



Cleaning Validation – Best Practices Course & Workshop

*New Regulatory Expectation & Standards
(Includes 3 Case Studies)*

Registration Fee: £865

Date: March 25-26, 2010

Course Description

A two day program for technical and managerial staff seeking better decision making and more solid justifications regarding the Cleaning Validation (CV) programme as well as more sensible and productive execution of the Cleaning Validation (CV) Plan.

The program is organized around 4 areas where common industry practice and conventional wisdom is not necessarily best practice or even justified practice for some firms:

1. *Beyond MACO (1/000 dose and 10 ppm)- Better practices for risk assessment and justification of cleaning targets and residue limits.*
2. *Beyond SOPs-Better process understanding with parametric description and control of the cleaning process*
3. *Beyond Swabbing and HPLC- Better practices for inspection and measurement of cleanliness*
4. *Beyond "3"- The CV program as a foundation for ongoing process improvement (as a "journey, rather than a destination")*

Conventional cleaning validation practices in these four key areas will be critically evaluated against new regulatory expectations and standards defining cGMPs in light of PAT and Quality Systems concepts.

In addition to presentation of concepts, actual industry examples and references, this will involve a true workshop format with some small group activities and some hands-on work to illustrate issues with current practices or demonstrate better practices. Participant teams will evaluate, weigh alternatives, do calculations and make plans and recommendations. Teams will be provided with spreadsheets and tools they can take with them. You are encouraged to bring a cleaning scenario or problem to the workshop.

You will leave with better rationale, better evaluation and audit approach and better fundamental understanding of underlying residue removal and residue measurement practices and parameters.



Key Topics & Agenda

Day 1-AM

Beyond MACO (1/000 dose and 10 ppm)- Better practices for risk assessment and justification of cleaning targets and residue level.

8:00-10:00

- Introductions & Overview
- Conventional practice- MAC (MACO) as the criteria
- GMPs for the 21st Century and the new regulatory expectations

10:00-10:20 Break

10:20-11:20

- Suggested Practice- MAC as a reference point in risk assessment
- Process capability as the criteria
 - Visually clean
 - Cleaning to an analytical limit of detection

11:20-12:00 **Team Case Study/Exercise**

12:00-13:00 Lunch

DAY 1-PM:

Beyond SOPs-Better process understanding with parametric description and control of the cleaning process

13:00-15:00

- Process evaluation, development and control
- Agent + Method + Procedure (Sequence, Duration, Interval)
- Automated vs. manual
 - Cleaning methods
 - Process Indicators

3:00-3:20 Break

3:20-5:00 **Team Case study**

DAY 2-AM:

Beyond Swabbing and HPLC- Better practices for inspection and measurement of cleanliness

8:00-10:00

- Analytical and Sampling Practices

10:00-10:20 Break

10:20-12:00 **Team Case study**

12:00-13:00 Lunch



DAY 2-PM:

Beyond "3"- The CV program as a foundation for ongoing process improvement (as a "journey, rather than a destination")

13:00- 14:00

- Monitoring, Validation Maintenance and Change Control Practices

14:00-15:00 Team presentations

Faculty

Mr. Steven A. Weitzel

Technical Director

Critical Process Cleaning

Mr. Steven A. Weitzel is Technical Director for Critical Process Cleaning, Inc. Previously, he held technical and management positions at Novaflux Technologies, Bristol- Myers Squibb, Calgon Vestal/Merck, Mallinckrodt, Dow and Princeton BioGroup with experience in engineering, manufacturing and validation of medical devices and in-vitro diagnostics, bulk compounds, oral dosage products, terminally sterilized and aseptic parenterals. He is a frequent industry speaker and is consulted regarding process cleaning, validation and environmental control.

Mr. Weitzel holds a B.S. degree in Chemical Engineering from the University of Missouri, Columbia and an MBA from Washington University. He is a member of the ISPE and the PDA.

Who Should Attend

This course is intended for professionals having familiarity and experience with the basic subject as it applies to research and manufacturing of biopharmaceuticals, APIs and fine chemicals, cosmetics and personal care products, nutraceuticals.

- Process Engineering
- Production
- Quality Assurance
- Validation
- R&D
- Validation Laboratory

CERTIFICATE OF ATTENDANCE AND COURSE MATERIAL

- All participants will receive a certificate of attendance upon completion of the course.
- The participants will be receiving specially prepared course manual



Location

Park Inn – Central London

Just a stone's throw from the **British Museum** and within walking distance to **Covent Garden & Oxford Street**, the Park Inn is nestled between London's financial district and the West End.

Conveniently located within the heart of **historic Bloomsbury**, the Park Inn is situated between Russell Square and Holborn tube stations and is within easy reach of Kings Cross and Euston Train stations.

Address:

92 Southampton Row, London, England, WC1B 4BH
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Registration

Please refer to the register tab on the CATD website (www.catdglobal.com) or click on the title of the course on the conferences/meeting or home page to register on line.

If you have any problem registering please do not hesitate to contact us at info@catdglobal.com or call us at + 44 (0) 20 8485 1234 or fax us at + 44 (0) 20 8485 1234

***Registration Fee Includes:**

Presentation Materials, Luncheon, Refreshment and Free Parking

***Please indicate any special Dietary requirements when registering for the course**

Contact for More Information

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