNGINGER

H.E. Junginger
Center for Drug Research,
Germany

Prof. Dr. Hans E. Junginger has studied Pharmacy and received his Ph.D degree in Pharmaceutical Chemistry. After his 'Habilitation' in Pharmaceutical Technology he was 1980 2004 Head of the Department of Pharmaceutics at the Leiden/Amsterdam Center for Drug Research at Leiden University in The Netherland. In 2004 he went with early retirement is now visiting professor at the Faculty of Pharmaceutical Sciences at the Naresuan University in Phitsanulok, Thailand.
Prof. Junginger was president of APV (1986 1990), CRS (1994 1995) and was the Scientific Secretary of FIP 1995 2003. He received major awards in his research area and holds 3 honorary doctorates (Gent (1995), Potchefstroom (2003) and University of London (2004).
He has published more than 280 articles and 40 Ph.D. students graduated under his supervision. He is or was at the Editorial Board of all major pharmaceutical journals.
His major research areas are novel drug delivery systems with special emphasis of oral and nasal delivery of hydrophilic (peptide) drugs and vaccines and (trans)dermal drug delivery.

B S1-007

BIOGRAPHY Y. CAPAN

Y. Capan
Hacettepe University,
Turkey

Yilmaz apan completed his B.S. degree at Hacettepe University, Faculty of Pharmacy, Ankara-Turkey in 1972 and Ph.D. degree at the University of Lille II, Faculty of Pharmacy, Lille-France in 1978. Prof. apan was a Visiting Scientist at the University of Lille II, Faculty of Pharmacy in 1982-1983 and at the University Paris-Sud, Faculty of Pharmacy, Paris-France in 1989, 1990, 1992, 1993, and 1996. Prof. apan was a Visiting Professor at Louis Pasteur University, Faculty of Pharmacy, Strasbourg-France in 1991, 1994, 1995 and 2001 and at the University of Kentucky, College of Pharmacy, USA in 1998-1999, 2002 and 2004. Prof. apan is currently a member of the American Association of Pharmaceutical Scientists (AAPS), Association of Pharmaceutical Sciences of Ankara (FABAD), Turkish Pharmacists' Association (TEB) and Pharmacist's Chamber of Ankara (AEO). Dr. apan was a member of the consultant committee of bioavailability and bioequivalence and Committee of Drug Licensing at the Ministry of Health. Dr. apan has published over 60 scientific papers. His research fields are mainly biopharmaceutics, drug delivery and drug targeting.

BIOPHARMACEUTICS AND DRUG DEVELOPMENT PROCESS

S1-001

PREDICTING PHARMACOKINETICS IN HUMAN FROM PRECLINICAL, IN VITRO AND IN SILICO DATA.

M. Rowland
University of Manchester,
United Kingdom

Drug discovery and development has historically been largely empirical, but is now rapidly changing towards more mechanistic and predictive approaches. This is certainly so for pharmacokinetics where in vitro and in silico technologies are becoming available. However, the individual pieces of diverse data need to be integrated which is best done within the framework of whole body physiologically based pharmacokinetic (WBPBPK) models.

Unlike empirical models, WBPBPK models comprise body tissues and organs linked together via the vascular circulation, onto which are overlaid drug specific data. These models allow ready incorporation of tissue composition data eg binding constituents, enzymes and transporters, including variability and uncertainty, as these data become available. They also predict the temporal profiles in various tissues, including sites of efficacy and toxicity, as well as events in plasma. Such an approach is therefore applicable to all compounds and is now gaining increasing application at the very early stages of drug selection, with likely impact eventually in the design of molecules to ensure desired pharmacokinetic features, aided by the relationship between physicochemical and structural properties of compounds and pharmacokinetic parameter values. They also permit ready scaling of data from animals to predict pharmacokinetics in human, which assists in planning the human development program.This presentation will illustrate the important features and recent developments in pharmacokinetic modelling, show some applications, as well as identify some of the technical aspects involved.

S1-002

CHALLENGES IN THE DEVELOPMENT AND REGISTRATION OF PROBLEMATIC GENERIC PRODUCTS

K.K. Midha[1], J.W. Hubbard[1], R. Patnaik[2], V.P. Shah[3],
[1]Pharmalytics Inc., [2]Watson Laboratories, [3]Food and Drug Administration,
Canada United States of America

We discuss unresolved issues in the registration of multisource products and make suggestions for their resolution. Two products are therapeutically equivalent if, after the same molar dose, they show similar safety and efficacy profiles. The products must be Pharmaceutically Equivalent or Pharmaceutically Alternatives. Pharmaceutical equivalence includes the nature of the active pharmaceutical ingredient(s), the role of different crystal structures (polymorphs), different hydrated or unhydrated crystals (isoforms) and amorphous forms. These issues are also germane to naturally derived drugs, to biologics and products of biotechnology. We also ask if different classes of drugs should have tailor made BE standards depending on their properties and type of formulation. BE studies of highly variable drugs require large numbers of subjects to achieve statistical power. Scaling to the within-subject variability permits use of fewer subjects by widening the BE acceptance limits for BE. For narrow therapeutic range drugs, standard BE limits may be narrowed by scaling. Parallel group designs are appropriate for drugs with very long half-lives. The BE of dermatological products is problematic since dermatopharmacoki-netic methods have not been accepted by drug regulators. Pharmacodynamic BE of some dermatological products needs large numbers of subjects for statistical power. Endoge-nous substances given as drugs must be corrected for baseline levels of endogenously produced agents which is complicated when diurnal variations are a factor. Progress will be made in the resolution of these difficult issues by fostering vigorous international de-bate.

S1-003

RECENT ADVANCES IN IMPROVING BIOAVAILABILITY OF POORLY SOLUBLE DRUGS

N.S. Shah
Hoffmann Larcoche inc,
United States of America

Modern compounds emerging from discovery are poorly soluble and exhibit poor and variable bioavailability and have significant food effect. The presentation will address drug delivery technologies to address these bioavailability issues. it will cover advances in particle technology, lipid delivery, amorphous formulation, complexation and pro-drug approaches.

S1-004

DEVELOPMENT OF SUCCESSFUL CONTROLLED RELEASE DOSAGE FORMS

A.A. Sakr
University of Cincinnati,
United States of America

This presentation summarizes some of the work which we carried out recently.
Once/Day Propranolol Tablet: using Kollidon SR, controlled release Propranolol tablets were developed and tested in humans in comparison with the market product Inderal LA Capsules. The developed tablets succeeded in extending the release of Propranolol over 24 hours and compared favorably with the market product (Sakr et al. Pharm. Ind., 63, 624-629 (2001) , Sakr et al, Pharm. Ind., 2005, in press). Extended Release Bumetanide Pellets: a multiple response optimization technique was applied to manufacture extended release (ER) Bumetanide pellets using fluid bed layering and coating techniques by applying various polymers. It was found that the ER optimized formulations had similar diuretic/saliuretic effects in rabbits but better drug excretion to urine production efficiencies that the IR formulations (Sakr et al., J. Contr. Rel. 73, 329-338 (2001), Sakr et al., Int. J. Pharmaceutics 267, 129-140 (2003). Buspirone Extended Release Tablets: Buspirone extended release (ER) matrix tablets were developed using various polymers, and tested in vitro and in vivo in human volunteer. The bioavailability of the ER formulations was about three times higher than the IR (Sakr et. al. US Patent 6,268,368 B1, Sakr et al., J. Clin. Pharmacol, 41, 783-789 and 886-894 (2001), Sakr et al. J. Contr. Release, 88, 147-157 (2003). Nisin Colonic Delivery: The polypeptide antimicrobial agent Nisin was formulated into a tablet coated in Wurster Fluid Bed using methacrylic polymers. Gamma scintigraphy was used to test/validate the successful colonic delivery (Sakr et al., Pharm. Ind., 61, 1145-1149 (1999).

S1-005

DELIVERY AND ABSORPTION OF HYDROPHILIC DRUGS

H.E. Junginger
Center for Drug Research,
Germany

As delivery systems nano- and/or microparticles or suitable liposomal carriers have extensively been studied. All those microparticulate approaches suffer from the poor and irreproducible adherence to the mucosal gut wall which is an absolute prerequisite for any peptide absorption across the mucosal linings and also for any interaction of the delivery systems with the gut wall to change its permeability (e.g. to reversibly open the tight junctions and to allow for paracellular transport of the peptides). With the use of so-called superporous hydrogels (SPHs) or composites (SPHCs) these drawbacks may be overcome and reproducible and predictable peroral peptide absorption with high bioavailability becomes feasible. Both SPH and SPHC polymers are able depending on their chemical composition to quickly swell in the physiological environment and to increase their volume about 200 fold. This volume increase is sufficient for swollen hydrogels to mechanically stick at the intestinal gut wall and to deliver the incorporated drug directly to the gut wall inducing simultaneously the opening of the tight junctions of the gut wall and de-activating the deleterious gut enzymes by locally sucking them up. After the peptides have been delivered and absorbed across the gut wall the superporous hydrogels become overhydrated and their structure is broken down by the peristaltic forces of the gut and the remnants of the delivery systems are easily excreted together with the feces as miniparticulate systems.

S1-006

NANOPARTICLE TECHNNOLOGY AND ITS PHARMACEUTICAL APPLICATION

Y. Capan
Hacettepe University,
Turkey

Nanoparticles are submicronic colloidal systems prepared by a variey of polymers. Depending on the manufacturing method, nanosperes or nanocapsules can be prepared. Nanoparticles were firstly developed by Birrenbach and Speiser during the 1970s.

The studies involving colloidal systems have largely focused on liposomes for a long time, but in certain cases nanoparticles are preferred because of their higher stability. The most important feature of nanoparticles is that targeting to the tissue and therefore higher intracellular penetration of drugs could be achieved.

There are several applications of nanoparticle technology in pharmaceutics. These include but are not limited to cancer chemotherapy, gene delivery, peptide/protein delivery etc. The target tissue or organ may also vary; such as the lymphatic system or the tumor tissue itself.

Nanoparticles could also be used as a carrier system for the targetted delivery of drugs to the brain. The brain the major organ in the body, has a unique protective barrier, the so-called blood brain barrier (BBB). Owing to the presence of the BBB, >98% of new drugs discovered for the central nervous system (CNS) do not enter the brain following systemic administration. Brain drug delivery plays an essential role in modern drug development for the central nervous system (CNS). Modern methods of CNS drug discovery may select drugs that yield the expected pharmacological effect after direct injection into the brain, but not after systemic administration, because BBB transport of the drug is negligible. Thus, nanoparticulate drug carrier systems may circumvent this challenge by targeting.

