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EVENTS LIST

Regulatory Requirements and Principles for Cleaning Validation

Date : Mar 08, 2018 - 09:00 AM - Mar 09, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/regulatory-requirements-and-principles-for-cleaning-validation-mar-2018

Organizer : GlobalCompliancePanel

Venue : Hilton Zurich Airport

Location : 1 Main St,
Los Angeles, CA, US, ZIP: 00000

This 2 day course will cover practical guidance on cleaning validation regulatory compliance, in conjunction with, risk-based, reasonable and informed decision making and activity planning. This two day interactive course will cover fundamental principles of a cleaning validation program, exploring such concepts as the determination of residues to be targeted, selection of analytical and sampling methods, determination of appropriate limits in various pharmaceutical and biotechnology processes, and establishment of scientific rationales acceptable to regulatory inspectors.

The program will describe the requirements for establishing an effective cleaning validation program, including the development of a general policy, a "Cleaning Validation Master Plan" and the appropriate documentation for each study to be performed. In addition, requirements for maintenance of the validated status will be reviewed. Regulatory requirements and the latest industry practices will also be included in the discussion.

Why you should attend:

Attendance at 2 day seminar will be beneficial to personnel directly involved in the development of cleaning procedures, cleaning validation programs and plans. Additionally, those responsible for cleaning validation protocols and execution activities, including validation and laboratory personnel, as well as, beginning or seasoned operational personnel who will eventually participate in such efforts, will find this course particularly useful. This includes Analytical Method Development, Quality Control and Quality Assurance personnel.

Individuals in management who interact with the above or communicate with regulatory agency inspectors to rationalize or defend cleaning validation programs will also benefit from attending this course. There are no prerequisites for attending, but a basic knowledge of general science and equipment cleaning processes is helpful.

Areas Covered in the Session:

- Understand the importance and underlying principles of cleaning validation and the requirements to have adequate cleaning procedures for manufacturing equipment in contact with the product
- Understand the FDA perspectives on cleaning validation and areas of concern during regulatory inspections
- Be able to set up cleaning validation procedures, protocols and reports that meet current FDA, WHO, PIC/S and EU regulations
- Prepare and defend your own cleaning validation approach/program and avoid costly delays and/or rejections by regulatory agencies

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Who Will Benefit:

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- Senior Quality Managers
- Quality Professionals
- Production Supervisors
- Validation Engineers
- Process Owners
- Quality Engineers
- Quality Auditors

Day 1 Schedule

Lecture 1:

FDA Requirements and Industry Standard Practices

Lecture 2:

How to Develop/Review your Cleaning Procedures and the Adequate Selection of Cleaning Agents and Parameters

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Lecture 3:

How to Develop a Cleaning Validation Policy/Program

Lecture 4:

How to Implement a Robust Cleaning Validation Plan

Day 2 Schedule

Lecture 1:

Laboratory Issues in Cleaning

Lecture 2:

Microbiological aspects of a cleaning validation program for manufacturing equipment

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Lecture 3:

Keys to Cleaning Validation Maintenance - Remaining Compliant

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Lecture 4:

Current FDA concerns about validation of cleaning processes

Joy McElroy

Principle Consultant, Maynard Consulting Company

Upon earning a degree in Zoology at North Carolina State University, Joy made her debut in the pharmaceutical industry in 1992 at Pharmacia & Up John performing Environmental Monitoring and Sterility Testing. Her hard work allowed her to move into a supervisory role at Abbott Laboratories where she oversaw their Quality Control Lab.

Now with 12 years experience as a consultant, and over 20 years total experience in the pharmaceutical and biotech industries, Joy has gained extensive knowledge of Quality Assurance, Process and Cleaning Validation, and Equipment Qualification. She has written and executed Equipment Qualification and Validation Protocols for numerous Companies such as Mallinckrodt, Wyeth Lederle, Merck, BioMerieux, Catalent, Phillips Medisize, Xcelience, and Novartis.

Joy specializes in Equipment Qualification, Cleaning Validation,Sterilization, Environmental Monitoring, and GMP Compliance Auditing.

Please contact Marilyn Turner: Phone: +1 929 900 1853 Email: marilyn.turner [a] nyeventslist.com for registrations

Event Categories :