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Webinar on

Contamination Controls For Non-Sterile Drug Product Manufacturing Facilities

Learning Objectives

At the end of this training module, the participants should be able to

Identify the current key regulatory and industry sources driving non-sterile drug contamination control programs

Understand the 3 industry-based contamination control strategies, their origins, and differences

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This webinar is intended as an introductory overview of current industry best practices for minimizing the risk of non-sterile drug product contamination during the manufacturing process.

PRESENTED BY:

Carl Patterson is a seasoned Pharmaceutical Manufacturing, Aseptic Processing, and Quality Assurance Professional who is based in San Diego, California. As soon as he discovered the importance of biotechnology in the area, he was inspired to enter the pharmaceutical manufacturing industry.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

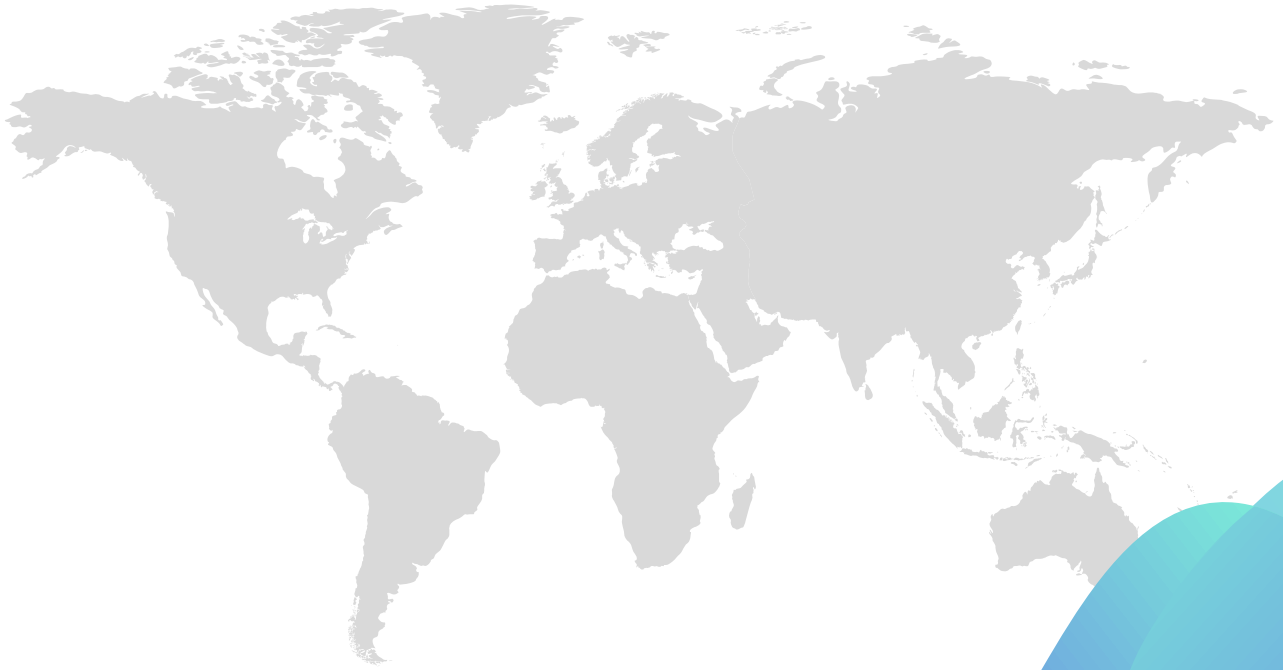
Webinar Description

This presentation is intended as an introductory overview of current industry best practices for minimizing the risk of non-sterile drug product contamination during the manufacturing process. A brief overview of the primary regulatory requirements and industry standards will be presented, (FDA, EU, ISO, ICH, USP, PDA, USP), followed by presentation and analysis of 3 differing approaches for contamination control, as derived from FDA, ISO, and USP.

Until recently, microbiological control strategies for non-sterile and sterile drugs alike have remained static, despite major technological and regulatory changes in the pharmaceutical industry. Compendial methods and limits have essentially been harmonized during the last 20 years, and there is now an array of rapid and real-time measurement technologies available to the QC microbiologist. However, today's strategies for collecting and using microbiological data to demonstrate the state of bioburden control vary by industry and regulatory source. Additionally, these strategies are not fully aligned with the practical interests of the pharmaceutical industry, namely cost, time, and value. This training module discusses 3 of the primary microbiological control strategies for establishing and demonstrating appropriate contamination controls for non-sterile drug products and explains their origins and the differences between them.

Who Should Attend ?

This introductory-level course is designed for beginning and junior QC microbiologists, as well as non-microbiologist technical practitioners, such as engineering and operations staff involved in manufacturing, facility, and utility support and process design.



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