BIOGRAPHIES CHAIRS AND SPEAKERS S2

B S2-001

BIOGRAPHY G. BROOKS

G. Brooks
University of Reading,
United Kingdom

Gavin Brooks graduated with a first class honours degree in Pharmacy (1984) and obtained a PhD in the areas of organic chemistry and pharmacology (1988) from The School of Pharmacy, University of London. He registered as a Pharmacist with the RPSGB in 1985. In 1988, he joined the Imperial Cancer Research Fund Laboratories in London as a post-doctoral research fellow before being recruited (1992) as a Group Leader to the Department of Cardiovascular Research, The Rayne Institute, St. Thomas' Hospital, London where he began focusing on the mechanisms that control physiological and pathophysiological cardiovascular cell growth. In 1997, he joined Prolifix Ltd. as head of their cardiovascular programme and in 1999 returned to academia where he now is Professor of Cardiovascular Research at the University of Reading. In 2001, he was elected a Fellow of the American Heart Association and in January 2004, he became Head of the new Reading School of Pharmacy. He currently serves as co-chairman of the FIP Special Interest Group on Pharmaceutical Biotechnology and has edited two textbooks for the Pharmaceutical Press on biotechnology issues.

B S2-002

BIOGRAPHY A.M. MOLOKHIA

A.M. Molokhia
European Egyptian Pharm. Ind.,
Egypt

Education :
B.S., School of Pharmacy, University of Alexandria 1964
PhD, College of Pharmacy, University of Michigan, USA, 1973.

Work Experience:
Academia : Research and teaching Pharmaceutics courses at Universities in Egypt, USA and Saudi Arabia, 1964-1989.Adjunct Professor to teach ' Quality Assurance ' at Universities of Ben-Ghazi, Libya, 1994, 1995 and 1996.Sixth October University, Egypt, 1999-2002.Misr for Science and Technology University, 2004.Ain Shams University, 2004.
Industry : Chairman, European Egyptian Pharmaceutical Industry Company (EEPI), 2004- Present.Director to Research and Development at Pharco Pharmaceuticals, Alexandria, Egypt, 1989-1996.
Regulatory :Chairman to the National Organization for Drug Control and Research, 1996-2004.
Other Activities:

- Author and Coauthor of more than 55 research articles.
- Presented more than 50 research papers and professional presentations at different National and International Meetings.
- Supervision of more than 25 M.S., and Ph.D students.
- Observer or Temporary Advisor to several WHO organized workshops in Egypt, Tunisia and Jordan, 1992-Present.
- Short Term WHO Consultant to several countries in EMRO, 1996- Present.
- Invited Speaker to DIA 35th Annual Meeting on Drug Control and Research, Baltimore, USA, July 1999.
- Invited Speaker to UNIDO Consultation on Industrial Utilization of Medicinal and Aromatic Plants, Vienna, Austria, 1992.
- Member to several professional and scientific Committees in Egypt and abroad.

B S2-003

BIOGRAPHY A. M. KARIM

A.M. Karim
Ain Shams University, Faculty of Science,
Egypt

Professor Amr M. Karim is Director of Ain Shams University Genetic Engineering Research Services Unit and Professor of Molecular Biology at the Faculty of Science Ain Shams University, Cairo, Egypt. Dr Karim is a member of a number of national committees on science and technology including the Genetic Engineering and Biotechnology Sector Committee of Egypts Supreme Council of Universities, the Basic Sciences Research Council and the Interdisciplinary Sciences and Drug Research Divisions at the Academy of Scientific Research and Technology as well as Egypts Cabinet Biotechnology Board. He chaired the workgroup for the report on human resource development prepared by the Genetic Engineering Committee of the National Council for Education, Scientific Research and Technology. Dr. Karim was a co-convener of the ELSI track of the second conference of the Africa Genome Initiative held in Cairo (March 2004). He currently serves on the interim steering committee of the NEPAD North African Biosciences Network.

Professor Karim holds a Ph.D. in biochemistry from Temple University, Philadelphia, Pa. and has held fellowship positions at the University of Colorado and the Liver Research Center of the Albert Einstein College of Medicine, New York as well as Research Assistant Professor at SUNY, Buffalo. He is a member of the WHO Schistosome Genome Network and has been involved in a number of international collaborative research projects on vaccines and diagnostics for endemic diseases. At Ain Shams University he is a member of the boards of the Center for Genetic Engineering and Biotechnology, the Medical Research Center and the Center for Scientific Studies and Consultations.

B S2-004

BIOGRAPHY R. TREDREE

R.L. Tredree
St George Hospital,
United Kingdom

Professor Roger Tredree is Chief Pharmacist of St Georges Healthcare NHS Trust and Visiting Professor at Kingston University in London, UK. . He is a member of various national and international pharmacy groups, and is President of the Hospital Section of the International Pharmaceutical Federation (FIP) and the FIP representative to the World Health Organization on the Essential Drugs List. He is Vice-chair of the Procurement and Distribution Interest Group of the Guild of Healthcare Pharmacists, and a member of the National Pharmaceutical Supplies Group. Roger Tredree has held a number of senior posts in the UK National Health Service and has also worked in retail pharmacy. He has broad experience of operational and commercial management, multidisciplinary team building, staff training and recruitment.

B S2-005

BIOGRAPHY D.J.A. CROMMELIN

D.J.A. Crommelin
Utrecht University,
Netherlands

Daan JA Crommelin Ph.D.
Professor Daan JA Crommelin studied pharmacy in Groningen and graduated as a pharmacist in 1975. He obtained his Ph.D. degree at the University of Leiden in 1979 on a thesis entitled: 'In vitro release studies on drugs suspended in non-polar media'. In 1979 and 1980 he worked as a post-doctoral fellow with Prof WI Higuchi at the University of Michigan. In 1980 he was appointed faculty member at the Department of Pharmaceutics and he became full professor and Head of the department in 1984. In the summer of 1992 he became scientific director of the Utrecht Institute for Pharmaceutical Sciences (UIPS). In 1993 he was appointed adjunct professor at the Department of Pharmaceutics and Pharmaceutical Chemistry at the University of Utah. In September 1995 he founded and became scientific director of OctoPlus, a company focused on providing pharmaceutical formulation know how and the development of new drug delivery systems. Since June 2002 he is dean of the Faculty of Pharmaceutical Sciences. In July 2003 he stepped down as scientific director of UIPS. From September 2004 he will chair the FIP Board of Pharmaceutical Sciences for four years and chair the organization committee for the 3rd Pharmaceutical Sciences World Congress in Amsterdam in 2007.

B S2-006

BIOGRAPHY K. A. SHAIKH

K.A. Shaikh
Shantha Biotechnics Limited,
India

Worked in the Middle East for 10 years taking care of the investment and business of a very high net worth individual. Helped in establishing the Coca-Cola business in the Middle East and later for a brief period of two years worked for establishing the brand in the Sultanate of Oman and United Arab Emirates. The business interests handled by me during these years ranged from Cement Manufacturing to Mining to Aviation, amongst others. Returned back to India in 1996 to promote Biotech enterprises, which I helped, establish as an Indo-Arab Joint Venture. Shantha Biotechnics as it is know is the largest dedicated biotech lab in the private sector in India. It has been credited with the development of Indias first genetically engineered health care product. The company has one subsidiary in USA. Shantha West Inc., is based in San Diego, USA, dealing in research of new Therapeutic Monoclonal Antibodies targeted against Cancers.

B S2-007

BIOGRAPHY H. HARASHIMA

H. Harashima, K. Kogure, H. Akita, H. Kamiya,
Hokkaido University,
Japan

Dr. Harashima is a Professor of Laboratory for Molecular Design of Pharmaceutics, Graduate School of Pharmaceutical Sciences, Hokkaido University. He has graduated Faculty of Pharmaceutical Sciences, The University of Tokyo in 1981. He retired Graduate School of Pharmaceutical Sciences and became an Assistant Professor of The University of Tokyo in 1985. He promoted to be an Associate Professor at The Tokushima University in 1987. He has been a full Professor of Hokkaido University since 1999. His work is firmly based on quantitative analysis of pharmacokinetics and pharmacodynamics of drugs with carrier system. Recently, he has succeeded in developing a multifunctional envelope type nano-device(MEND), which exerts as high transfection activities as adenovirus using octaarginine as a membrane permeable ligand.

Recent Publications:
1) H. Akita, R. Ito, I.A. Khalil, S. Futaki and H. Harashima. Quantitative three-dimensional analysis of the intracellular trafficking of plasmid DNA transfected by non-viral gene delivery system using confocal laser scanning microscopy. Mol. Ther. 9:443-51 (2004).
2) I. A. Khalil, S. Futaki, M. Niwa, Y. Baba, N. Kaji, H. Kamiya, and H. Harashima. Mechanism of improved gene transfer by the N-terminal stearylation of octaarginine: Enhanced cellular association by hydrophobic core formation. Gene Therapy 11: 636-644 (2004).
3) K. Kogure, R. Moriguchi, K. Sasaki, M. Ueno, S. Futaki, and H. Harashima. Development of A Non-viral Multifunctional Envelop-type Nano Device By A Novel Lipid Film Hydration Method. J. Cont. Rel. 98:317-323 (2004).

PHARMACEUTICAL BIOTECHNOLOGY IN THE POST-GENOMIC ERA

S2-001

CURRENT ISSUES SURROUNDING BIOTECHNOLOGY PRODUCTS IN THE AFRICAN CONTINENT

A.M. Karim
Ain Shams University, Faculty of Science,
Egypt

The development of recombinant DNA techniques has set the stage for a new era of information-based modern biotechnology with vast developmental potential and diverse applications. Africa along with many developing countries stands to be excluded from the opportunity of integration in an emerging global bioeconomy. This is unfortunate because the nature of the technology provides opportunities for inclusion. With progress in mapping the human genome and that of many parasites, unlimited opportunities for development of new drugs and therapeutic modalities will be unraveled in the next few decades. Traditional definitions of disease are increasingly being replaced by molecular biology definitions and this will steer the drug development process into radically new directions. The potential of genomics in producing more specific and effective drugs will be realized through a shift in the drug discovery process towards development of drugs which exploit the digital informatic nature of RNA and DNA molecules. Production of therapeutic proteins, the unraveling and exploitation of new catalytic and regulatory roles for RNA molecules and progress in gene therapy are steps in that direction. Through addressing genetic differences between individuals pharmacogenomics offers further opportunities for developing more effective drugs at reduced costs. Genotypic drug discovery is changing the drug industry and offering a wide spectrum of new opportunities. Developing countries can share in those opportunities through development of appropriate scientific infrastructures and by taking advantage of modern communication technologies.

