QUALITY AND COMPLIANCE MANAGEMENT FOR VIRTUAL COMPANIES

2 DAY VIRTUAL SEMINAR

Introduction

Running a pharmaceutical company is not easy, especially if you have an outsourcing model. There are multiple crucial steps for which you need to depend on contract manufacturers and researchers. Additionally, due to the majority of outsourced products, the team may lack quality assurance and GMP compliance.
To evolve from your current expertise and enter Phase 2 and 3 of clinical trials, it is essential to have a strong hold on pharmaceutical GMP compliance. This seminar consists of two days of rigorous training for professionals from virtual companies. You will learn all major requirements and expectations that are applicable to you and your team.

Course Overview

RAs a virtual company also, it is your responsibility to adhere to the guidelines laid by FDA, EMA, and Health Canada. However, the first step is to diagnose your company's requirements and pick industry best practices to be followed.
The pharma GMP compliance for virtual companies is not just limited to your own practices. It is essential to choose the right contractors after proper qualification testing and monitoring. In addition to strengthening your brand or business's value, this training will allow you to grow and expand in the coming months.

Who Will Benefit

- Quality Managers and Analysts: Gain ideas about managing product quality when the company transitions from an outsourcing model.
- Clinical Operations: Understand the requirements for a clinical product's approval in the market.
- ·Document Control Specialists: Learn the requirements of the FDA in terms of documents so that you can present them during the inspection.
- Regulatory Professionals: Supervise the overall function and perform internal audits effectively.

Know Your Faculty

Kelly Thomas, Vice President at America's Quality Operations, has 20 years of hands-on experience in the industry. She has worked with reputed facilities like FDA, EMEA, IMB, JP, and Health Canada. Her core expertise includes computer system validation, equipment process validation, and facilities validation. In addition, she will guide you on implementing a robust quality system, evaluating the KPIs of the facility, and executing high-quality management.

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Agenda Day 01

- Introductions and participant expectations for the program
- Fundamentals of Good Manufacturing Practice
- What is GMP?
- Purpose of GMP
- Basis in law: US, Europe, Canada
- Elements that apply to all virtual companies
- Elements that depend on how operations are conducted: How to tell what applies to your company

Data Integrity: What it is and why it is important to GMP

- Fundamentals of Good Clinical Practice (GCP)
- What is GCP?
- Purpose of GCP
- Basis in law: US, Europe, Canada
- Elements that apply to all virtual companies
- Elements that depend on how operations are conducted: How to tell what applies to your company

Regulatory and business risks: The case for compliance

- Virtual company organizational structure and responsibility for QA/GMP/GCP
- Virtual company quality system structure and management
- Policies, procedures, documentation management
- Metrics and management review considerations

Selection, qualification, and monitoring of contractors

- Initial due diligence – public information sources to gage compliance
- Qualification of vendors
- Quality agreements – determining and documenting responsibilities for GMP
- Vendor audit program
- Day One Q&A and recap of progress meeting stated course expectations

Agenda Day 02

- Regulatory Inspections
- Purpose of an inspection
- Reasons for inspections
- Inspections at virtual company headquarters locations – purpose and scope
- Inspections at CMOs and Contract Labs
- GMP inspections versus Preapproval inspections – FDA
- GCP inspections of sponsors of clinical trials
- EMA inspections – contrast with FDA
- Health Canada inspections

Logistics for managing inspections at your location

- Information sources about inspections on agency websites: What you need and how to find it easily
- Preparation for inspections
- Overall process – ready room support
- Receiving and hosting the inspectors
- Providing documents
- Answering questions
- Interpersonal dos and don’ts for interacting with inspectors
- Managing the exit discussion at the conclusion of the inspection

Inspections at your contract organizations

- Make sure your CMO and contract lab are “PAI ready”
- Training employees to assure inspection readiness – pitfalls to make sure you avoid
- Conducting mock inspections effectively

Post-inspection communications with the inspecting agency

- How to write an effective response
- Common mistakes to avoid
- Following up to ensure the response is satisfactory
- When to request a meeting, and if granted, how best to handle it

Enforcement considerations

- FDA enforcement process – domestic and ex-US
- EMA enforcement
- Health Canada
- Final Q&A, discussion, and conclusion

Quality and Compliance Management for Virtual Companies

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Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
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