EPL Bio Analytical Services

Excellence, Passion and Leadership in Agriculture

Presented by:
Angela L. Barricklow-Dawson, B.S. RQAP-GLP
Quality Assurance Specialist
adawson@eplbas.com
Important Details Lab QA’s are Expected to Check
QA is Responsible for Maintaining Study/Facility Compliance

- Protocol and/or Amendments
- Standard Operating Procedures
  - Organization and Personnel
  - Facility
  - Equipment
  - Testing Facility Operations
  - Test Control Reference Substances
  - Protocol
  - Records and Reporting
- Good Laboratory Practice Standards
How Does QA Provide This Service?

- Reviewing the facility and its corresponding records
- Review all study related materials
- Maintaining complete independence

In this presentation I will provide examples of what QA can look at in regards to a study and how these areas can assist in auditing the facility concurrently.
Protocol - Facility

- QA maintains a copy of the master schedule
  - Review it
  - Indexed by Test substance
  - Contains test system, nature of study, initiation date, study status, sponsor and study director identified
Protocol - Facility

- Ensures that Testing Facility Management has in place adequate personnel, resources, facility, equipment, materials and methods needed to conduct the study as scheduled

- Assigns a study director and can replace them if necessary
Protocol - Study

- QA.....

  - Maintains a copy of the protocol/amendments

  - Verifies that amendments document changes and reasons for the changes and are approved and maintained with the protocol

  - Ensures that deviations are reported to study director and corrective action is taken and documented

  - Checks that the protocol is approved by sponsor and signed/dated by the study director
Protocol - Study

- Reviews the Protocol for but not limited to:
  - Descriptive title and purpose for the study
  - Identifies test, control, reference substances
  - Name address of sponsor and testing facility
  - Experimental start and termination dates
  - Justification for selection of test system
  - Identification of the test system
  - Experimental design and the control for bias
  - Type and frequency of tests and analyses to be made
  - Proposed statistical methods
  - Records to be maintained
Sample Receipt Records
Sample Receipt Records - Facility

QA can look at.....

- Storage Units
  - How are they monitored
    - Electronically or by hand recording
    - Is calibration of thermometers or thermocouples required? If so how often and where is this documented?
    - Who is responsible for the units
  - What happens if they go down
    - Is there a back up generator
    - Is the outage documented with corrective action? Where? When?
    - Did the outage effect the sample integrity? If so, was the study director notified?
Sample Receipt Records - Facility

- Adequate Separation
  - Is each individual study separate from one another? How?
  - Are test, control and reference substances separate from test systems
  - What precautions are in place to minimize cross contamination

- Proper identification
  - Labeling – identity, strength, purity or other characteristic present
  - Sponsor Identification on samples received
  - Is it necessary to put your own unique code on the samples
Sample Receipt Records - Facility

- Documentation of Receipt and Distribution of Test, Control, and Reference Substances
  - Was there a Certificate of Analysis identifying necessary information
  - MSDS
  - Shipping information
  - Does distribution include date and quantity removed? How are these records maintained?
  - Are these records archived
  - Reserve sample
Sample Receipt Records - Study

QA Reviews.....

- Chain of custody records
  - Do they agree with samples or TCRs outlined in the protocol
  - Is inventory complete and intact? If not was the study director notified or a deviation prepared
  - Where and how are they to be stored and did they maintain compliance during shipment
  - Do samples require further processing
Sample Receipt Records - Study

- Sample Processing
  - Is there authorization to further process the samples
  - Is there documentation as to how the samples were processed
  - What equipment was used and how is it kept clean
  - Are the areas established to minimize cross contamination
  - Is the personnel trained to perform this function and is it documented in their training file
Special Guest Appearance by

Glycine Max

or

“Max”
Laboratory
Laboratory - Facility

- Personnel
  - Have proper education, training and experience
  - Understand functions they are to perform
  - Current summary of their training and a CV
  - Training file up to date and maintained
  - Take necessary safety precautions while working in the lab
  - Organizational chart
Laboratory - Facility

- Laboratory
  - Separate laboratory space to perform routine or specialized procedures
  - Is the lab adequately sized to perform ongoing studies
  - Separate areas for storage of test systems, TCRs and reagents/solutions
  - Separate area for archival of data and specimens
  - Designed to maintain a degree of separation to minimize any adverse effect on a study
  - Is there a floor plan
Laboratory - Facility

