Training Course Agenda

Quality and Compliance Management for Virtual Companies Training Course (PDA 211)

DAY 1

8:30 Welcome and Introduction

A. Introductions and participant expectations for the program
B. Fundamentals of Good Manufacturing Practice
    a. What is GMP?
    b. Purpose of GMP
    c. Basis in law: US, Europe, Canada
    d. Elements that apply to all virtual companies
    e. Elements that depend on how operations are conducted: How to tell what applies to your company
C. Data Integrity: What it is and why it is important to GMP
D. Postmarketing reporting – small molecule drugs vs biologic drugs (FDA requirements)
E. Pharmacovigilance – pre and postmarket – FDA and EMA differences
F. Regulatory and business risks: The case for compliance
G. Virtual company organizational structure and responsibility for QA/GMP
H. Virtual company quality system structure and management
    a. Policies, procedures, documentation management
    b. Metrics and management review considerations
I. Selection, qualification and monitoring of contractors
    a. Initial due diligence – public information sources to gage compliance
    b. Qualification of vendors
    c. Quality agreements – determining and documenting responsibilities for GMP
    d. Vendor audit program
J. Day One Q&A and recap of progress meeting stated course expectations

16:00 End of Day 1

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DAY 2

8:30 Recap Day 1 then Day 2 Content

A. Regulatory Inspections
   a. Purpose of an inspection
   b. Reasons for inspections
   c. Inspections at virtual company headquarters locations – purpose and scope
   d. Inspections at CMOs and Contract Labs
   e. GMP inspections versus Preapproval inspections – FDA
   f. EMA inspections – contrast with FDA
   g. Health Canada inspections

B. Logistics for managing inspections at your location
   a. Information sources about inspections on agency web sites: What you need and how to find it easily
   b. Preparation for inspections
   c. Overall process – ready room support
   d. Receiving and hosting the inspectors
   e. Providing documents
   f. Answering questions
   g. Interpersonal dos and don'ts for interacting with inspectors
   h. Managing the exit discussion at the conclusion of the inspection

C. Inspections at your contract organizations
   a. Making sure your CMO and contract lab are "PAI ready"
   b. Training employees to assure inspection readiness – pitfalls to make sure you avoid
   c. Conducting mock inspections effectively

D. Post-inspection communications with the inspecting agency
   a. How to write an effective response
   b. Common mistakes to avoid
   c. Following up to ensure the response is satisfactory
   d. When to request a meeting, and if granted, how best to handle it

E. Enforcement considerations
   a. FDA enforcement process – domestic and ex-US
   b. EMA enforcement
   c. Health Canada

F. Final Q&A, discussion, and conclusion

16:00 End of Event