S2-002

HANDLING AND STORAGE OF BIOTECH PRODUCTS

R.L. Tredree
St George Hospital,
United Kingdom

Problems in the storage and handling of biopharmaceuticals have been identified. These are related to the lack of awareness among healthcare professionals and patients of the importance of correct storage and handling of biopharmaceuticals, of reliable information on the impact of incorrect storage and handling, and of overall standards for cold-chain management. There are concerns related to delivery to the pharmacy, the ward and the patients home (when refrigeration may not be maintained), and to storage in the ward, pharmacy and patients refrigerators, which often have inadequate temperature control or are poorly managed. A number of strategies for solving these problems have been identified.

S2-003

PROTEIN FORMULATION AND DELIVERY: BOTTLENECKS AND CHALLENGES

D.J.A. Crommelin
Utrecht University,
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.

Recently, the critical importance of selecting the proper formulation protocol was proven again, when changes in formulation of marketed proteins were made and unexpected side effects occurred.

In this presentation challenges will be discussed that one encounters in the process of formulating high quality, pharmaceutical biotech products.

S2-004

MANIPULATING THE GENOME TO TARGET CARDIAC REGENERATION

G. Brooks, K.A. Bicknell,
University of Reading,
United Kingdom

Heart muscle cells (cardiomyocytes) lose the ability to divide as the heart matures which has serious consequences for patients who suffer a heart attack (myocardial infarction [MI]) since the damaged adult heart is unable to regenerate new muscle tissue. Instead, scar tissue forms that can lead to heart failure, which is one of the most important causes of morbidity and mortality in Europe. Understanding the molecular mechanisms responsible for precisely when and why cardiomyocytes lose the ability to divide is crucial if we are to develop new therapies for repairing a heart following an MI. We, and others, have shown that molecules constituting the cell cycle machinery (cyclins, cyclin-dependent kinases (CDKs) and CDK inhibitors) are key regulators for controlling growth in cardiomyocytes. Thus, we recently have demonstrated for the first time that targeted over-expression of the CDC2-cyclin B complex in adult myocytes leads to an increase in the total number of myocardial cells and that inhibition of the G1-S phase transition in myocytes leads to abrogation of hypertrophic growth that can result in heart failure. Thus, the identification and controlled delivery of specific cell cycle regulators into adult cardiomyocytes might permit manipulation of their expressions in these cells in vivo in an effort to push them back into normal cell division where they could repair a damaged heart.

S2-005

CURRENT ISSUES IN GENE DELIVERY

H. Hasshima, K. Kogure, H. Akita, H. Kamiya,
Hokkaido University,
Japan

Dramatic advancements have occurred in the field of drug delivery system (DDS) during the past 10 years. Tumor targeting with long circulating liposomes that contain antitumor agents (passive targeting) has been successfully demonstrated in clinical trials. Active targeting with ligands specific to cell surface receptors has also been developed. In this presentation, I will focus on the next generation of DDS 'Programmed Packaging', in which intracellular trafficking and the disposition of DNA for gene therapy are controlled.

For the efficient gene delivery into the nucleus of target cells, the non-viral vectors must overcome several barriers, such as the plasma membrane, the endosomal membrane and the nuclear membrane. Thus, to overcome the barriers, the non-viral gene delivery system must be equipped with various functional devices such as ligands for specific receptors, pH-sensitive fusogenic peptides for endosomal escape and a nuclear localization signal (NLS) for enhanced nuclear delivery.

We recently proposed a novel non-viral gene delivery system multifunctional envelope-type nano device (MEND) to realize Programmed Packaging. The ideal MEND which consists of a condensed DNA core and a lipid envelope structure equipped with the various functional devices. The compacted core has some advantages, such as the protection of DNA from DNase, size control and an improvement in packaging efficiency. I will introduce newly developed octaarginine modified MEND, which can exert as high trasfection activities as Adenovirus.

S2-006

PHARMACEUTICAL BIOTECHNOLOGY IN THE POST-GENOMIC ERA

D.J.A. Crommelin
Utrecht University,
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.

Recently, the critical importance of selecting the proper formulation protocol was proven again, when changes in formulation of marketed proteins were made and unexpected side effects occurred.

In this presentation challenges will be discussed that one encounters in the process of formulating high quality, pharmaceutical biotech products.

BIOGRAPHIES CHAIRS AND SPEAKERS S3

B S3-001

BIOGRAPHY S. KEITEL

S.K. Keitel
BfArM,
Germany

Dr. Susanne Keitel is a licensed pharmacist and holds a Ph.D. in pharmaceutical technology. Her working experience includes four years as a scientist in process development and five years as head of the department 'Pharmaceutical Development/Oral Dosage Forms' at Schering AG, Berlin. Since October 1997, Dr. Keitel is heading Division 3, Pharmaceutical Quality, at the Federal Institute for Drugs and Medical Devices (BfArM), Germany. In addition, she is Acting Head of Division E, European Procedures, since October 2003. She is vice chair of the Joint CPMP/CVMP Quality Working Party and a member of the EMEA Pediatric Working Party, the Notice to Applicants Group and has been rapporteur for the ICH stability guidelines. At present, she is a member of the Expert Working Group Pharmaceutical Development' (ICH Q8).

B S3-002

BIOGRAPHY A.P. SAM

A.P. Sam
Organon,
Netherlands

Dr Tom Sam is Director CMC Development, Regulatory Affairs International, Organon, the Netherlands. He was head of Organon's Pharmaceutics 'Novel Dosage Forms' and 'Solid Dosage Forms' Sections. He is president of FIP's Industrial Pharmacy Section (www.industrialpharmacy.org), member of the WHO Expert Committee on Specifications of Pharmaceutical Preparations, moderator of the Quality module of the European Regulatory Affairs course, organiser of the European Symposia on Controlled Drug Delivery, and organiser of the Quality International conference 'Managing Quality throughout the Product Life Cycle', a two-day international conference organised by the International Pharmaceutical Federation (FIP) in partnership with the Royal Pharmaceutical Society of Great Britain, Monday 21 to Tuesday 22 November 2005, at the Royal Pharmaceutical Society, London, UK.

B S3-003

BIOGRAPHY P. MACHERAS

P. Macheras
University of Athens,
Greece

Panos Macheras is Professor and Director of the Laboratory of Biopharmaceutics and Pharmacokinetics at the University of Athens, Department of Pharmacy. He received his B. Pharm. (1970) and Ph.D degree in Pharmaceutical Chemistry (1977) from the University of Athens, Greece. He also received a Ph.D degree (1981) in Biopharmaceutics-Pharmacokinetics from King's College, University of London, U.K. Dr. Macheras has published more than 120 journal articles and three books in the field of Biopharmaceutics-Pharmacokinetics. His research interests include studies on dissolution, release, gastrointestinal absorption, protein binding, drug-cyclodextrins interaction, bioequivalence, pharmacokinetics and applications of fractal concepts in biopharmaceutical systems. In 1988, he was Visiting Associate Professor at the College of Pharmacy, University of Michigan. Dr Macheras serves on the Editorial Board of the journals, Pharmaceutical Research, International Journal of Pharmaceutics, European Journal of Pharmaceutical Sciences. He is a Fellow of the American Association of Pharmaceutical Scientists. He received an Honourable mention at the Eurand Awards 2000 and he was the second place winner of the Eurand Awards 2003 for his work in oral drug delivery.

B S3-004

BIOGRAPHY A. BICA

A. Bica, A. Farinha,
LEF,
Portugal

Nationality: Portuguese
Professional Activity: Study Director and Biopharmaceutics Coordinator at Laboratrio de Estudos Farmaceuticos (LEF)
University Degrees:
Since 2005 Master graduate in Economics and Management of Science and Technology ISEG Instituto Superior de Economia e Gesto
Since 2000 PhD Student in Pharmaceutical technology, Faculty of Pharmacy of Porto
1993 Graduation in Pharmacy, Faculty of Pharmacy of Lisbon
Professional Degrees:
2003 Expert in Pharmaceutical Industry
by the Portuguese Pharmaceutical Society
Professional Experience:
Since 1993 Biopharmaceutics Coordinator at Laboratrio de Estudos Farmaceuticos
1992 a 1993 Associate research fellow of the Biochemical group of Faculty of Pharmacy of Lisbon Centre of metabolism and genetic Monitorization and diagnosis of genetical patologies
Between 1991 a 1993 Department of Regulatory Affairs of Farmatra
Actividades Farmaceuticas, Lda.
Field of Professional Specialization:
Bioequivalence/Bioavailability
Dissolution, in vitro/in vivo correlations
Implementation of Quality Systems
Publications
For the last ten years, has been the responsible for the publication of the results of many in vitro comparative studies concerning the pharmaceutical quality of medicines available in Portuguese pharmacies, in LEFs Bulletin. There have been published 42 numbers of this Bulletin, until now. Has the author and co-author of more than 50 papers (between posters and scientific articles) in pharmaceutical publications. Has participated as speaker in several congresses and workshops.

B S3-005

BIOGRAPHY H.D. FRIEDEL

H.D. Friedel
Bayer HealthCare,
Germany

Dr. Friedel is head of the department Integrated Quality Management, which is part of the Global Quality Assurance of Bayer HealthCare. He is responsible for developing and implementing a Global Quality System for Bayer HealthCare. His special areas of interest in Quality Assurance are product development of pharmaceutical drug products and process analytical technology (PAT). He spent 15 years in the quality control for pharmaceutical drug products under development in different positions and achieved extensive international experience in product development, dissolution testing, stability studies, laboratory automation, computer validation, and regulatory submissions. He was involved in the development of solid oral dosage forms with fast dissolving and extended release characteristics, parenteral drug products, liposomes, suspensions and aerosols. He graduated in pharmacy and chemistry in Marburg, Germany and received his Ph.D. in pharmaceutical chemistry on isolation and structure elucidation of sesquiterpenes from tolubalsam.

DISSOLUTION TESTING – A PIVOTAL TOOL FOR DEVELOPMENT AND QUALITY OF DRUGS

S3-001

VALIDATION OF DISSOLUTION TESTS: OUTCOMES OF COLLABORATIVE STUDIES IN DIFFERENT LABORATORIES AROUND THE WORLD

A. Bica, A. Farinha,
LFF,
Portugal

Dissolution testing represents a valuable tool for both the evaluation of the reproducibility of industrial production and the discrimination between formulations within the scope of the prediction of the in vivo availability of the administered drug. These two perspectives contain different approaches when establishing the dissolution test conditions: in the first case a sensitive power is desired, while in the later, discrimination is the target.

