Compliance Coordination: Contract Quality Assurance for GLP Test Sites

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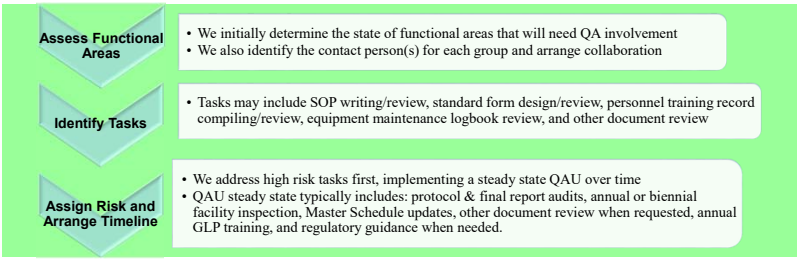
Abstract

Participation in complex studies by small, independent specialty contract research organizations or university laboratories is often needed to maximize testing capabilities on limited study samples. Contracting the quality assurance needs to a professional consultant group makes sense for these small facilities that may lack the physical space and the economic resources to employ a full-time QAU. These facilities may also lack a thorough understanding of GLP terminology and infrastructure. Coordinating off-site quality assurance support with internal procedures and processes requires skill and knowledge on both sides to ensure full regulatory controls over operations. This poster shares the fundamental strategy we employ to initiate a typical collaboration. In addition, we explain selected approaches to resolving various challenges that developed as some of our partnerships evolved.



QAU Oversight

IT
- Hardware/software inventory and management
- Maintenance records and problem reporting
- Access security and records
- Business continuity; backup power
- Backup/recovery including testing

Corporate
- Intellectual property / proprietary information policy or SOP
- Facility access security
- Disaster recovery
- Personnel safety
- SOP management
- Staff training

Shipping
- Samples and/or test material: receipt, storage, use, tracking, disposal chain of custody
- Return shipping
- Environmental monitoring of storage conditions
- Sample retention, when applicable

Lab Operations
- Assay and software validations
- Protocol & sample analysis
- Data collection, transfer, analysis
- Equipment maint. & calibration
- Reagent preparation, storage, expiry
- Report preparation
- Archive

QAU
- BSI SOPs & training records at site
- Master Schedule maintenance
- Provide site staff GLP training
- Implement protocol/report audits
- Annual/biennial facility audits
- Periodic process-based audits
- Provide ongoing guidance

We initially review SOPs that address the above topics and collaborate with the appropriate contact person to ensure that processes are sufficiently controlled. We verify that an over-arching SOP clearly describes roles and responsibilities and a contract describes our obligations as site QAU. BSI SOPs apply to QA audits, reporting, report distribution, and regulatory advising. Site SOPs describe frequency of facility inspections, process-based audits, and GLP training as well as the Master Schedule maintenance process. We maintain current inventories of documents on file at the test site. If our SOPs or staff training records are updated, the new versions are sent to the test sites and replace outdated versions. Site visits are required to perform facility inspections, conduct training, perform process-based or in-process phase audits, and host client visits to the site. Communication with management and the Principal Investigator is ongoing through email and conference calls. Protocols, study data, and final reports for each study are securely transferred to BSI for auditing. Audit reports are distributed, responses generated and verified, and closed as described in our BSI SOP.

Specific Challenges

In-Process Audits
Depending on the site, in-process audits can be not applicable (independent pathologists) or replaced by periodic process-based audits (highly repetitive or non-GLP analytical procedures) and the omission is noted in the Compliance Statement, when applicable.

Missing Protocol Amendments
Particular attention needs to be paid to test facility and test site interactions. For example, omission from the protocol amendment distribution list can result in incomplete test site study files and potential Master Schedule errors (if the Study Director is replaced).

University Site Models
Training is critical to ensure that: GLP concepts of Study Director, Principal Investigator, Test Facility/Site Management, and QAU are clearly understood; precedence of the study protocol over other procedures; how and why QA audits are conducted; and how to respond appropriately to audit report observations.