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Seminar on

The Responsibilities of the Quality Department…From Approval to Rejection and Everything In-Between!

Date : May -28-29-2020

Learning Objectives

The quality department within companies is responsible for nearly all activities to various degrees that have an 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 are more common today than ever before, are also verified to meet the quality standards set both by the company and the regulatory requirements. The seminar will also 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.

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It is no surprise to anyone who reviews regulatory citations to notice the number of deficiencies cited that are associated with the quality systems implementation.

PRESENTED BY:

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.

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Date : May-28-29-2020

Time : 08 : 30 AM EST to 04 : 30 PM EST

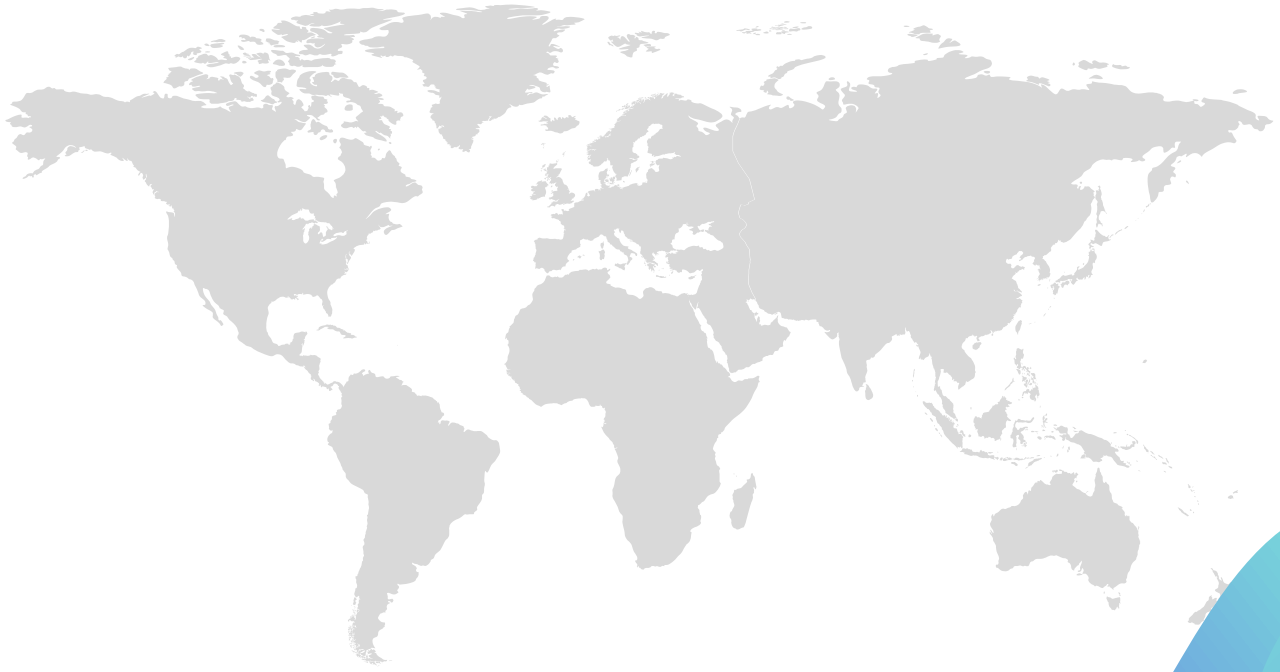
Price: $1,299.00

Seminar Description

It is no surprise to anyone who reviews regulatory citations to notice the number of deficiencies cited that are associated with the quality systems implementation. Almost every year, the top-cited deficiencies for drug manufacturers or medical device companies tend to include the lack of procedures dealing with the responsibilities of the quality unit or procedures themselves not being followed. 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 two-day 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 its implementation are reviewed to help verify the level of effectiveness in assuring consistent control and quality of materials, components, and final product.

Who Should Attend ?

Quality unit personnel (QA and QC)
Upper Management
Vendors/Suppliers
Manufacturing
Production
Engineering



