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Control of the Principles of Good Laboratory Practices in Belgium and non-OECD countries

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GLP STUDY

MEANS AN EXPERIMENT OR SET OF EXPERIMENTS IN WHICH A *TEST ITEM*

IS EXAMINED UNDER LABORATORY CONDITIONS OR IN THE ENVIRONMENT

TO *OBTAIN DATA ON ITS PROPERTIES AND/OR ITS SAFETY*,

INTENDED FOR SUBMISSION TO APPROPRIATE REGULATORY AUTHORITIES

Norms

- Research & Development (study)

  - GLP, GCP
  - ISO 9001

- Production

  - ISO 9001
  - GMP
  - HACCP

- Controle (testing)

  - ISO 9001
  - ISO 17020
  - ISO 17025
  - ISO 15189

Principles concern

1. Organisation: Management-Study director-Principle investigator-Archivist- Study personnel
2. Quality Assurance Unit (audits)
3. Facility
4. Apparatus, Materials, reagents
5. Test systems
6. Test items
7. Standard Operating procedures
8. Study (study plan, performance)
9. Study report
10. Archiving

Subjects addressed in both ISO/IEC 17025 and the GLP directives

- Management and organization;
  - definition of responsibilities,
- Standard operating procedures (SOPs) for
  - maintenance, calibration and use of equipment, procedures for the chain of custody (reception, registration and storage of test items/samples), training of staff,
- Retention of valid reference materials,
- Use of valid test methods
- Test report/study report.

Areas unique to GLP

- Monitoring of a facility and the processes including the specific study,
- Availability of the study plans and master schedules for all the studies,
- A defined Archivist
- A defined Quality Assurance unit.

Areas unique to ISO/IEC 17025

- Service to the client,
- Processing of complaints,
- Preventive actions,
- Calculation of the uncertainty,
- Participation in interlaboratory comparisons such as proficiency testing, traceability and uncertainty of the measurements,
- and customer review.

GLP principles

- GOOD LABORATORY PRACTICE IS A QUALITY SYSTEM, CONCERNED WITH THE ORGANISATIONAL PROCESS AND THE CONDITIONS UNDER WHICH NON-CLINICAL HEALTH AND ENVIRONMENTAL SAFETY STUDIES

ARE PLANNED, PERFORMED, MONITORED, RECORDED, REPORTED AND ARCHIVED

“!!Retraceability!!”

Scope of GLP

Non-clinical Safety Testing of Chemicals, synthetic, natural or biological origin or living organisms

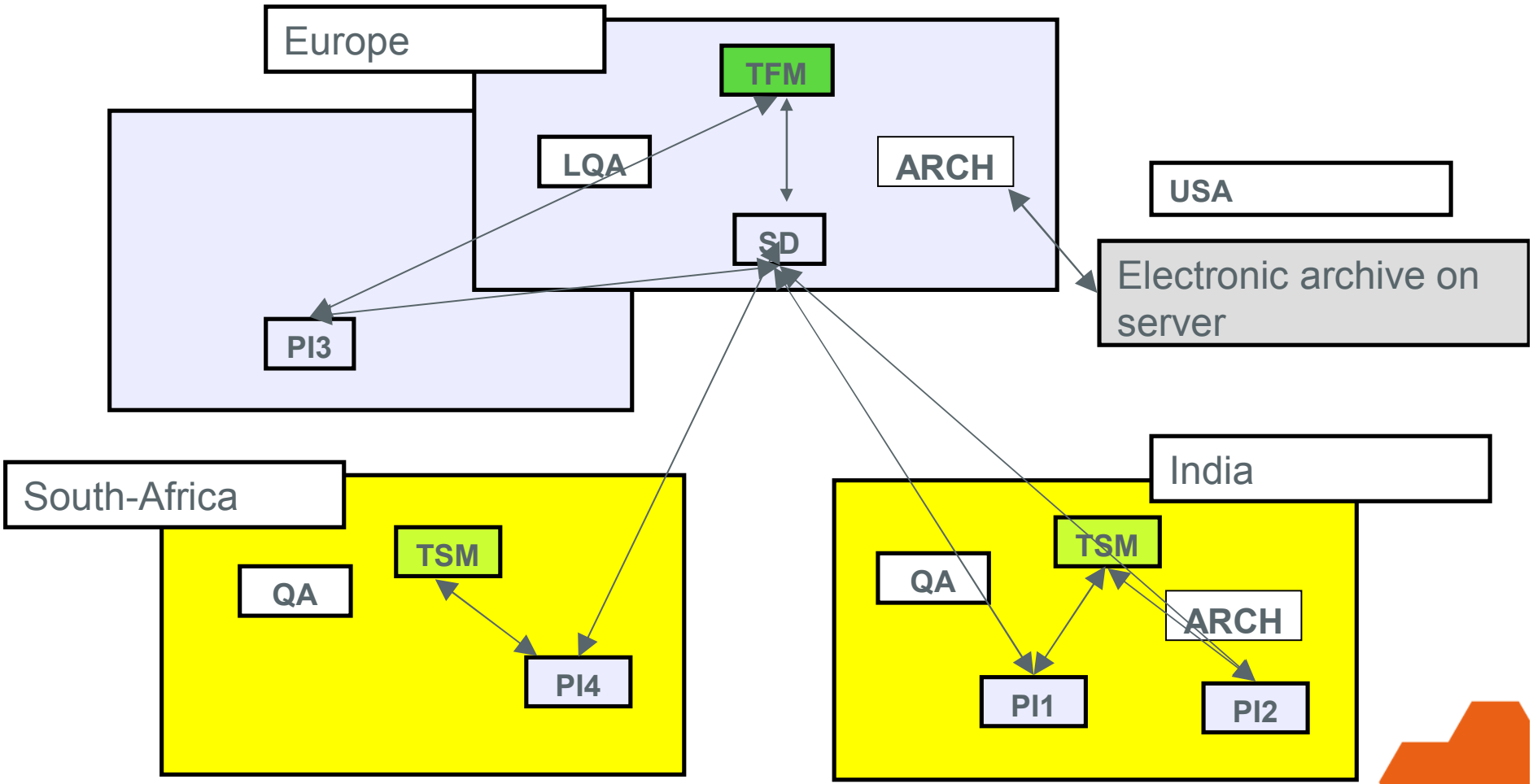
Obtain data on their properties and/or Safety

