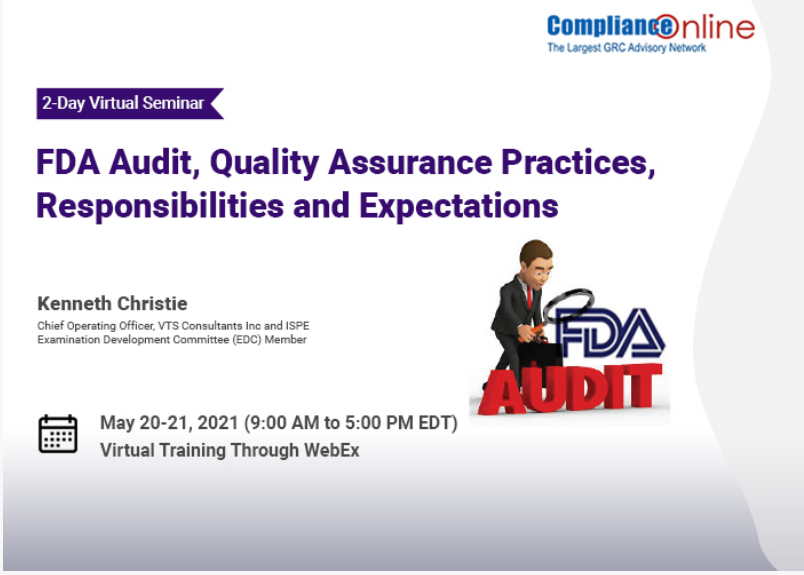
ComplianceOnline Hosts 'FDA Audit, QA Practices, Responsibilities and Expectations' Seminar for FDA Regulated Companies

"FDA Audit, Quality Assurance Practices, Responsibilities and Expectations" Seminar has been added to ComplianceOnline.com's offering.



FDA Audit, Quality Assurance Practices, Responsibilities and Expectations

SAN JOSE, CA, UNITED STATES, May 5, 2021 /EINPresswire.com/ -- ComplianceOnline, the world's leading provider of regulatory training for regulated companies is holding a 2-day virtual seminar entitled 'FDA Audit, Quality Assurance Practices, Responsibilities, and Expectations' on May 20-21, 2021. The seminar will be presented by Kenneth Christie, Chief Operating Officer, VTS Consultants Inc, and ISPE Examination Development Committee (EDC) Member.

It is no surprise to anyone who reviews regulatory citations to notice the number of deficiencies cited that are associated with quality systems. Today, the basis for all FDA audits both within the US and internationally is based on the quality systems approach and the six systems that comprise it. Whether the audit is a full or partial audit, the quality system within a company will always be inspected and this seminar will help review what are the expectations and the common areas to be familiar with. As a basis for regulatory audits, the quality system, its procedures and their implementation are reviewed to help verify the level of effectiveness in assuring consistent control and quality of materials, components and final product.

This training will examine the differences between Quality Assurance and Quality Control and the responsibilities of each. In addition, attendees will discuss what characteristics quality personnel should possess. The current expectations for an effective quality system program as defined in both the FDA and EU requirements and guidance documents will be reviewed. Topics to be covered will range from the development of a quality manual and procedures, the

importance and scope of audits (internal, vendor, third party and regulatory) along with review of various case studies to help further illustrate points discussed.

The quality department within companies is responsible for nearly all activities to various degrees that have impact on the quality, safety or efficacy of the final product or material produced. It is also responsible for helping assure that contracted services, which is more common today than ever before, are also verified to meet the quality standards set both by the company and the regulatory requirements. The training will review special topics of interest to auditors such as CAPA programs and investigations that address deviations and out of specification (OOS) results. Attendees will be given ample opportunity to ask questions, discuss actual case studies and to learn about the vast scope of responsibility that the quality system regulations expect and the roles of their own positions.

Learning Objectives:

Upon completing this course participants should:
• Understand the regulatory expectations of the quality unit and its role in the Quality System Requirements (QSR)
• Review the Quality areas that are the point of focus during regulatory, corporate or third party audits.
• Review typical checklist that can be used as a template for the performance of audits
• Evaluate the importance of training, its documentation, and common concerns being raised over "operator error"
• Review the importance and regulatory guidance offered for the investigation of deviations/out-of-specification results.
• Review the current focus on data integrity issues and the current guidance document regarding it
• Review the top 10 most commonly cited drug GMP deficiencies for 2019-2020
• Understand the weaknesses of each person's current quality system and discuss possible recommended corrective actions

Who will Benefit:

This course is designed for people within the quality unit, those impacted by quality requirements, third party suppliers who are evaluated against quality issues and their adherence to them, along corporate management who is required to provide the time and resources to correct quality issues identified. This includes individuals that have Quality Management Systems responsibilities for making general improvements in their organization's performance. Following personnel will benefit from the course:
• Senior quality managers
• Quality professionals
• Regulatory professionals
• Compliance professionals

- Production supervisors
- Manufacturing engineers
- Production engineers
- Design engineers
- Process owners
- Quality engineers
- Quality auditors
- Document control specialists

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: May 20-21, 2021 (9:00 AM to 5:00 PM EDT)

About the Speaker:
Kenneth Christie has over 30 years of sterile manufacturing and regulatory GMP consulting experience in the areas of quality assurance and validation management in the pharmaceutical and biotechnology industries. Mr. Christie is currently the chief operating officer for VTS Consultants, Inc., located in Amherst, MA. His responsibilities specifically include quality system auditing, GMP training, and serving as a subject matter expert for aseptic manufacturing processes, medical devices, APIs and solid dosage processing equipment, utilities, and systems on a global basis. He also performs vendor audits, site pre-approval inspections and assists clients with addressing and correcting regulatory observations.

Mr. Christie was the validation manager at Parke-Davis' Sterile Products Facility where he was involved in the review and approval of all facilities, equipment, and system commissioning/qualification activities. He had routine interaction with the FDA and European inspectors (EMEA), corporate management and third party contract-manufacturing representatives to defend validation practices and to assure regulatory compliance for the manufacture of aseptically produced products.

Mr. Christie is a speaker and trainer for several professional organizations in the US, Canada, Europe, and Asia and is a published author of several articles dealing with the challenges of aseptic processing. Additionally, he serves as a member of the ISPE's Professional Certification (PCC) Commission as an Examination Development Committee (EDC) member.

Mr. Christie has a BS degree in biology from Shippensburg State University (PA) and an executive MBA degree from Michigan State.

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.

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