Quality Oversight of Pharmaceutical Contract Manufacturing Organizations - Recorded Webinar

Description: If you use pharmaceutical Contract Manufacturing Organizations (CMOs), your company has ultimate responsibility and accountability for product quality, safety, and efficacy; as well as cGMP compliance. Furthermore, FDA has stated that organizations using CMOs will be held accountable for CMO compliance to cGMPs, as well as CMO adherence to the contracting firm’s regulatory commitments. Therefore, issues identified at your CMO may result in FDA 483s and/or Warning Letters issued to your company. In other words, you cannot just outsource operations and forget about it. You must select the proper CMOs and actively manage the operations performed on your behalf. 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.

Objectives of the Presentation:
- Learn basic regulatory requirements for CMO quality oversight
- Learn key points for selecting and qualifying CMOs
- Learn key parts of a Quality Agreement and how to enforce it
- Learn how to fully understand your CMOs operations and compliance profile
- Learn what to look for when reviewing key CMO records
- Learn how to resolve issues identified in CMO records
- Learn how to manage CMOs on an ongoing basis, including periodic audits

Why Should you Attend:
This webinar will help all personnel involved in utilizing CMOs understand how to manage their CMO program from start to finish. This includes selection and qualification, review of CMO records, and routine audits. Key focus will be placed on the Quality Agreement, CMO Batch Records, CMO Change Controls, and CMO Deviations / CAPA. The importance of actively managing your CMO partnership will also be discussed.

Who can Benefit:
- Quality Assurance Management
- Contract Manufacturing Management
- Pharmaceutical / Chemistry Development Management
- Quality Control Laboratory Management

Topic Background:
The increasing globalization of the pharmaceutical supply chain has led to an increase in the use of Contract Manufacturing Organizations (CMOs). The use of CMOs provides many benefits; however, it can present certain 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 Letters from 2014, the majority of which were related to serious compliance and data integrity issues at foreign CMO sites. Since FDA is also holding firms using CMOs responsible for CMO non-compliance, it is imperative that a robust CMO management system be in place at your organization.

Contents: In accordance with regulatory obligations, there are strict procedures in place to minimize the risk that could be used for money laundering purposes including:
- Regulatory Requirements for CMO Oversight
- Selection and Qualification of CMOs
- The Quality Agreement
- How well do you know your CMO?
- Review of Key CMO Records
- Batch Records
- Change Control
- Deviation Investigations / CAPA
- OOS Investigations
- CMO Management & Periodic Audits

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