The Benefits of Laboratory Accreditation and Certification

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Definitions

- Licensure
  - Non-voluntary process by which a government agency regulates and grants permission for an *individual* to engage in a specific profession

Definitions

- Certification
  - Confirmation that an object, person, or organization meets or exceeds a specified standard by some form of external review, education, assessment, or audit

Definitions

- Accreditation
  - Voluntary process that certifies the competence of an institution or agencies in a specified subject or areas of expertise by a certified third-party agency "Accrediting Body"
    - An Accrediting Body is an official organization that is certified to grant accreditation
    - Accreditation bodies operate according to ISO/IEC 17011

Definitions

- Laboratory Accreditation
  - A laboratory has fulfilled all the requirements of a set standard (ISO17025, NELAC)
  - Assures the laboratory is technically competent and has a Quality Management System (QMS) designed to deliver valid, defensible, and traceable test results
  - All results are of known and documented quality

Good Laboratory Practices GLP

- GLP was initiated by the FDA based on the discovery of QC issues and lack of industry standards
  - Industrial Bio-Test Laboratories (IBT)
  - G.D Searle & Company (Searle)
- Scientific misconduct
  - Fabrication of data
  - Concealment of records and data
  - Aspartame, Flagyl and Aldactone

Good Laboratory Practices GLP

- Opening remarks on the state of pharmaceutical research in the United States, 1976 by Edward Kennedy
  - "Accurate science is the best protection the American people have from unsafe and ineffective drugs."
  - "Inaccurate science, sloppy science, fraudulent science – these are the greatest threats to the health and safety of the American people. Whether the science is wrong because of clerical error, or because of poor technique, or because of incompetence, or because of criminal negligence is less important than the fact that it is wrong"

Good Laboratory Practices GLP

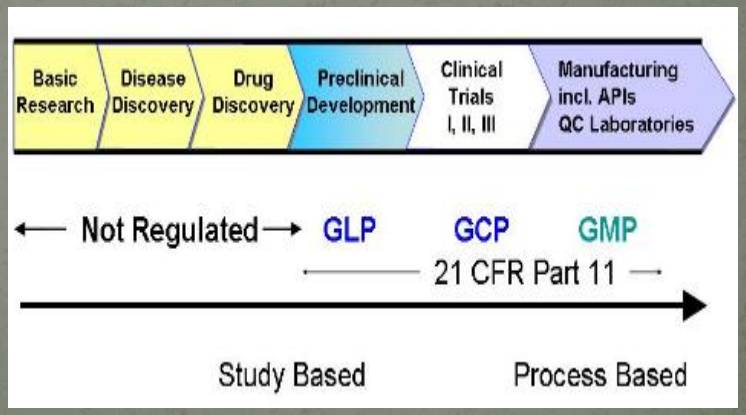
- January, 1976 Searle submitted a draft GLP guidelines
- November, 1976 incorporated into the Federal Register
- December 1978 final GLP regulations were published
- June, 1979 regulations became law
- Revision made in 1984

Goals of GLP

- Ensures that the data submitted are a true reflection of the results that are obtained during the study
- Ensures all the data is traceable and appropriately documented
- Promotes international acceptance of tests

GLP Key Components

- Standard operating procedures (SOP)
- Statistical procedures for data evaluation
- Instrument validation
- Reagent and material certification
- Analyst certification and training
- Laboratory certification
- Sample tracking
- Documentation of records



History of ISO/IEC 17025

- General requirements for the Competence of Testing and Calibration Laboratories
  - ISO: International Standards Organization
  - IEC International Electrotechnical Commission
- Guide 25 became ISO/IEC 17025
- 1999 First Edition of 17025 (Guide 25)
- 2005 Second Edition of 17025
- Standard is written in a general fashion for all types of laboratories

Components of ISO/IEC 17025

1. Management Requirements (ISO 9000)
   - Quality System
   - Document control and records
   - Corrective and Preventative Actions
   - Purchasing, Contracts, Clients
2. Technical Requirements
   - Personnel and training
   - Method Validation
   - Equipment calibration and maintenance
   - Measurement and sample traceability
   - Testing quality control
   - Reporting

History of NELAC / NELAP

- NELAC
  - National Environmental Laboratory Accreditation Conference
    - An association comprised of State and Federal agencies formed to promote acceptable performance standards
- NELAP
  - National Environmental Laboratory Accreditation Program
    - The program that implements the accreditation standards by Accrediting Authorities "AA"

History of NELAC

- 1978 - USEPA initiated the laboratory certification program for drinking water
  - Operation delegated to the state agencies
- 1990 - Environmental Monitoring Management Council EMMC
- 1991 - Committee on National Accreditation of Environmental Laboratories (CNAEL)
- 1995 – National Environmental laboratory Conference
- 1999 - NELAP was established in 11 states
- 2003 – Latest NELAC standard implemented in 2005

Goals of NELAC

- Develop uniform accreditation standard
- Adopt standards for use in all accreditation programs
- Develop a system for recognition of state agencies.
  - Create Accrediting Authorities "AA"
- Implementation of the program that is voluntary by state
- Develop a set of accreditation requirements based on the ISO standards