Behind the inherent difficulties to achieve the above stated, the vast number of variables with a potential impact on the overall performance of the dissolution test represent an additional challenge, which has been addressed by several authors, through many dissolution studies.

LMCS, has contributed to this discussion through the design of several studies, including the assessment of dissolution performance of different products, containing different active ingredients, including dissolution calibrators as well as products from worldwide markets (glibenclamide, phenytoin, furosemide, carbamazepine, prednisone, glyburide, theophylline, warfarin, nifedipine, propafenon) with the participation of laboratories from Americas, Europe, Africa, Asia and Australia. The purpose, besides the assessment of products quality, has been the identification and the investigation of variability problems closely related with in vitro dissolution testing.

The outcome of this work will be compiled and presented, as a means to share the conclusions drawn, adding elements to future approaches within the scope of dissolution testing and validation.

S3-002

DEVELOPMENT OF DISSOLUTION TEST METHODS IN THE PHARMACEUTICAL INDUSTRY

H.D. Friedel
Bayer HealthCare,
Germany

The dissolution test has become an indispensable tool in the development of new solid oral dosage forms and the assessment of the physical stability of the formulation. To generate reliable dissolution data a careful development of the dissolution test method is required. An appropriate in-vitro-dissolution test method should meet the following criteria:

Sufficient discriminatory power to identify critical manufacturing variables
Low variability of the method
In-vitro-in-vivo comparison
Assessment of the physical stability of the formulation

For the selection of the formulation the first experiments are carried out with the same standard dissolution conditions using the paddle apparatus. After evaluating the results the dissolution test parameters are optimized. The volume of the experimental work highly depends on the stage of the development of the formulation. The influence of the following test parameters on the dissolution profile is generally studied:

Dissolution medium: pH dependency, kind and concentration of surfactant
Rotation speed of the paddle
Influence of sinkers
Deaeration of the medium

Based on the dissolution test results the process parameters are optimized. The dissolution test can give information about the influence of the active pharmaceutical ingredient and the excipients on the properties of the formulation and about the stability of the formulation.

In the future, Near-Infrared Spectroscopic Methods offer the potential to move forward from the traditional dissolution test to a non-destructive analytical method. An example will be provided, in which the dissolution behavior of a drug product can be predicted from the NIR data.

BIOGRAPHIES CHAIRS AND SPEAKERS S4

B S4-001

BIOGRAPHY A.P. SAM

A.P. Sam
Organon,
Netherlands

Dr Tom Sam is Director CMC Development, Regulatory Affairs International, Organon, the Netherlands. He was head of Organon's Pharmaceutics 'Novel Dosage Forms' and 'Solid Dosage Forms' Sections. He is president of FIP's Industrial Pharmacy Section (www.industrialpharmacy.org), member of the WHO Expert Committee on Specifications of Pharmaceutical Preparations, moderator of the Quality module of the European Regulatory Affairs course, organiser of the European Symposia on Controlled Drug Delivery, and organiser of the Quality International conference 'Managing Quality throughout the Product Life Cycle', a two-day international conference organised by the International Pharmaceutical Federation (FIP) in partnership with the Royal Pharmaceutical Society of Great Britain, Monday 21 to Tuesday 22 November 2005, at the Royal Pharmaceutical Society, London, UK.

B S4-002

BIOGRAPHY M.M. NASR

M.M. Nasr
US FDA,
United States of America

Dr. Mobeb Nasr is the Director of the Office of New Drug Chemistry (ONDC), Center for Drug Evaluation and Research, FDA. ONDC is responsible of all aspects of quality assessments (pre and post-marketing) of new drugs regulated by CDER. In 1989, after 10 years in academia, Dr. Nasr joined the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Analysis, as a research chemist and in 1998 became the director of the Division of Pharmaceutical Analysis. Dr. Nasr obtained his Ph.D. degree in Chemistry at the University of Minnesota in Minneapolis. Dr. Nasr holds a B.S. degree in Pharmacy and a Master degree in Pharmaceutical Analysis both from Cairo University, Egypt. Dr. Nasr's research interests include pharmaceutical analysis, chromatography, spectroscopy, computer modeling, chemical kinetics, and reaction mechanisms. Dr. Nasr is a member of FDAs Council on Pharmaceutical Quality.

GOOD CHEMISTRY, MANUFACTURING AND CONTROL PRACTICE

S4-001

PHARMACEUTICAL QULAITY ASSESSMENT - THE NEW CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC) REVIEW PARADIGM IN THE 21ST CENTURY

M.M. Nasr
US FDA,
United States of America

The U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research, Office of New Drug Chemistry (ONDC) is responsible for reviewing the chemistry, manufacturing, and controls (CMC) section of new drug applications. Consistent with the FDAs initiative concerning modernization of the regulation of pharmaceutical manufacturing and product quality (Pharmaceutical Current Good Manufacturing Practices for the 21st Century: A Risk-Based Approach), ONDC is establishing a modern, risk-based pharmaceutical quality assessment system. The new quality assessment system emphasizes quality by design in the evaluation of critical aspects of pharmaceutical quality attributes with a strong focus in manufacturing science; integration of review and inspection functions; implementation of project management functions; and establishment of a strong scientific organization. The new system encompasses several initiatives whose objectives are to allow rapid introduction of new technologies into pharmaceutical manufacturing and expedite review of applications without compromising the high quality of drugs in the United States. The major features of the new paradigm are:

A science-based organization that is more efficient, effective, and flexible in managing CMC issues and workload.

Dedicated pre-marketing and post-marketing divisions.

Pharmaceutical assessment leads to perform initial assessment, identify critical pharmaceutical quality areas, and develop a 'Big-Picture' assessment protocol and timeline to complete the review.

A new manufacturing science branch.

A project management staff.

S4-002

TOWARDS ONE WORLD-WIDE HARMONIZED MANUFACTURING PRACTICE STANDARD FOR DRUG SUBSTANCES AND DRUG PRODUCTS?

A.P. Sam
NV Organon,
Netherlands

Essentially similar GMP standards should apply world-wide, since API manufacturers and pharmaceutical companies have to assure the quality of their products independent of the place of manufacture or the location of the patient. Despite recent attempts to harmonize GMPs, the current standards for manufacturing practice differ for the various regions in the world in many aspects. This 'disharmony' in GMP standards derives from different historical backgrounds, and from different approaches, regimes, philosophies and policies. The presentation discusses the arguements pro and con for world-wide harmonization.

BIOGRAPHIES CHAIRS AND SPEAKERS S5

B S5-001

BIOGRAPHY P.J. HOUGHTON

P.J. Houghton
Kings College London,
United Kingdom

Professor Houghton graduated in pharmacy at Chelsea College, University of London in 1968 and was awarded his PhD in 1973. Since 1972 he has lectured and undertaken research in pharmacognosy, being made Professor in Pharmacognosy in 1999. He was designated a Fellow of the Royal Pharmaceutical Society of Great Britain (RPSGB) in December 1994.

Professor Houghton has published over 175 research papers on many topics connected with the chemistry and biological activity of plants and their constituents. At present his major research areas include substances from plants of potential use in treating CNS degenerative disease, cancer and wounds. Professor Houghton has many international contacts and collaborations and has given lectures in a large number of different countries and at several international conferences.

Professor Houghton is Assistant Editor of the Journal of Ethnopharmacology and Pharmaceutical Biology. He is current President of the International Society for Ethnopharmacology, President of the Natural Products Special Interest Group of the Board of Pharmaceutical Sciences of FIP and a member of the Board of the Society for Medicinal Plant Research. He is a member of the herbal and crude drugs committee of the British Pahrmacopoeia and serves on the Complementary and Alternative Medicine Working Group set up by the RPSGB

B S5-002

BIOGRAPHY A.A.M. ABDEL-LATEFF

A.A.M. Abdel-Lateff
Faculty of Pharmacy,
Egypt

C. V.

Ahmed Abdel-Azim Mahdy Abdel-Lateff (Ph. D)
Department of Pharmacognosy, Faculty of Pharmacy, El-Menia University, El-Menia 61519, Egypt E-mail: AH_MAHDY@hotmail.com

Tertiary Education

1985-1990

Study of Pharmaceutical Sciences, Assiut University, Assiut, Egypt, graduated in July 1990 with distinctions

Oct. 1990 - Dec. 1991

Military service (Pharmacist in Big drug store in Nasser City, Cairo, Egypt)

Dec. 1991-Dec. 1997

Graduate studies at Department of Pharmacognosy, National Research Centre, Dokki-Cairo 12622, Egypt. Title of the Master thesis: A study on Cytotoxic Principles of Selected Annonaceae Species' award a prize of the best research in the natural product chemistry from MEPACO company in March 1997.

Oct. 1999-May 2004

Graduate studies at the Institute for Pharmaceutical Biology, University of Bonn, Germany. Title of the Ph.D. thesis: 'Secondary Metabolites of Marine-Derived Fungi; Natural Products Chemistry and Biological Activity', and on line http://bas.ulb.uni-bonn.de/diss_online/math_nat_fak/2004/ abdel-lateff_ahmed. Scholarship from the Egyptian government

June 2004-Current

Lecturer, Department of Pharmacognosy, Faculty of Pharmacy, El-Menia University, El-Menia 61519, Egypt

Academic Position

1991-1997

Assistant researcher at Department of Pharmacognosy, National Research Centre, Dokki-Cairo 12622, Egypt.

1997-2004

Assistant Lecturer, Department of Pharmacognosy, Faculty of Pharmacy, El-Menia University, El-Menia 61519, Egypt.

June 2004-onwards

Lecturer, Department of Pharmacognosy, Faculty of Pharmacy, El-Menia University, El-Menia 61519, Egypt.

B S5-003

BIOGRAPHY D.Y. YOUSSEF

D.Y. Youssef
Suez Canal University,
Egypt

Dr. Dina Youssef born in 1961 in Sharkia, Egypt, 1984 B.Pharm. (Honor) from Assiut Univ., Egypt, 1988 M.Sc. in Pharmacognosy, Assiut Univ.; 1995 Ph.D. in Natural Products Chemistry, Albert-Ludwigs-University, Germany; 1995-1996 Post-doctoral Fellow, Albert-Ludwigs-Univ., Germany; 1996-1998 Lecturer of Natural Product Chemistry at Suez Canal University (SCU); 1999-2000 Fulbright Postdoc. Fellow at Univ. of Hawaii at Manoa, Honolulu, U.S.A.; 2001 Assoc. Prof. at SCU; 2002 J.S.P.S. Visiting Prof. at the Univ. of Tokyo; 2001-present Head of the Department of Pharmacognosy and the group of Marine Natural Product Chemistry at SCU.

