



Navigating the Global Regulated Environment: Advanced GLP Training for Managing Multi-Site Studies

Presented by: the Mid-Atlantic Region Society of Quality Assurance

Although the GLP regulations have remained the same, compliance has become more challenging due to the global nature of the industries governed by the regulations. This training will assist in identifying and developing solutions to global compliance issues and will include:

- A review of the roles and responsibilities outlined in: “OECD Principles on Good Laboratory Practice” (Number 1) and “The Application of the OECD Principles of GLP to the Organization and Management of Multi-site Studies” (Number 13)
- Planning and preparing for a multi-site study
- Challenges in study conduct and communication
- Data Management and Archiving
- Establishing Lead and Test Site QA roles
- Evaluating Part 11 compliance
- Inspection Readiness
- Utilizing non-OECD member facilities

This one day training will be offered on October 28, 2009, following the 2-day SQA Symposium: Global Regulatory Compliance Challenges.