Accreditation Organizations

- ANSI-ASQ National Accreditation Board (ACLASS, ANAB, FQS)
- The NELAC Institute (TNI)
- EPA Drinking Water Laboratory Certification Program
- NIST National Voluntary Laboratory Accreditation Program (NVLAP)
- American Industrial Hygiene Association (AIHA):
- American Association for Laboratory Accreditation (A2LA)

Importance of Accreditation

- Accurate and informed decisions
- Types of decisions
  - Protection of public health
  - Protection of the environment
  - Compliance to regulatory standards
  - Process control and determining treatment effectiveness
  - Developing future regulatory standards

Importance of Accreditation

- Public: Promotes confidence in the data generated to protect public health and the environment
- Data users: Consumer confidence, the laboratory has been evaluate an met a set standard of competency
- Profession: Promotes adherence to accepted standards
- Laboratory: Commitment to continuous improvement and provides internal and external evaluations and a mechanism for accountability and ethical standards

Value of Accreditation

- Assures customers that results are accurate, traceable, and reliable
- Laboratory is assessed annually
  - Quality System
  - Accurate Standard Operating Procedures (SOP)
  - Using valid and appropriate test methods
  - Technically competent staff
    - Annual training, Initial and ongoing DOC
  - Equipment calibration and maintenance
  - Maintain traceability (samples and results)
  - Performing and passing PT samples
  - Laboratory Ethics program

NEORSD Decision

- NPDES permit requires a structured quality control program
  - The permittee/laboratory shall use suitable QA/QC procedures when conducting compliance analyses with any part 136 chemical method or an alternative method specified by the permitting authority.(§ 136.7)
- Required for Ohio EPA Credible Data Program (Level III)
- Required by various clients
- Increases client confidence in our data
  - Complies with a set of industry recognized standards
  - Audited on an annual basis
- Creates a continuous improvement process
  - Internal and External audits
  - Formalized Corrective Actions
- Incorporates Good Laboratory Practices (GLP)

What does Accreditation consist of?

- Creation of a **Quality Management System** that documents, monitors, and provides a continuous improvement process of the laboratory's operations, policies, procedures and methodologies following recognized guidelines
- Document what you do and do what you have documented
  - If it is not documented it did not happen

Components of a Quality System

1. *<u>Quality Assurance</u>*
   - *An overall management plan to guarantee the integrity of data ("our system")*

2. *<u>Quality Control</u>*
   - *A series of analytical measurements used to assess the quality of the analytical data ("our tools")*

The Quality System

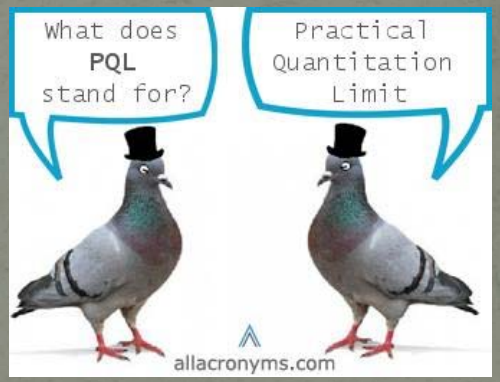
- The "System"
  - Planning and Assessment
  - Corrective Actions
  - Reporting
  - Purchasing and Training
  - ***Quality Manual***
- The "Tools"
  - Standard operating procedures
  - QC Standards and protocol
    - ICV, CCV……
  - Data review techniques
  - Communication
  - Documentation
  - PE Samples

NEORSD Quality Manual

- Includes all documentation or references to the laboratory's procedures and policies that have been established to meet the requirements of NELAC
- SOP 5001 Quality Assurance Manual
  - General SOP that outlines the Quality System
  - Supported by 41 Quality System and 84 Analytical Operating Procedures
  - Controlled Forms 358
  - Total SOP 155
- All Analyst have received training on the Quality Manual and all critical SOPs

Components of a Quality System

- Training and Demonstration of Capabilities
- Document Management and Control
- Internal Audits
- Corrective Actions / Non-Conformance
- Proficiency Testing
- Annual MDL / PQL
- Ethics and Data Integrity
- Traceability
- Equipment and Maintenance



Benefits of Accreditation

- Continuous Improvement Process
  - CAPA –Corrective Action and Preventative Actions
  - Demonstration of Capabilities
  - Training **(Ethical Conduct)**
  - Traceability (samples and reagents)
  - Internal and External Audits
  - Documentation
- Data of Known and Documented Quality

Challenges of Accreditation

- Starting the process
- Writing SOP after SOP…….
- Performance Evaluation – Standards
- Annual Fees
- Modification to Fields of Accreditation
- Subcontracting
- Documentation
- Can't be completed in a weekend

Obtaining Accreditation

- Research Accrediting Organization
  - A2LA, ISO 17025, TNI (NELAP)
- Analyze your current system (GAP Analysis)
  - Hire a consultant
- Identify resources and create a QM Team
  - Acquire needed documentation
  - Update or create SOPS, forms and logs
  - Training and Education
  - Constant evaluations of procedures
- NEORSD Laboratory 3 year process

Accreditation ≠ Perfection

- In all laboratories
  - Mistakes and errors occur
  - Analyst fail PE Samples
  - Instrument breakdown
  - QC samples fail

- A Quality Management System has procedures in place for preventing, investigating, correcting, and documenting errors to ensure that the data generated is of known and documented quality

Questions

William A. Foster

Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives.

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