Dr. Dina Youssef, pharmacist, and natural product chemist since 1984, has strong theoretical and experimental expertise in area of chemistry and structure elucidation of secondary metabolites. His post-doctoral research career has brought him to work in a number of top leading universities in USA, Japan, and Germany. As a result he has published over 35 publications in Refereed International Journals and Conference. Seven years ago, Dr. Youssef has established the first laboratory of 'Marine Natural Products Chemistry' in Egypt at SCU for exploitation of the wealth of Red Sea organisms. Most of his researches have been focusing on discovery of new drug leads from Red Sea marine organisms with selectivity against human solid tumors, tuberculosis, and inflammation. Moreover, Dr. Youssefs lab is focusing on the topics of symbiosis in marine invertebrates, marine microbes, and targeted semisynthetic modifications of bioactive natural products. In 2004, he has received 'State Recognition Award in Medicine (Egypt).

B S5-004

BIOGRAPHY S. VON LAUE

S. von Laue
Society for Cultural Development (SCD),
Egypt

Sigward von Laue is currently Scientific Advisor at the SEKEM Academy, and SEKEM University (u.c.), Cairo, Egypt as well as coordinator of DOPSE-TEMPUS a higher education program in phytopharmacy. He graduated from Kings College London, UK in 1995, and received his PhD from Sheffield University, UK in 1999 with a scholarship from the YCR. He was invited by Pharmacia Upjohn and others as a speaker to several international symposia and worked as a Poste Vert for INSERM Paris, France, several biotechnology companies, as well as a consultant to the pharmaceutical industry.

BIOGRAPHIES CHAIRS AND SPEAKERS S5

B S5-005

BIOGRAPHY N. TAMBOULY

N. Tambouly
Society for Cultural Development (SCD),
Egypt

Dr. Nebal Darwish Zaki El-Tambouly, Professor of Pharmacognosy, Faculty of Pharmacy, Cairo University and currently in the position of director of the Research and Drug development in SEKEM Academy Ph. D. of Pharmaceutical Sciences / March 1990 (Universit Louis Pasteur-Strasboarg-France). Selected for Fullbright research grant in U.S.A. from June 1997 to June 1998 University of North Carolina, School of Pharmacy at chapel Hill.
Received the award of the best Scientific Research from Caiso University, in March 1996, the National award for promotion of biological sciences from the academy of Scientific Research in Egypt 1998.

B S5-006

BIOGRAPHY D. BISHAY

D.B. Bishay
Assiut University,
Egypt

Teaching assistant, Pharmacognosy Department, Faculty of Pharmacy, Cairo University from 1962 to 1969. A.R.E. Government Mission Member at the Medical Academy of Poznan-Poland, 1969-1972. Lecturer of Pharmacognosy, Faculty of Pharmacy, Assiut University, from March 1973 to April 1977. Associate professor of Pharmacognosy, Faculty of Pharmacy, Assiut University from April 1977 till March 1982. Professor of Pharmacognosy, Faculty of Pharmacy, Assiut University, from March 1982 till date. Fulbright Visiting Scholar during the period August 18, 1985 - August 15, 1986 doing research on cytotoxic agents from plants in the University of Illinois at Chicago, College of Pharmacy, USA, as a part of the project of NCI and programme for collaborative research in the pharmaceutical sciences at Chicago, Illinois University. Chairman of Pharmacognosy Department, Faculty of Pharmacy, Assiut University, from June 1987 till June 1990. Member of the pharmaceutical Society of Egypt from 1963. Member of the Syndicate of Pharmacists of Egypt from 1962. Member of the Phytochemical Society of Europe from 1979. Member of American Society of Pharmacognosy from 1986. I have published more than 90 papers in the field of Pharmacognosy.

B S5-007

BIOGRAPHY M.T. KHAYYAL

M.T. Khayyal
Faculty of Pharmacy, Cairo University,
Egypt

Prof. Dr. Mohamed Taky El-Din Khayyal, (MTK), emeritus Professor of Pharmacology, Faculty of Pharmacy, Cairo University, Egypt, was born in Cairo on 26th October 1937. He graduated in 1958 from the Faculty of Pharmacy, Alexandria University, and later obtained his Ph.D. from the School of Pharmacy, London University in September 1964. MTK is an active member of many national and international scientific societies, in some of which he has held executive positions. These include Vice-President of the Egyptian Society of Pharmacology and Experimental Therapeutics, Secretary General of the Union of African Societies of Pharmacology, active member of the British Pharmacological Society, the German Pharmacological Society, the Egyptian National Committee of Pharmacology, the Egyptian Pharmaceutical Society, and the Egyptian Toxicology Society. He has also served for almost 20 years as a consultant to the Egyptian Ministry of Health on various drug regulatory Committees as well as to local Pharmaceutical companies. Recently, (July 2002), he was elected to the Executive Committee of the International Union of Pharmacology (IUPHAR). In 2003, he has been appointed as Academic Councillor to the newly founded German University in Cairo for Pharmacy & Biotechnology affairs.
MTK has received grants and fellowships from various international organisations, such as the International Atomic Energy Agency, Vienna, Austria, (1973), Alexander von Humboldt Foundation, Germany, (1978), and the Fulbright Foundation, USA, (1987).

NATURAL PRODUCTS

S5-001

RATIONAL FOR PHYTOPHARMACEUTICALS IN EGYPT

S. von Laue
Society for Cultural Development (SCD),
Egypt

Holistic approaches to science, technology, economics and health care are constantly gaining in importance. Phytopharmaceuticals associated with traditional medicine or complementary and alternative medicine (TM/CAM) enjoy increasing popularity, spurring ever more research efforts by companies, civil society and the public sector.
Despite recent advances, relatively little data are available for the majority of remedies, due to the complex composition of plant derived medicines, challenges in production and standardisation, limited funds and a difficult intellectual property rights (IPR) situation. However, public funding in the USA has increased 25 fold since 1995 and China recently announced US$1.7 billion for TM/CAM research. Furthermore, the WHO recommends the integration of TM/CAM in all national healthcare strategies, pointing to an enormous growth potential of this market.
Simultaneously it has become quite clear that regular allopathic single active component treatments, though highly specific are associated with a variety of side effects. These remedies are doubtlessly necessary for all life threatening situations, yet of limited use in many chronic illnesses and multimorbidity. Therefore, the development of novel approaches, including the use of multi-component drugs and complex combinations like plant extracts, with their repeatedly documented synergistic actions of the active components, requires serious consideration. Phytopharmaceuticals might hence provide the opportunity for countries like Egypt to successfully compete in the development of effective sustainable solutions for many current medical challenges, like life-style induced diseases and cancer.

S5-002

MOLECULES OF PHARMACEUTICAL INTEREST FROM RED SEA MARINE ORGANISMS

D.Y. Youssef
Suez Canal University,
Egypt

Medicine benefits immensely from the rich pharmacopoeia of our environment; according to one recent analysis, about 57% of the 150 most prescribed drugs in the US are derived from natural products. Most, however, are from terrestrial plants and microorganisms. Our drug discovery program at Suez Canal University is focusing on search for new drug leads from marine organisms with selectivity against human solid tumors, inflammation, and tuberculosis. Most of our research on marine-derived natural products is focusing on Red Sea organisms, where the biodiversity of marine invertebrates is unique and abundant. We have conducted an extensive program for investigation on a large number of marine invertebrates (sponges, tunicates, soft corals, gorgonians, mollusks), cyanobacteria, and marine microbes. We have identified several new/novel biologically active compounds with selectivity against solid tumors, anti-inflammatory, and anti-tuberculosis activity. An example of our recent work on sponge-derived marine natural products is provided by our recent study on Theonella swinhoei collected in Hurghada. Sponges of this genus are known to produce cytotoxic and antifungal macrolides and peptides. We were able to isolate and identify a novel cyclic macrolide, with a 42-membered dilactone moiety named hurghadolide A, together with swinholide I. Hurghadolide A and swinholide I showed potent cytotoxic activity against a panel of cancer cells with IC50 = 0.15 and 0.008 ug/mL, respectively. In addition, both compounds were potent antifungal against Candida albicans (W.T.) with MIC = 31 and 62 ug/mL, respectively. More examples of our findings will be discussed and presented.

S5-003

THE INTEGRATIVE APPROACH OF SEKEM TO PHYTOPHARMACEUTICALS DEVELOPMENT IN EGYPT

N. Tumbouly
Society for Cultural Development (SCD),
Egypt

Modern phytopharmaceuticals are only distantly related to the potions and tonics mixed by traditional healers. Scientific evaluation through evidence based medicine necessitates the reliable characterisation and standardisation of extracts from plants or other organisms, as well as strict quality control procedures.
SEKEM is an initiative that combines sustainable social, cultural and economic activities to promote comprehensive learning and development, as well as the healing of man and the environment. The successful systemic approach through biodynamic agriculture, integrative education, scientific research and modern manufacturing equipment provides the basis for the development and production of high quality phytopharmaceuticals. This development is inspired by over 5000 years of traditional knowledge and builds on the supply of high quality herbal raw material, free of pesticides or other inorganic chemicals. It relies on a sound scientific basis, established through the integration of botanic, biochemical, pharmaceutical and medical research. Plant origin and breeding as well as subsequent growth conditions are optimized just as much as extraction conditions, methods of standardization, packaging, storage and most importantly verification of pharmaceutical and clinical efficacy. In Egypt, phytopharmaceutical medicines are subjected to the same controls as ordinary allopathic ones and increasingly used for the treatment of mild to moderately severe or chronic diseases and as adjuvant.
SEKEMs vision, to develop effective and side effect free phytopharmaceuticals therefore aims to enable Egypt to successfully compete internationally in this rapidly growing market.

S5-004

STUDIES IN MEDICINAL PLANTS OF EGYPT

D.B. Bishay
Assiut University,
Egypt

Egypt occupies a key position between the Asiatic and African countries, and i floristic composition shows affinities in all directions. The Mediterranean part forms natural continuation of the Algerian-Tunisian flora; the southern part (Gebel Elb includes most of the plants of the Red Sea Hills of Northern Sudan, while the Sin Peninsula has a flora of its own most closely related to that of Iran. In addition, Egyptian desert flora is that typical of the great African desert belt which stretches up India.

