The Global Health Network

National Skills Sharing Workshop

Managing the Laboratory Relationship

19TH SEPTEMBER 2014

Jennifer Norman
Quality Assurance/External Project Manager, Division of Clinical Pharmacology
UCT

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Start up: Protocol development

- Forge a mutually beneficial relationship with your analytical laboratory
- Facilitate open channels of communication
- Involve the laboratory in the protocol development

Prevent nasty surprises down the line
- +  = Fail
Factors influencing laboratory selection

- Accreditation
- Test availability
- Geographical location
- Past experiences
- Other or previous researchers experiences
- Previous audit findings

Researcher’s aim: To perform the study within budget, delivering high quality data on time.
The only source of knowledge is experience.

- Albert Einstein
• What is laboratory accreditation?
• Why do laboratories seek accreditation?
• Should you preferentially choose accredited laboratories?
• How do you evaluate accreditation certificates?
Key requirements

• A documented management system that gives direction to the laboratory activities and directives to the staff to achieve effectiveness and efficiency in the laboratory;

• Ensures the qualifications, training and on-going competence monitoring of staff;

• Access to appropriate, serviced, calibrated equipment;

• The use of appropriate, controlled and validated methods;

• Specimen management;

• Environmental management;

• Confidentiality and professionalism.
Accreditation

- Accreditation is the **best indicator** that the lab has the capability to do a **good** job.

- If any analysis is not performed in-house, all **supporting labs** should be accredited, as well.

- Accreditation is **not** proof of the quality of all of their data. It means that the lab is capable of providing accurate, representative, comparable, complete, and defensible data.
Directory of Accredited Facilities

Each Facility contains a schedule linked in PDF format. Schedules can be viewed after selecting a specific laboratory or body.

Accredited Facilities

- Blood Transfusion Services
- Calibration Laboratories
- Forensic Laboratories
- Legal Metrology
- Medical Laboratories
- Pharmaceutical
- Testing Laboratories
- Veterinary
- B-BBEE Verification Agencies
- Certification Bodies
- Inspection Bodies
- Proficiency Testing
- GLP and GCP

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A certificate of accreditation is not complete without the schedule of accreditation.

- CERTIFICATE = Yes, we are accredited
- SCHEDULE = We are accredited for X, Y, Z only.
Communicate development during protocol.
Laboratory requirements

• Sampling (tube) type, DBS?
• Label scheme and label type (storage)
• Printing
• Preparation of trial packs by whom?
• Documentation required and responsibility:
  – Laboratory manual
  – Request forms (PKW
  – “Time to freezer” forms
  – Shipping inventory
• On site storage and shipping instructions
Obtained the sample specific instructions for the protocol (if needed)
Regulatory Issues

- Which regulatory guideline should be followed in the clinical laboratory?
- Accreditation = ISO (International Standard Organisation)
- Regulatory studies = GLP (Good Laboratory Practice)
- OECD and FDA GLP = Animal or non-clinical safety studies

!!GAP!!
As Good Clinical Laboratory Practice (GCLP) is based on GCP and Good Laboratory Practice (GLP), a brief history of both is important. 

Up and until the early 1970s, many private and public laboratories applied GLP type principles in one form or another. There were no national/industry regulations.

In 1972, New Zealand formally introduced GLP as a Testing Laboratory Registration Act, covering staff records, procedures, equipment, and facilities. In the same year, Denmark introduced a law to promote GLP. In August 1976, FDA released a draft GLP document and published GLP regulations in the Federal Register. This resulted from violations noted by the FDA in an investigation of a pharmaceutical company. GLP violations included poor record keeping, data storage, inadequate personnel training, poor test facility management and fraud.

In December 1978, FDA published final GLP regulations and made compliance with them the law in the United States in June 1979. These regulations were collected in Title 21: “Food and Drugs” of the Code of Federal Regulations (CFR) as Part 58: “Good Laboratory Practice for Nonclinical Laboratory Studies.” Subsequently, FDA’s Office of Regulatory Affairs (ORA) released two guidelines for industry documents to ensure the proper and consistent interpretation of the directives by industry and by FDA’s field investigators.

In September 1987, the FDA published its “Final Rule” - Compliance Program Bioresearch Monitoring: Good Laboratory Practices.

The Organization for Economic Co-operation and Development (OECD) Principles of GLP cover organizational process and conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. A 1989 OECD Council Decision-Recommendation (C(89)87[Final]) established that OECD Member countries, in which testing of chemicals for purposes of assessment related to the protection of human health and the environment being conducted pursuant to the principles of GLP, shall establish procedures for monitoring compliance with GLP based upon facility inspections and study audits. In this regard, the Standards Council of Canada (SCC) established a GLP Compliance Monitoring Authority (GLP MA) recognized by the OECD. It functions in accordance with the OECD document Revised Guide for Compliance Monitoring Procedures for GLP (1995). Data generated in an OECD Member country in accordance with the OECD Principles of GLP is accepted in Member countries for purposes of assessment and other uses relating to protection of human health and the environment; that is, the Mutual Acceptance of Data (MAD).
Good CLINICAL Laboratory Practice

- Two guidances in existence:
  1. BARC
  2. WHO TDR
- Not recognised by FDA
Regulatory Audits... A Word

- There is no GLP accreditation.
- ISO affords an accessible and workable system for a Quality Management System.
- There is no regulatory requirement to use an accredited lab.

An insurance policy
The single biggest problem in communication is the illusion that it has taken place.

- George Bernard Shaw