

CATD Webinars

Microbiology Series

Quality System for QC Microbiology Lab

Registration Fee: £185

Date: April 15, 2010

Course Duration: 90 min. 2:00pm-3:30pm GMT (London Time)

Key Topics & Agenda

The Quality Control (QC) laboratories play a critical role in pharmaceutical manufacturing. The primary function of the QC group is data generation. QC analysts are responsible for the testing and release of raw materials to the manufacturing group, testing of in-process, release and stability product samples as well as support testing for validation activities such as equipment cleaning and change-over activities. The microbiology QC group usually has the additional responsibility of performing environmental monitoring (EM) and testing clean utilities. All data generated must be reliable and accurate since they confirm the quality, safety, identity, and efficacy of drug products manufactured. Therefore, QC laboratories must operate in a *state of control* to provide assurance of continued process performance and product quality. In this presentation, the author will discuss how to implement a quality system for a QC microbiology laboratory that ensures compliance with current GMP requirements and regulatory expectations.

Training Objectives

- Describe the role of the Quality Control Unit in pharmaceutical manufacturing
- Review the FDA Quality System Inspection Technique
- Explain the steps for implementing quality systems in a cGMP environment
- Identify key elements in a quality system for the QC microbiology laboratory
- Discuss *Hot Topics* for the QC micro lab operations
- Review recent regulatory citations

Faculty

Ms. Lucia Clontz, M.Sc.

Ms. Lucia Clontz is an expert microbiologist who works for Diosynth Biotechnology, a part of Merck. For more than 20 years, Lucia has managed numerous validation projects, established quality systems for microbiology laboratories, and participated in compliance audits. Lucia has BS degrees in Chemistry, minor in Chemical Engineering,

and in Marine Sciences. Lucia also holds a Masters of Science degree in Microbial Biotechnology and a Graduate Certificate in Molecular Biotechnology from the North Carolina State University. Lucia is currently enrolled in a doctoral program in Health Sciences. Lucia, a published author, has lectured many courses in the U.S. and abroad, is co-founder of the Biofilm Networking Group and a member of the USP Pharmaceutical Waters Expert Committee.

Registration

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