The science and public health communications of Egypt have long be interested in the botanical, chemical and pharmacological properties of plants in th country. The literature is rich with reports concerning numerous findings, some plants their parts cause health problems because of their toxicities; others are important sour of therapeutic agents and/or essential and fixed oils, gums and waxes for medical pharmaceutical purposes.

Pharmacognosists, pharmacologists and chemists throughout the world ha drawn upon Egyptian plants for laboratory investigations of their chemical constitu and biological activities.

The Pharmacognosy Department, College of Pharmacy, Assiut Univers in upper Egypt has long been interested to investigate many plants growing in diffe localities in Egypt specially in southern part of upper Egypt and Red Sea coastal regi

S5-005

PHARMACOLOGICAL STUDIES ON PROPOLIS: ITS POTENTIAL USE AS AN ADJUVANT IN BRONCHIAL ASTHMA.

M.T. Khayyal
Faculty of Pharmacy, Cairo University,
Egypt

Extracts of propolis (beeswax) have been reported to exhibit a wide spectrum of biological activities. The present work reports on a rational study with a standardized aqueous propolis extract (APE), starting from its anti-inflammatory properties in experimental settings up to its clinical use in asthma. In acute and chronic models of inflammation in the rat, APE showed good anti-inflammatory activity. In isolated sensitized guinea pig lung, APE markedly reduced the release of leukotrienes and prostaglandins. Inflammatory responses which were markedly exaggerated under the influence of ionizing radiation, were effectively checked by APE dose-dependently. Because of its potent anti-oxidant properties, APE was further tested against CCl4 induced hepatotoxicity both in vitro and in vivo and proved to guard against lipid peroxidation, to maintain intracellular levels of GSH. A small limited clinical trial was carried out on human volunteer asthmatics, who responded very well to APE as adjuvant therapy. A larger scale double blind clinical study was then undertaken on 46 patients who were taking the extract for 2 months. Pulmonary function tests as well as immunological parameters and inflammatory mediator levels were carried out before, then 1month and 2 months after taking APE or placebo. The number of nocturnal attacks was greatly reduced in the APE treated patients and the pulmonary functions were markedly improved. There was a significant reduction in the plasma levels of TNFa, ICAM-1, IL-6, IL-8, PGF2a and LTs, but an increase in IL-10., showing good correlation between clinical findings and immunological parameters tested.

B G01-001

BIOGRAPHY R. HANSSON

R. Hansson
Faculty of Pharmacy / Uppsala university,
Sweden

I am a pharmacist and have since 1981 a PhD (Pharm) in pharmaceutical biochemistry from the Faculty of Pharmacy at the University of Uppsala, Sweden. Since my graduation I have been a senior lecturer in pharmaceutical biochemistry at the Faculty of Pharmacy. I have now a position as assistant professor of pharmaceutical biochemistry at the Faculty. In addition to teaching biochemistry to pharmacy students, I am also the co-ordinator of one of the education programmes at the Faculty. As the co-ordinator I have an interest in the development and integration of different courses in the curriculum, the outcomes and quality of the education as well as the profile of the pharmacist.
In my research at the faculty I have been focused on the biosynthesis and metabolism of bile acids. My interest is the evolution and development as well as the differentiation and role of the cytochrome P450 enzyme family, especially the role of cytochrome P450 in biosynthesis and metabolism of endogenous substrates.
Since five years I am the general secretary of the FIP Academic Pharmacy Section. As such I take part in arranging the programmes for the section during the annual FIP congresses. Between the congresses I keep in contact with the section members as well as with the officers of the board of the section and the IPSF.
Finally, I have since 2000 up to the end of 2004 had a position as the president of the Swedish Pharmaceutical Association, the professional organisation for pharmacists in Sweden. As the president of the Association, and before 2000 as vice-president, I have had and still have an interest in the development of the pharmaceutical profession.

B G01-002

BIOGRAPHY T WULIJI

T. Wuliji
International Pharmaceutical Students,
Netherlands

Tana Wuliji
President 2004-2005
International Pharmaceutical Students Federation
twuliji@varsity.co.nz

Tana Wuliji was elected President of the International Pharmaceutical Students Federation in August 2004 at the 50th IPSF Annual Congress in Halifax, Canada. IPSF was founded in 1949 and today represents over 350,000 pharmacy students from 74 countries worldwide and aims to study and promote the interests of pharmacy students and encourage international cooperation amongst them. Over the past year she has been responsible for coordinating the public health, education, professional development, and pharmacy awareness projects of the federation and maintaining partnerships with organizations such as WHO, UNESCO, CPA and FIP in joint endeavors. Tana graduated from the Pharmacy School of the University of Otago, New Zealand in 2002 with a Bachelor of Pharmacy. She spent two years at Hawkes Bay Hospital in New Zealand as a clinical hospital pharmacist following her graduation. In 2003 Tana became the founding President of the New Zealand Association of Pharmacists and Students, uniting the two schools of pharmacy for the first time. She received recognition from the Royal Society of New Zealand for excellence in science in 1998, she was also invited as a guest speaker at the 2004 Asia Pacific Economic Countries Science Ministers Meeting. Tana was the recipient of the Boots Healthcare United Kingdom Externship Grant in 2002. She balances her pharmacy work with music, as a private piano teacher for the past eight years.

B G01-003

BIOGRAPHY L.A. ZWICKER

L.A. Zwicker
IPSF,
Canada

Lesley Zwicker served as the Chairperson of Pharmacy Education for the International Pharmaceutical Students Federation for the 2004-5 term. Ms. Zwicker graduated from the College of Pharmacy, Dalhousie University, Nova Scotia, Canada in 2003 with a B. Sc. Pharmacy and is currently working as a community pharmacist in Chester, Nova Scotia.

B G01-004

BIOGRAPHY K.M. RYAN

K .M. Ryan
University of Otago,
New Zealand

I am a Senior Lecturer in Social Pharmacy, Healthcare Ethics and Pharmacy Practice at the School of Pharmacy, University of Otago, Dunedin, New Zealand. I teach introductory sociology and healthcare ethics to undergraduate pharmacy students and qualitative research methods to postgraduate health sciences students. My research interests include consumer perspectives in health, including information gathering and evaluation, decision-making and electronic health records; pharmaceutical services delivery, including geographic information systems technology applied to pharmacy databases and electronic transfer of prescriptions; pharmacogenomics, particularly ethical and social issues; and womens health, particularly lactation and infant feeding. I live with my husband, Greg, in a small seaside town north of the city of Dunedin. We have two adult children but, alas, no grandchildren yet!

B G01-005

BIOGRAPHY J. SHAW

J.P. Shaw
The University of Auckland,
New Zealand

Professor John Shaw is Head of the School of Pharmacy at the University of Auckland. Pharmacy is a relatively new discipline at Auckland, having been established in 2000. Pharmacy students are now taught alongside medical and nursing students. This is the only location in New Zealand where these three groups of undergraduate students are co-located.

He teaches pharmacology and therapeutics to all three groups, and his research interests are in medicines utilisation, non-traditional prescribers, and evaluation of novel clinical pharmacy services. He is a member of the Minister of Health's New Prescribers Advisory Committee (NPAC) and of the New Zealand Pharmacy Council.

This mix of disciplines at Auckland allowed the exploration of multidisciplinary teaching initiatives, of which Maori Health Week is one example. In this programme, students in mixed professional groups address the challenges of delivering culturally acceptable healthcare services to New Zealand's indigenous population. The initiative was recently awarded a University Teaching Excellence Award and has been submitted for a national Tertiary Teaching Excellence Award.

EDUCATING PHARMACISTS TO EMPOWER PATIENTS

G01-001

STUDENTS' PERSPECTIVES ON THEIR LEARNING EXPERIENCES

L.A. Zwicker
IPSF,
Canada

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 programme and personal influences affected students' perception of their programme and their plans for the future.

G01-002

TEACHING SOCIAL PHARMACY TO UNDERGRADUATES: INTERNATIONAL SURVEY AND WEB-BASED RESOURCE CENTRE

K .M. Ryan
University of Otago,
New Zealand

The pharmacy curriculum has undergone many changes in the last few decades. Pharmacy courses have moved from being largely scientific, meeting the needs of drug development and control, to including several clinical, social, administrative and practice elements. Classification of courses differs considerably on both national and international levels. Titles of courses appear to be largely based on historical grounds. A web site was established to provide an international networking focal point, for teachers involved in teaching the social sciences to pharmacy students. The site included a web-based questionnaire that enabled the collection of baseline data related to teaching, curricula and research activities. The web site was designed to enable the collaborative sharing of course outlines and teaching resources. Sixty-two respondents, from 17 countries, had taken the survey by 30 September 2004. Eighteen different disciplines were identified, ranging from the traditional social sciences, such as sociology and psychology to newer disciplines, such as pharmacoepidemiology and pharmacoinformatics. The most commonly taught disciplines were communication skills, law and ethics, health promotion/education, business management/social and administrative pharmacy and the history of pharmacy. Over 30 different subject areas were identified with the most common being national systems of health, professionalisation, the development of the health professions and professional pharmacy organisations. Data were also collected about knowledge, skills and attitudes being engendered in students; course evaluation; student assessment and faculty qualifications and research activities.

BIOGRAPHIES CHAIRS AND SPEAKERS G2

B G02-001

BIOGRAPHY M.S. AIRAKSINEN

M.S.A. Airaksinen
University of Helsinki,
Finland

Professor Airaksinen started her academic career in the University of Kuopio, Finland during 1985-1999, earning there doctorate (Ph.D.) and masters degree in social pharmacy. Before starting her current job as the first Professor in Social Pharmacy in the University of Helsinki in 2004, she worked as Project Manager in a 4-year national joint programme TIPPA to promote concordance-based communication practices in community pharmacies. The programme was operated by authorities, professional bodies, universities and continuing education centres. She has been active in the WHO/EuroPharm Forums 'Questions About Medicines' project. In 1996-1997, she served as Scholar-in-Residence at the United States Pharmacopeia (USP), Rockville, MD, USA. Since 2000, she has been serving the FIP Pharmacy Information Section as a member of the Executive Committee. Since 2003, she has been chairing the Council of Europe ad hoc Working Group on *Safe* Medication Practices.

