# ComplianceOnline Hosts Seminar on Effective Quality Oversight of Pharmaceutical Contract Manufacturing Organizations

*"Effective Quality Oversight of Pharmaceutical Contract Manufacturing Organizations (CMOs)" Seminar has been added to ComplianceOnline.com's offering.*


SAN JOSE, CA, UNITED STATES, March 24, 2021 /EINPresswire.com/ -- ComplianceOnline, the largest GRC advisory network, announces a seminar to continue educating all personnel responsible for CMO oversight understand how to ensure effective quality oversight of CMOs- from start to finish. The seminar will be presented by Andrew Campbell, Pharmaceutical Consultant - Quality & Compliance, and will be held on April 13-14, 2021 (7:30 AM to 1:30 PM PDT).

The globalization of the pharmaceutical supply chain has resulted in the increased use of Contract Manufacturing Organizations (CMOs). The use of CMOs provides many benefits; however, it also presents unique compliance risks, particularly since operations are not under your direct control. Compliance risks are highlighted by FDA Warning Letter trends, the majority of which are related to serious cGMP compliance and data integrity issues at foreign CMO sites. Companies using CMOs are fully responsible for product quality, safety, efficacy, and cGMP compliance. Furthermore, FDA has clearly stated that firms using CMOs will be held accountable for CMO compliance to cGMPs, as well as for CMO adherence to Sponsor regulatory commitments. Issues identified at your CMO may result in FDA 483s and/or Warning Letters issued to your firm. Therefore, it is imperative that organizations have a robust CMO management system. At the end of the day, their ability to provide proper quality oversight of CMOs is the key to assuring product safety and safeguarding their firm's compliance profile.

The seminar will provide In-depth on Selection and Qualification, CMO Audits, Quality Agreements, Oversight 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 addressed. Techniques for assuring robust CMO Oversight programs in light of COVID-19 restrictions will also 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. Case studies will allow participants to practice skill sets in cooperation with the instructor.

Learning Objectives:

Upon completing this course, participants should be able to:
- Understand the CMO business model
- Understand the regulatory requirements for CMO quality oversight
- Understand how to structure your organization for effective CMO oversight
- Understand key points for selecting and qualifying CMOs
- Know how to prepare for and conduct CMO Audits
- Know how to develop a Quality Agreement and how to execute it
- Understand key points for reviewing CMO records
- Know how to resolve issues identified in CMO records
- Know how to manage CMOs on an ongoing basis

Who will Benefit:

This course is designed for people tasked with oversight of these CMO functions:

- Manufacturing operations
- Quality Control operations
- Quality Assurance operations

The following personnel will benefit from the course:

- Pharmaceutical Development
- Quality Control
- Validation
- Regulatory Affairs
- Quality Assurance
- Project Management

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: April 13-14, 2021 (7:30 AM to 1:30 PM PDT)

About the Speaker:

Andrew Campbell has 25 years of pharmaceutical quality assurance and quality systems experience in both industry and consulting roles. Mr. Campbell has worked in clinical supply and commercial manufacturing environments, and has experience with integrated manufacturing and contract manufacturing business models. He has extensive expertise in the areas of deviation - CAPA, change control, GMP auditing, GMP training, and regulatory inspection preparation and management.

Working with large and small companies, Mr. Campbell has successfully developed, remediated and implemented key quality systems. He is a skilled GMP auditor, and has audited multiple API, drug product, packaging, testing, and distribution facilities. He is an experienced GMP trainer, and has developed customized and interactive training presentations for many companies. He has also provided FDA inspection support for several clients, including readiness training, on-site assistance during inspections, and authoring written responses to inspectional observations. Prior to becoming a consultant in 2007, Mr. Campbell worked for Ligand Pharmaceuticals as director of quality systems.

About ComplianceOnline.com:

ComplianceOnline is a leading provider of regulatory compliance training programs for companies and professionals in regulated industries. ComplianceOnline has successfully trained over 55,000 professionals from 15,000 companies to comply with the requirements of regulatory agencies. ComplianceOnline is headquartered in Palo Alto, California, and can be reached at http://www.complianceonline.com. ComplianceOnline is a MetricStream portal. MetricStream (www.metricstream.com) is a market leader in Enterprise-wide Governance, Risk, Compliance (GRC), and Quality Management Solutions for global corporations.

For more information on ComplianceOnline or to browse through our training programs, please visit our website

Priyabrata Sahoo
ComplianceOnline
+ +1-888-717-2436
email us here
Visit us on social media:
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