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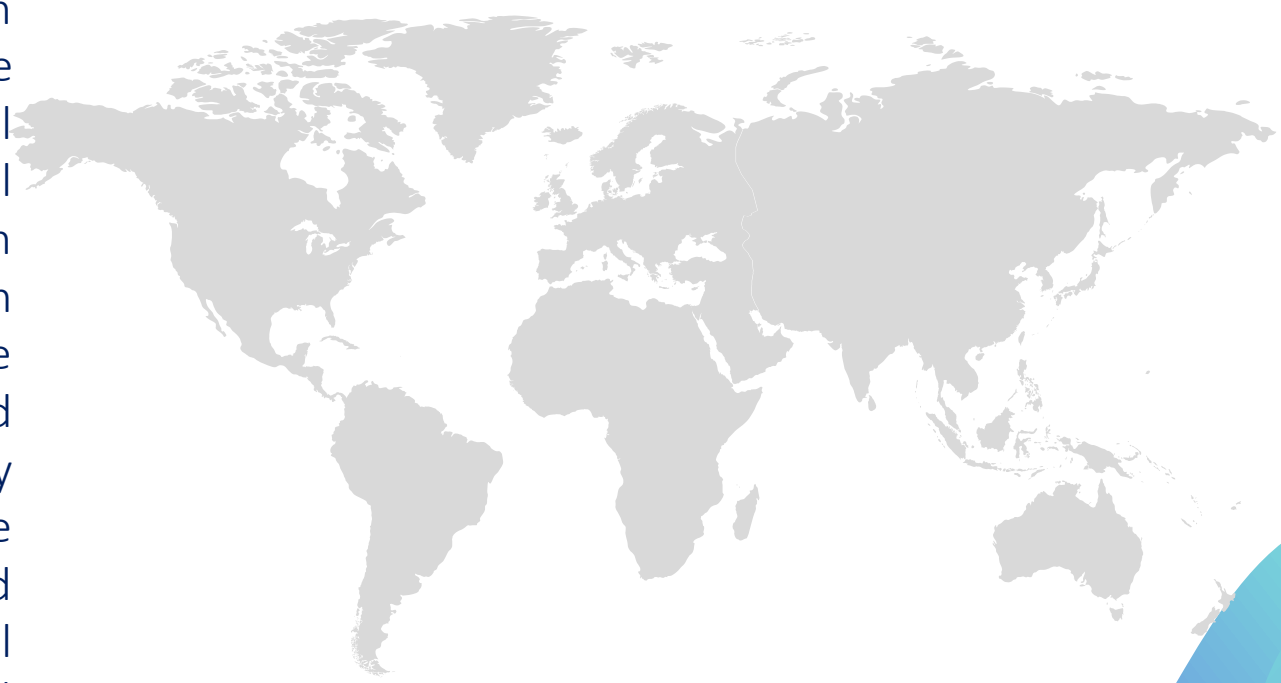
Why Should You Attend ?

This seminar 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), the review and approval of all controlled documents along with a review of actual case studies to help further illustrate points discussed. Audit checklists will be provided and discussed in terms of what issues should be avoided and how best to address observations made.



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Agenda – Day 1

REGISTRATIONS AND BREAKFAST - 8:30 AM TO 8:45 AM

SPEAKER AND PARTICIPANT INTRODUCTIONS - 8:45 AM TO 9:00 AM

SESSION ONE - 9:00 AM TO 10:00 AM

AREAS COVERED - Quality System Regulations

✓ Review of Regulatory requirements for the quality organization within companies. Will examine the current FDA (21 CFR parts 210-211 and 820), EU and Health Canada requirements.

BREAK - 10:00 AM TO 10:15 AM

SESSION TWO - 10:15 AM to 12:00 PM

AREAS COVERED - Quality System Requirements for Audits

✓ Discuss the importance of audits as a means of assuring compliance and the ability of the Quality System to meet its responsibilities

✓Review the current FDA approach to audits and expectations of the quality system unit

LUNCH - 12:00 PM TO 1:00 PM

SESSION THREE - 1:00 PM to 3:00 PM

AREAS COVERED - Importance of Audits

✓ Review the importance of internal and vendor audits and provide a checklist of items to be covered and reviewed. Discuss expectations for applicable procedures covering these topics

BREAK - 3:00 PM TO 3:15 PM

SESSION FOUR- 3:15 PM to 4:15 PM

AREAS COVERED - Auditing Preparation

Discuss audit techniques that will help assure successful results when preparing for audits. Review an audit checklist

FINAL QUESTIONS / COMMENTS - 4:15 PM TO 4:30 PM

Agenda – Day 2

BREAKFAST - 8:30 AM TO 9:00 AM

SESSION FIVE- 9:00 AM TO 10:00 AM

AREAS COVERED - Handling Out-of-Specification Results (OOS)

✓ Review current industry guidelines for the investigation of “Out-of-Specification” (OOS) laboratory results

BREAK - 10:00 AM TO 10:15 AM

SESSION SIX - 10:15 AM to 12:00 PM

AREAS COVERED - Operator Error for Deviations

✓Discuss current concerns by FDA and EU auditors regarding “operator error” when listed as the “root cause” for deviation investigations

Discuss the importance of the CAPA process and change control programs that help maintain compliance and prevent occurrences of deviations

LUNCH - 12:00 PM TO 1:00 PM

SESSION SEVEN- 1:00 PM to 3:00 PM

AREAS COVERED

✓ Review the importance and requirements for vendor evaluations and quality agreements; what to look for, what to be included, etc.

✓Discuss actual case studies as to actions taken by vendors and their potential impact on component, service or product quality

BREAK - 3:00 PM TO 3:15 PM

SESSION EIGHT- 3:15 PM to 4:15 PM

AREAS COVERED - Most Commonly Cited Drug Manufacturing Deficiencies

✓ Review the 10 most common GMP deficiencies for drug manufacturers cited by the FDA during 2018-2019

FINAL QUESTIONS / COMMENTS - 4:15 PM TO 4:30 PM

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To register please visit:

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