Tests in laboratories, greenhouses and fields

Required by regulations for the purpose of registering or licensing

Multi-site studies

STRUCTURE of A MULTISITE STUDY



Sectors

- Chemical substances (REACH) & Preparations
- Medicinal products for humans
- Veterinary Medicinal Products
- Cosmetics
- Feeding Stuff
- Food stuffs & Food additives
- Novel Foods and novel food ingredients
- Pesticides (Plant protection) + GMO
- Biocidal products
- Detergents
- Eco-Label
- …….

Inspection Process
(see manual available on internet)

*** REQUEST for**
verification of "COMPLIANCE WITH GLP PRINCIPLES"

*** PRE-INSPECTION**

*** INSPECTION**
*** Preliminary report**
*** Corrective actions**
*** Re-inspection**

*** REPORT**
*** STATEMENT OF COMPLIANCE**

Certified Belgian test facilities are specialized in

- **Physico-chemical determination**
- **Non-clinical analysis of samples**
  - **formulation analysis,**
  - **determination of degradation products,**
  - **residue studies,**
  - **stability studies,**
- **Characterization of gene products**
- **Pharmacogenomic studies and biomolecular analyses**
- **Safety studies:**
  - **Toxico/pharmacokinetic, bioavailability, pharmacodynamic, metabolism**
- **Toxicology/genotoxicity/immunotoxicity studies/In vitro studies**
- **Ecotoxicology studies**
- **Field trials**
- **Microbiological studies**

OECD COUNCIL ACTS ON GOOD LABORATORY PRACTICE

- 1981 Council Decision on Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30/Final]
- 1989 Council Decision/Recommendation on Compliance with Principles of Good Laboratory Practice [C(89)87/Final]
- 1997 Council Decision on Adherence of Non-Member Countries to the Council Acts related to the Mutual Acceptance of Data [C(97)114/Final]

OECD GLP working group "Objectives"

Promote the quality and validity of data generated in the testing of chemicals

Protect human health and the environment

Facilitate data recognition

Avoidance of duplicative testing

Animal welfare

Time and resource efficiency

Avoidance of non-tariff barriers to trade

On-site Evaluation Programme

"…mutual acceptance of test data is only possible if genuine mutual confidence in the manner in which inspections and study audits are carried out exists

and that this mutual confidence can be enhanced through the transparency resulting from on-site visits by teams of expert, objective observers."

- May 2010: Evaluation of Belgium by New-Zealand & Japan
- January 2012: Evaluation Visit of Thailand by Belgian, Spanish & Indian monitoring authority.

Training courses for authorities of non-MAD countries

- Training courses for Authorities and/or test facilities.
  - Zagreb_Croatia, December 2010;
  - Malaysia, June 2011

- Observators during an inspection:
  - India, Malaysia (during an inspection in Belgium)
  - India (Monitoring authority)
  - P.R. of China (ICAMA, SFDA,….)

Inspected facilities in non-MAD countries

- **Nutrichem** (Beijing_P.R. China); February 2006, May 2008, June 2010
  - Observators from ICAMA, CRC-MEP

- **FMC** (Shanghai_P.R. China); November 2006, November 2008
  - Observators from ICAMA

- **Indian Institute of Toxicology** (Pune_India); June 2009
  - Joint inspection with Indian Monitoring Authority

- **Charles River Laboratories** (Shanghai_P.R.China); January 2010

- **Wuxi App Tec** (Suzhou & Shanghai_P.R.China); June 2010 & May 2011
  - Observators from SFDA, National Center for Safety Evaluation of Drug, National Institute For The Control Of Pharmaceutical and Biological Products, & Jiangsu Food and Drug Administration

- **Pilarquim** (Shanghai_P.R.China); May 2011

- **Covance** (Shanghai P.R. China; July 2011

Belgian GLP Monitorate

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OECD GLP Working Group

http://www.OECD.org/ENV/GLP