- Resources/Materials
  - Sufficient number of personnel to conduct the study in a timely manner
  - Standard Operating Procedures
    - Easily accessible
    - Historically maintained
    - Authorized by TFM
    - Current version being used
Laboratory - Facility

- Resources/Materials
  - Reagents and Solutions
    - Obtained from reputable supplier
    - Labeled by identity, titer or concentration, storage, expiration date, who and when prepared
    - Where is the preparation information? Did it follow the method?
    - Are they expired
    - Adequate storage to keep separate and under appropriate conditions
    - Are MSDS or Certificate of Analysis easily available
Laboratory - Facility

- **Equipment**
  - Adequately inspected, maintained and cleaned
  - SOPs in place to outline schedules for maintenance/calibration and who is responsible for these actions
  - Written records of routine and non routine maintenance that are periodically archived. Where are these and are they archived?
  - Adequately maintained and available to perform the study

- **Methods**
  - Validating method prior to use
  - Independent Laboratory Validation
  - Published
Laboratory - Study

- QA inspects the study at intervals adequate to ensure the integrity of the study

  - In lab Phase Inspection
    - Watch technique of personnel and reviewing training files
    - Ensure method and protocol are followed or deviations documented and reported to Study director
    - Check for expired standards or solutions/labeled correctly
    - Review Maintenance files
    - Test system monitored according to protocol
Dana during her in-lab phase inspection
Laboratory - Study

- Data Generation
  - Recorded directly, promptly, legibly in ink
  - All entries dated/initialed by person entering data the day of occurrence
  - Changes made as not to obscure original entry, reason and initial/date of person making change are included
  - Reconstructable and complete
  - Automated systems identify individual responsible for direct data input
Laboratory - Study

- Reporting includes but not limited to:
  - Name and address of testing facility
  - Objectives/procedures in protocol including any changes to protocol
  - Statistical methods used to analyze data
  - Date initiated, completed, terminated or discontinued
  - TCR identified by name, strength, purity or other characteristics
  - Description of test system and how it was identified
  - Circumstances that effected quality or integrity of data
Laboratory - Study

• Reporting includes but not limited to:
  – Study director and personnel involved in the study
  – Description of methods
  – Description of transformation, calculations or operation and conclusions drawn from analysis
  – Location of specimens, raw data and final report
  – Signed QA page including dates of study inspections
  – Signed/dated by study director
  – Copy maintained by sponsor and testing facility
Archives
Archiving - Facility

QA Verifies….

- Separate area with limited access to only identified and authorized personnel
- Orderly and indexed for expedient retrieval of documents
- Able to minimize deterioration of records and/or specimens

- Examples of facility records archived:
  - Master Schedules and Organizational charts
  - Historical SOPs
  - Maintenance Files
  - Training and Personnel Records
  - QA records and reports
Archiving - Study

• What happens to data at the end of a Study?
  – All raw data, documents, records, protocols, specimens, and final report generated during the conduct of a study is archived
  – Transfer of these materials to archives is study director’s responsibility
  – Archives is identified in final report especially if off site archives are contracted

• The question is for how long?
Archiving - Study

- Records shall be maintained for the periods as follows:
  
  - Support an application for research or marketing that is approved by the EPA is for the duration the sponsor holds the permit
  
  - At least 5 years following the date the study was submitted to the EPA in support of an application for research or marketing
  
  - At least 2 years if not submitted to support an application
  
  - Specimens are maintained as long as they afford evaluation
    - QA must verify the disposal of specimens

IF YOU DON’T KNOW KEEP IT!!!!
and done!
QA Isn’t off the HOOK!!!!
Quality Assurance

- Who monitors QA...
  - TFM
  - Sponsor
  - EPA

- How is this done?
  - By periodically submitting to management and study director written status reports on each study noting problems and corrective action taken
  - Submitting facility audit reports to TFM noting any problems and corrective action taken for issues that apply solely to the facility
In Closing

- Suggestions for becoming a better auditor
  - Write SOPs outlining QA’s role and responsibilities at your facility
  - Attend training opportunities
  - Become a mentor or have someone mentor you
  - Get to know other QA representatives that you will be working with
  - Keep up to date with regulatory advisories, changes to the regulations, etc.
Arguing with QA is like mud wrestling with a pig: you get muddy and dirty and after a while you realize that the pig actually enjoys it.
A Better Way to Work with QA (chocolate also helps!)