Training Course Agenda

PDA 211.3 Quality and Compliance Management for Virtual Companies

DAY 1

8:30 Welcome and Introduction

A. Introductions and participant expectations for the program
B. Virtual company challenges, business risks of noncompliance
C. Introduction to FDA Law, Regulation and GXP Concepts
    a. Laws
    b. Regulations
    c. Guidance
    d. Impact of court precedents
D. Fundamentals of Good Manufacturing Practice
    a. Purpose of GMP
    b. Basis in law: US, international venues
    c. Elements that apply to all virtual companies
    d. Elements that depend on how operations are conducted: How to tell what applies to your company
E. Fundamentals of Good Clinical Practice
    a. Purpose of GCP
    b. Basis in law
    c. Sponsor obligations
    d. CRO role; selection and oversight of CROs
F. Data Integrity: What it is and why it is important to GMP
G. Postmarketing reporting – small molecule drugs vs biologic drugs (FDA requirements)
H. Pharmacovigilance – pre and postmarket – FDA and EMA differences
I. Virtual company quality system structure and management
    a. Policies, procedures, documentation management
    b. Management review considerations
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. 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
B. FDA Inspections Overview
   a. Purpose of an inspection
   b. FDA authority under law
   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. Mock inspections – points to consider
   g. FDA "Remote Regulatory Assessments" and "Remote Interactive Evaluations"
C. Logistics for managing inspections at your location
   a. Preparation for inspections
   b. Ready room support
   c. Receiving and hosting the inspectors – the "482" Notice of Inspection
   d. Providing documents
   e. Answering questions
   f. Interpersonal dos and don'ts for interacting with inspectors
   g. Managing the exit discussion at the conclusion of the inspection
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
E. FDA Enforcement options
   a. FDA enforcement process – domestic and ex-US companies
F. Final Q&A, discussion, and conclusion

12:00 End of Training Course