ComplianceOnine Hosts Seminar on Change Control Best Practices for Pharmaceutical, Biologics & Medical Device Companies

"Change Control Best Practices - Avoiding Unintended Consequences of Changes" Seminar has been added to ComplianceOnline.com's offering.

Change Control Best Practices - Avoiding Unintended Consequences of Changes

SAN JOSE, CA, UNITED STATES, April 26, 2021 /EINPresswire.com/ -- ComplianceOnline, the world's leading provider of training for regulated companies recently announced its upcoming 2-day virtual seminar entitled 'Change Control Best Practices - Avoiding Unintended Consequences of Changes.' The seminar taking place from May 18-19, 2021 will be presented by Andrew Campbell, Pharmaceutical Consultant - Quality & Compliance.

One of the top 10 FDA 483 and Warning Letter citations is for inadequate change control. Change control receives detailed scrutiny during FDA inspections, and FDA reviews change control documentation to determine that changes did not adversely impact products, processes, equipment, facilities, etc. A single inadequate change may lead to significant negative events, including the release of a sub-standard product or product recall. A pattern of inadequate changes may require costly and time-consuming system remediation efforts.

It is therefore critically important to assure that changes are properly described, justified, assessed for risk, implemented, and documented. Changes must also be prospectively reviewed by appropriate subject matter experts. Furthermore, certain major changes (e.g. manufacturing, specifications) may require regulatory filings and/or prior regulatory approval.

This seminar will help all personnel involved in proposing, assessing, and implementing changes to understand and successfully apply Change Control best practices. Key focus will be placed on

change proposals, justification/risk assessment, and change execution/implementation. The importance of proper planning, critical thinking skills, and coordination of all change activities will also be discussed. Techniques for assuring robust Change Control 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 change controls within their own organizations. Case studies will allow participants to practice skill sets in cooperation with the instructor.

This course is designed from a pharmaceutical manufacturing perspective; however, since the main focus is on techniques and practices, the course material may be equally applied to biologics and medical device environments. Please note that this seminar focuses on changes to equipment, facilities, materials/components, test methods, suppliers, specifications, etc. Document Change Control is discussed as a supporting element; however, it is not the main focus.

Learning Objectives:

Upon completing this course, participants should be able to:
- Understand the purpose of change control
- Understand regulatory requirements and FDA expectations for change control
- Identify what types of changes are /are not subject to change control
- Properly describe changes
- Properly justify changes
- Develop a comprehensive Change Execution Plan
- Conduct a proper change Risk Assessment
- Ensure proper execution of changes
- Ensure proper implementation of changes
- Develop a complete Change Control documentation package
- Utilize critical thinking skills throughout the change control process
- Avoid pitfalls during the change control process

Who will Benefit:

This course is designed for people tasked with:
- Authoring change proposals
- Assessing / approving change proposals
- Executing / implementing changes

The following personnel will benefit from the course:
- Change proposal authors
- Reviewers / approvers of change controls
- Change control system owners

- Production staff / management
- Engineering staff / management
- Validation staff /management
- QC staff / management
- Regulatory Affairs staff / management
- QA staff / management

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: May 17-18, 2021 (8:00 AM to 2:00 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

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