B G02-002

BIOGRAPHY C.W. ANDERSON

C.W. Anderson
School of Pharmacy,
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 FIP and on the board of the UK 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 Nottinghams principal investigator in the Community Pharmacy Medicines Management Project, a Department of Health funded multi-centre, randomised controlled trial, which has evaluated the role of pharmacists in advising patients and prescribers concerning appropriate treatment for coronary heart disease.

B G02-003

BIOGRAPHY A.J. WORSLEY

A.J. Worsley
University of Sunderland,
United Kingdom

Dr Alan Worsley is a registered UK pharmacist who graduated with a PhD in phytochemistry/ Medicinal Chemistry from Strathclyde University. He worked for five years at the National Poisons Information Service, the National Teratology informations Service and the Prescribing Support Unit, UK. He moved to Sunderland University in 2000, where he teaches on both undergraduate and postgraduate courses. He is involved with the online provision of postgraduate clinical pharmacy courses and with the Master of Science degree in Medical Informatics at the Royal College of Surgeons, Edinburgh. His research interests include, Rheumatology and Natural Product Chemistry.

B G02-004

BIOGRAPHY P.M. COELHO

P.M. Coelho
Universidade Fernando Pessoa,
Portugal

Pedro M.B. Coelho - born December 31st 1975.
Graduated (Pharmacist) from Faculdade de Farmcia Universidade do Porto - 1999
Msc Pharmaceutical Tecnhology from Faculdade de Farmcia Universidade do Porto - 2004.
MBA - Universidade Catlica Portuguesa - 2004
FIP-YPG 2004 Innovation Award Winner
Assistant Professor at Universidade Fernando Pessoa - Porto

E-LEARNING IN PHARMACY EDUCATION

G02-001

HOW E-LEARNING CONTRIBUTES TO LEARNING

C.W. Anderson
School of Pharmacy,
United Kingdom

E learning is learning facilitated and supported using information and communications technology including computers, mobile phones, personal digital assistants and interactive whiteboards. It can be delivered in a number of ways from supported learning to blended learning to learning that is delivered totally on line. E learning has the potential to improve an individuals learning experience. It can raise standards and widen participation. Whilst it cannot replace traditional lecturers, it can enhance the quality of their teaching. The delivery of e learning has been criticised for concentrating on delivery of materials and general learner management rather than considering the learning activities and their outcomes. Whatever the technology the most important element is always the learning, we must always account for the learners needs, motives, learning styles and prior experience. We should also consider the learning outcomes. Learning activities should always engage the learners and maximise their learning experiences. This is particularly important when designing programmes for so called digital natives, the generation who have grown up with technology.

G02-002

ONLINE POSTGRADUATE PHARMACY COURSE PROVISION

A.J. Worsley
University of Sunderland,
United Kingdom

The School of Pharmacy at Sunderland University has delivered a Post-Graduate Clinical Pharmacy Programme for over 25 years. The development of the post-graduate Certificate, Diploma and MSc Courses are an ongoing process. The courses were originally delivered as completely taught courses, with a gradual development into open-learning packages. Eventually, 'online' courses were developed, which introduced new problems and advantages with respect to service provision, updating material, student feedback, etc. The speaker will discuss the positive aspects and pitfalls of the online delivery of postgraduate pharmacy courses.

BIOGRAPHIES CHAIRS AND SPEAKERS G3

B G03-001

BIOGRAPHY M.J. ROUSE

M.J. Rouse
ACPE,
United States of America

Michael Rouse was born in Zimbabwe. He has worked in hospital and community pharmacy and was chief executive of Zimbabwes largest group of pharmacies. In 2001, Rouse joined the Accreditation Council for Pharmacy Education in Chicago, USA, where he works primarily on international activities and strategic initiatives. Rouse recently published papers on education and training of pharmacy technicians and continuing professional development for pharmacists. He is active in discussions regarding possible implementation of the CPD model for pharmacists lifelong learning. Rouse established and convenes the International Forum for Quality Assurance of Pharmacy Education, which has 170 members from 60 countries and organizations. Rouse has convened four international meetings of this body. Through the Forum, Rouse is coordinating the development of a global framework for quality assurance of pharmacy education. Rouse is a past-president of the Pharmaceutical Society of Zimbabwe and the National Pharmaceutical Council of Zimbabwe. For nearly 20 years, he has been an active member of the International Pharmaceutical Federation (FIP) and recently completed eight-year terms on FIPs Board of Directors and Board of Pharmaceutical Practice. He currently serves as a Director of FIPs Foundation for Education and Research. He has contributed to several FIP working groups and policy development, and materials resulting from his work are used to advance pharmacy practice in many countries. He has been a speaker at numerous national and international congresses and meetings, and has also been a consultant in several countries, particularly in the area of education reform and global trends.

B G03-002

BIOGRAPHY Y. ASIRI

Y. Asiri
King Saud University,
Saudi Arabia

Yousif Asiri is Vice-Dean for Academic Affairs and Assistant Professor of Hospital and Clinical Pharmacy, Department of Clinical Pharmacy, College of Pharmacy, King Saud University in Riyadh, Saudi Arabia. Asiri was born and grew up in Makkah (Mecca) where he moved after he got his high school diploma to Riyadh to study pharmacy. He graduated from College of Pharmacy at Riyadh and worked for two years as teaching Assistant. It was at the University of North Carolina in Chapel Hill School of Pharmacy and the University of North Carolina Hospital where he earned his M.S. Degree and completed a Residency in Hospital Pharmacy. Then he moved to University of Florida where he did some courses in pharmacy health care administration. His journey of education ended at the University of the Pacific, School of Pharmacy at Stockton, California where he earned his Ph.D. in Clinical Pharmacy. Asiri is a pharmacist by choice, commitment and concern. Currently, he teaches at the College of Pharmacy and participates in poisoning management at the University Hospitals. Additionally, he is responsible for the Academic Affairs at the College of Pharmacy. Asiri is a consultant to Saudi Food and Drug Authority and King Fahd Medical City. He is a member of several committees in the College of Pharmacy and the University. Outside of the University, Asiri is involved in several health related governmental organizations. He is a referee for several pharmaceutical journals nationally and internationally. Asiris faith is very important to him and he serves in several non-profit organizations. He is a frequent speaker at pharmacy meetings and is considered a pharmacy futurist.

B G03-003

BIOGRAPHY S.A. SAID

S.A. Said
Dubai Pharmacy College,
United Arab Emirates

Educational Background:
B. Pharm. and Pharm. Chemistry 'Honors' Cairo University; M. Pharm (Pharmaceutics), Cairo University; Ph. D. (Pharmaceutics), Cairo University.

Post Doctorate:
Clinical Pharmacy, College of Pharmacy, Minnesota University, U.S.A. 1977; Clinical Pharmacy, Alberta University, Canada (1978); Clinical Pharmacy - TQM, Netherlands (1988); Clinical Pharmacy, College of Pharmacy, W. Germany (1989); Total Quality Management in Higher Education, Cyprus(1997); Biotechnology , Spain (1998).

Biography (summary):
Lecturer, Cairo University, 1971-1976); Assistant Prof. (Riyadh University, 1976-1977); Associate Professor, Riyadh University (1977-1980); Prof. Cairo University (1980-1994); Visiting Professor, Lebanon, 1988; Visiting Professor Tripoli, Libya (1990); Visiting Professor Yemen (1991); Visiting Professor Ben Gazi Libya (1992); Visiting Professor Romania (1994); Visiting Professor, College of Pharmacy, Volgograde Univ. Russia (1994); Visiting Professor Ukraine (1994); Visiting Professor Romania (1995); Visiting Professor Spain (1997); Visiting Professor Syria (1998); Visiting Professor Cyprus (1999); Visiting Professor Romania (1999); Visiting Professor Syria (2000); Visiting Professor Dubai Pharmacy College, U.A.E. (2001 till date).

OPPORTUNITIES AND OBSTACLES FACING PHARMACY EDUCATION IN THE MIDDLE EAST

G03-001

OPPORTUNITIES AND OBSTACLES IN PHARMACY EDUCATION

Y. Asiri
King Saud University,
Saudi Arabia

Pharmacy education in the Middle East was built on a strong component of basic pharmaceutical sciences since its development in the early sixties. The main objective at that time was to graduate pharmacists with strong science backgrounds to work as chemists, herbalists, scientists and pharmacists. The main job of pharmacists then was to compound and dispense prescriptions with very little patient interaction. As a result of the widespread manufacturing of ready-made pharmaceutical products, pharmacists lost compounding authority to pharmaceutical manufacturers. Pharmacy educators realized the importance of revising pharmacy curricula to address the new challenges facing practicing pharmacists.

Two curricular changes were observed in the early seventies. The first was to reduce the amount of information students had to memorize by reducing the required credits. The second was the adaptation of the credit system and the insertion of concepts of clinical pharmacy.

The PharmD was introduced in the US and other countries started to follow the same patterns. In the Middle East some colleges still follow the old trend in pharmacy education and have more basic science rather than patient care materials. The opportunities of having patient care components in the curriculum are: (1) chronic disease patients, (2) demand for patient counseling, (3) eagerness of students to learn more, (4) the nature of health care system, (5) the image of pharmacists by public, (6) advancement of technology (automation). The obstacles are: (1) traditional pharmacy practitioners, (2) accepting a pharmacist among the medical team in some countries, (3) lack of facilities in some countries.

G03-002

QUALITY ASSURANCE IN PHARMACY EDUCATION

S.A. Said
Dubai Pharmacy College,
United Arab Emirates

Quality Assurance (QA) in Higher Education is an on-going process that ensures the delivery of desired standards and the institution has the ability to achieve a high quality for specific criteria. The latter include leadership, policy, strategy, students, society faculty, resources, processes, community services and partnerships. Guidelines for applying excellence criteria include determining the Results required, planning and developing Approaches, Deploying approaches and then Assessing and Reviewing approaches and their deployment. QA is a prerequisite for accreditation which requires development of standards followed by both self and external evaluation.

For achievement of QA there is a need for formation of QA, strategic planning, institutional research, training and development units. Planning for B. Pharm and Pharm. D. educational programs will be outlined. The use of results of evaluation to improve all levels is a must for institution effectiveness. Institutional research is an effective tool in collecting and analyzing data and disseminating results is vital for an effective operation of the institution. Self-assessment of each criterion used in DPC will be discussed through results of certain models such as admission and acceptance, educational program instructional delivery, resources, faculty, student development services and safety. Evaluation of educational program, includes bench-marketing, students and faculty perception, results on standardized tests, students papers reflecting their researches, portfolios and recitals appropriate to curriculum, completion rate, alumni performanceetc.

