Effective Quality Oversight of Pharmaceutical Contract Manufacturing Organizations (CMOs): One and a Half day In-Person Seminar

Description: The globalization of the pharmaceutical supply chain has led increased use of Contract Manufacturing Organizations (CMOs). The use of CMOs provides many benefits; however, it can present unique compliance risks, particularly since the operations are not in your facility and therefore not under your direct control. The compliance risks are highlighted by FDA Warning Letter trends, the majority of which are related to serious compliance and data integrity issues at foreign CMO sites.

If you use CMOs, your company has the ultimate responsibility for product quality, safety, efficacy, and cGMP compliance. Furthermore, FDA has clearly stated that organizations using CMOs will be held accountable for CMO compliance to cGMPs, as well as adherence to regulatory commitments. Therefore, issues identified at your CMO may result in FDA 483s and/or Warning Letters issued to your company. Since FDA is holding firms using CMOs responsible, it is imperative that your organization have a robust CMO management system. At the end of the day, your organization’s ability to provide proper quality oversight of CMOs is the key to assuring product safety and your company’s compliance profile.

This seminar will help all personnel responsible for CMO oversight understand how to manage CMOs - from start to finish. In-depth focus will be placed on Selection and Qualification, Quality Agreements, Understanding of CMO Operations, and Review of Key CMO Records. Considerations for different types of manufacturing will be highlighted, and techniques for managing difficult CMO situations will be discussed. This is a practical how-to course, designed to provide participants with skills they can immediately apply to CMO oversight within their own organizations. Group exercises will allow participants to practice skill sets with feedback from the instructor.

Learning Objectives:

Upon completing this course, participants should be able to:

- Understand the CMO business model
- Learn the regulatory requirements for CMO quality oversight
- Learn how to structure your organization for effective CMO oversight
- Learn key points for selecting and qualifying CMOs
- Learn how to prepare for and conduct CMO Qualification Audits
- Learn how to develop a Quality Agreement and how to execute it
- Learn how to understand CMO operations
- Learn key points for reviewing CMO records
- Learn how to resolve issues identified in CMO records
- Learn how to prepare for and conduct routine CMO audits
- Learn how to manage CMOs on an ongoing basis


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