Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Regulatory Requirements and Principles for Cleaning Validation

San Diego, CA

March 9th & 10th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees:

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

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.

Overview :

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

Agenda:

Day One

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

Lecture 3: How to Develop a Cleaning Validation Policy/Program

Lecture 4: How to Implement a Robust Cleaning Validation Plan

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

Day Two

Lecture 1: Laboratory Issues in Cleaning

Lecture 2: Microbiological aspects of a cleaning validation program for manufacturing equipment

Lecture 3: Keys to Cleaning Validation Maintenance - Remaining Compliant

Lecture 4: Current FDA concerns about validation of cleaning processes

Who Will Benefit:

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.

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

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Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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