BIOGRAPHIES CHAIRS AND SPEAKERS G4

B G04-001

BIOGRAPHY H. SASAKI

H. Sasaki
Nagasaki University Hospital,
Japan

EDUCATION:
1980-1984 - Kyoto University, School of Pharmacy, Kyoto, Japan (Ph.D.)
1978-1980 - University of Nagasaki, School of Pharmacy, Nagasaki, Japan (M.S.)
1974-1978 - University of Nagasaki, School of Pharmacy, Nagasaki, Japan (B.S.)
PROFESSIONAL EXPERIENCE:
2000-present - Professor and Director in Department of Hospital Pharmacy, Nagasaki University Hospital of Medicine and Dentistry, and Professor, Department of Clinical Pharmacokinetics, Course of Medical and Dental Sciences, Nagasaki University Graduate School of Biomedical Sciences
1995-2000 - Associate professor and Vice-director in Department of Hospital Pharmacy, Nagasaki University School of Medicine
1990-1995 - Associate professor in School of Pharmacy, Nagasaki University
1987-1989 - Research associate in School of Pharmacy, University of Southern California
1984-1990 - Assistant professor in School of Pharmacy, Nagasaki University
My research interest is drug delivery system including topical drug delivery and controlled drug delivery, and clinical pharmacokinetics for managing chemotherapy. I have published widely in the mechanisms of drug behavior and their active control formulations after topical and systemic application. My recent research emphasis is gene delivery system and drug pharmacokinetics for individualized medicine. I am a representative in Japanese Society of Pharmaceutical Health Care and Sciences, a branch secretary in The Pharmaceutical Society of Japan, a branch chairman in The Japanese Society of Hospital Pharmacists, and a branch vice-chairman in The Japan Pharmaceutical Association. I am a member in Editorial Advisory Board of Journal of Pharmaceutical Sciences.

B G04-002

BIOGRAPHY A.L. GRAY

A.L. Gray
University of KwaZulu-Natal,
South Africa

Andy Gray B Pharm, MSc (Pharm), FPS is a pharmacist whose research interests include the development of quality management tools for pharmaceutical services at district level, the implementation of District Health Systems, policy analysis (particularly the processes of development and implementation of Drug Policies), rational medicines use (particularly in the elderly and in relation to antimicrobial use) and the application of Highly Active Antiretroviral Therapy (HAART) in resource-constrained settings. He is a Senior Lecturer in the Department of Therapeutics and Medicines Management, Nelson R. Mandela School of Medicine, University of KwaZulu-Natal, Durban, South Africa. He is also the study pharmacist for the Centre for the AIDS Programme of Research in South Africa (CAPRISA). Mr Gray is a Fellow of the Pharmaceutical Society of South Africa, a past president of the South African Association of Hospital and Institutional Pharmacists and is currently Vice-President (Africa) of the Hospital Pharmacy Section of the International Pharmacy Federation (FIP).

HUMAN RESOURCES IN HOSPITAL PHARMACY

G04-001

CHANGES OF EDUCATION AND MANPOWER IN JAPAN

H. Sasaki[1], M. Nakashima[1], N. Ichikawa[1], K. Yamada[2],
[1]Nagasaki University Hospital, [2]Kagoshima University Hospital,
Japan

We will start a 6-years pharmacy education from April 2006, in Japan, after the School Education Law and Pharmacists Law were revised this year. Necessity of clinical education and practice for a pharmacist supported the extension of an education period. A lot of leading pharmacists and hospitals will be necessary for a clerkship of students. It is important that academic instructors cooperate with hospital pharmacists each other and raise an education quality.

This education change will give big influence of the pharmaceutical care provided by pharmacists. Hospital pharmacists have already increased a contribution to team medical care such as infection control, nutrition support, clinical research coordination, and pain control, and safe management. This tendency will be accelerated more.

On the other hand, many colleges of pharmacy are made newly and graduates increase. Although a surplus of a pharmacist is worried about, the increase of manpower could contribute to provide sufficient pharmaceutical care on all patients.

Thus we face a change of education and increase of manpower. Pharmacy has to change if we are going to take full advantage of these opportunity. I present those about the Japanese fact and a role of a future pharmacist.

G04-002

PROBLEMS IN THE AFRICAN CONTINENT

A.L. Gray
University of KwaZulu-Natal,
South Africa

The provision of appropriate human resources is a key determinant of the quality of any service, not least that provided in a hospital pharmacy. African countries face particular problems in this regard. Hospital pharmacies in Africa are, with the exception of some in middle-income countries, mostly located in the public sector. Government health services are under extreme pressure from an ever-increasing burden of disease and a chronic lack of resources. As staff salaries account for the single largest component of recurrent costs in such health systems, this places very real pressure on staffing levels. A number of African countries have no Pharmacy Schools, and rely upon training institutions in neighbouring countries. Suitably trained technicians may also not be available in all settings. Even in countries that do have access to suitable training institutions and an appropriate mix of professional and technical cadres, problems may occur. Of particular concern is the concerted recruitment of African professionals by developed country health care systems, both government and private. Such migration can have dire consequences for a country with already stretched human resources. The countries of Southern Africa provide representative examples of these problems. Potential solutions include the use of community service commitments, locally relevant training and the effective use of mid-level workers.

BIOGRAPHIES CHAIRS AND SPEAKERS G5

B G05-001

BIOGRAPHY L. MCCLURE

L. McClure
PSNC,
United Kingdom

Lindsay studied pharmacy at the Robert Gordon University in Aberdeen, Scotland. Throughout her student days, she was involved in pharmacy student organisations at a local, national and international level including serving as IPSF (International Pharmaceutical Students' Federation) President in 2000/2001.

After qualifying as a pharmacist in 1999, Lindsay spent 2 years working as a community pharmacist before joining the Pharmaceutical Services Negotiating Committee (PSNC) as an administrative pharmacist. Lindsay is currently PSNC's Head of Information Services with her responsibilities including working with the Department of Health in England on the implementation of various national IT projects.

Lindsay is currently Chair of the FIP Young Pharmacists Group.

B G05-002

BIOGRAPHY G. GALLEGO

G. Gallego
The University of Sydney,
Australia

Gisselle Gallego holds a Bachelor of Pharmacy from the Universidad Nacional de Colombia. She worked as a Hospital Pharmacist and later became a Clinical Research Associate at Merck Sharp & Dohme in Colombia. She is currently enrolled in a PhD investigating access to High Cost Drugs in Public Hospitals at the University of Sydney in Australia and is based at the Therapeutics Centre, St. Vincents Hospital. She has worked in clinical research at AstraZeneca in Sydney and is currently working part time in a Community Pharmacy.

PLUGGING THE BRAIN DRAIN: THE MIGRATION OF YOUNG PHARMACISTS

G05

THE MIGRATION OF YOUNG PHARMACISTS- AN INDIVIDUAL PERSPECTIVE

G. Gallego
The University of Sydney,
Australia

As stated by the WHOs World Health report 'The most critical issue facing health care systems is the shortage of people who make them work'. As expressed by Diallo in the Bulletin of the WHO; the migration of health professionals is a worldwide concern because of its impact in developing and developed countries alike. Young pharmacists, migrate to countries such as Australia, Canada, USA and the United Kingdom. However there is also migration between high income countries. An example of this is the continuous flow of young pharmacists between the UK and Australia. Although changes in recognition of professional qualifications will influence this. Globalization and further disappearance of boundaries have also allowed a free flow of professionals between countries.

The migration of health personnel has been described as a complex issue. The professional, social and economical reasons behind a persons decision to emigrate vary. It may be to study or work with the aim of settling, or be short term. The case study of Australia will be explored. An individual perspective will be given about the challenges and difficulties faced when migrating to a different country. The pros and cons and approaches such as 'exchange programs', 'joint learning initiatives' and partnership building' will be discussed.

BIOGRAPHIES CHAIRS AND SPEAKERS G6

B G06-001

BIOGRAPHY L.A. ZWICKER

L.A. Zwicker
IPSF,
Canada

Lesley Zwicker served as the Chairperson of Pharmacy Education for the International Pharmaceutical Students Federation for the 2004-5 term. Ms. Zwicker graduated from the College of Pharmacy, Dalhousie University, Nova Scotia, Canada in 2003 with a B. Sc. Pharmacy and is currently working as a community pharmacist in Chester, Nova Scotia.

B G06-002

BIOGRAPHY K.W. JOHNSON

K.W. Johnson
Management Sciences for Health,
United States of America

As Director of the MSH SEAM Program and Deputy Director for Program Administration, Information, and Communications, Keith W. Johnson is responsible for a variety of developing country initiatives that focus on increased access to essential medicines and other health commodities. He is also responsible for program development and implementation relating to the creation, application, and dissemination of information resources necessary for making appropriate drug access and use decisions, including the development and publication of Managing Drug Supply. Mr. Johnson received his undergraduate training at the University of Nebraska (Pharmacy), his graduate training at the University of Minnesota (Social and Administrative Pharmacy and Educational Psychology), and his postgraduate training at Harvard University's Center for Community Health and Medical Care. Prior to his current position at MSH, he worked at the United States Pharmacopeia (USP) in several capacities, with his last position being that of Vice President of Information Development and Director of the New and Off-label Use Division. In addition, from 1993-2000 he served as Director of the USP Rational Pharmaceutical Management (RPM) project, focusing on drug information and rational use initiatives in developing countries. Mr. Johnson currently teaches at the Georgetown University School of Medicine.

B G06-003

BIOGRAPHY L. MCCLURE

L. McClure
PSNC,
United Kingdom

Lindsay studied pharmacy at the Robert Gordon University in Aberdeen, Scotland. Throughout her student days, she was involved in pharmacy student organisations at a local, national and international level including serving as IPSF (International Pharmaceutical Students' Federation) President in 2000/2001.

After qualifying as a pharmacist in 1999, Lindsay spent 2 years working as a community pharmacist before joining the Pharmaceutical Services Negotiating Committee (PSNC) as an administrative pharmacist. Lindsay is currently PSNC's Head of Information Services with her responsibilities including working with the Department of Health in England on the implementation of various national IT projects.

Lindsay is currently Chair of the FIP Young Pharmacists Group.

B G06-004

BIOGRAPHY N. VIBERG

N. Viberg
Karolinska Institutet (KI),
Sweden

Biography Nina Viberg (previously Thelander)
MSc Pharm
PhD student at the Department of Public Health Sciences, Division of International Health, Karolinska Institutet, Sweden
Secretary of Pharmacists Without Borders, Sweden
Participant of the second rotation of the IPSF Neema project in Tanzania