



Cleaning Validation: Advanced Topics

For Pharmaceutical and Biotechnology Manufacturers

Essential techniques to be in regulatory compliance

January 18-19, 2012 • Embassy Suite Hotel • Isla Verde, P.R

Outline

Cleaning has achieved a position of importance in the pharmaceutical industry. **Current Good Manufacturing Practices (cGMP)** regulations recognize that cleaning is critical to ensure **product quality** because virtually from the initial stages of bulk production to the final dosage form, every aspect of manufacturing involves cleaning.

This course is designed for those with a basic grounding in cleaning validation, **who want to explore topics in more depth** as well as topics not ordinarily covered in a basic cleaning validation course. It is a 2-day training seminar for pharmaceutical manufacturers on cleaning and cleaning validation.

Some of the themes to be covered are:

- Issues in Cleaning Validation Swab Recovery Studies
- Issues in Selecting Analytical Methods for Cleaning Validation
- Cleaning Validation Issues for Parts Washers
- Product and Equipment Grouping Strategies
- Use of Visual Limit
- Issues in Validating Manual Cleaning Processes

Includes: Interactive discussion designed to address how to successfully validate cleaning processes and any other concern you might have. The object of this session is to get your entire questions directly answered by our expert.

REGISTER NOW!

Email: echocg@echo-cg.com

Phone: (787) 704 .6864
(787) 226 .6803
(787) 399 .3990

Who should attend

This training is designed for professionals engaged in the design, execution, and validation of cleaning processes who possess a basic grounding in cleaning validation. This includes validation scientists, analytical chemists, microbiologists, QA/QC scientists, production engineers, toxicologists, regulatory specialists, and their managers.

About the Instructor

Destin A. LeBlanc is an internationally recognized expert in the area of cleaning and cleaning validation for pharmaceutical process equipment. Mr. LeBlanc has over twenty-five years of product development and technical service experience, primarily in cleaning and antimicrobial applications, specialty chemicals and medical technologies, the last ten of which have been involved with various aspects of cleaning and cleaning validation in pharmaceutical and medical device manufacturing. He has lectured internationally on issues related to contamination control, and has written widely on cleaning validation issues. He is the author of the book *Validated Cleaning Technologies for Pharmaceutical Manufacturing*. He is a member of PDA, ISPE, and AAMI, and is on the faculty of the PDA Training and Research Institute. He is a graduate of the University of Michigan and the University of Iowa.

Learning Objectives

At the completion of this course, attendees will be able to understand topics in cleaning process validation that will help them in the addressing of deviations that might occur during their exercises.

Sponsored by:





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Course Schedule

First Course Day: Wednesday, January 18, 2012

DAY 1

9:00 to 9:10	Welcome and Introductory Remarks
9:10 to 10:40	Issues in Cleaning Validation Sampling Recovery Studies
10:40 to 11:00	Break
11:0 to 12:30	Issues in Selecting Analytical Methods for Cleaning Validation
12:30 to 1:30	Lunch
1:30 to 3:00	Dealing with Highly Hazardous Actives
3:00 to 3:20	Break
3:20 to 4:05	Issues in Campaigns
4:05 to 4:50	Cleaning Validation Issues for Parts Washers
4:50 to 5:00	Q&A

Second Course Day: Tuesday, January 19, 2012

DAY 2

9:00 to 10:00	Utilizing Stratified Sampling for Protocol Compliance
10:00 to 10:40	Rationalizing Limits for Bulk Biotech Manufacture
10:40 to 11:00	Break
11:00 to 12:30	Product and Equipment Grouping Strategies
12:30 to 1:30	Lunch
1:30 to 3:00	Uses of a Visual Limit
3:00 to 3:20	Break
3:20 to 4:05	Limit Setting for Rinse Sampling
4:05 to 4:50	Issues in Validating Manual Cleaning Processes
4:50 to 5:00	Q&A

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Registration Form

1. Please type or print your name, address and affiliation.

Mr. Ms. Dr. **First Name** **Middle Initial** **Last Name**

Job Title **Company**

Business Address

City **State/Province** **Zip Code** **Country**

Phone **Fax** **E-mail**

2. Course & Fees: REGISTER TODAY!

Early Registration Fee \$895 (Due Date: December 22, 2011)

Regular Registration Fee: \$1,095

3. Please check the appropriate box

Check Enclosed Charge to: **Master Card** **Visa** **AMEX**

Account Number: **Expiration Date:**

Cardholder Name:

Signature _____ **Date** _____

4. Return complete form with payment (Payment must be included to be considered registered) made to:

ECHO Consulting Group
PMB 274
200 Ave. Rafael Cordero Suite 140
Caguas, PR 00725-3757

Professional education interest: (Check all that apply):

- | | | | | |
|--|--|--------------------------------------|---|--|
| <input type="checkbox"/> Validation | <input type="checkbox"/> Sterilization | <input type="checkbox"/> Parenterals | <input type="checkbox"/> Engineering | <input type="checkbox"/> Statistics |
| <input type="checkbox"/> Maintenance | <input type="checkbox"/> Microbiology | <input type="checkbox"/> Utilities | <input type="checkbox"/> Aseptic Processing | <input type="checkbox"/> Cleaning Validation |
| <input type="checkbox"/> Computer Validation | <input type="checkbox"/> Biotechnology | <input type="checkbox"/> HVAC | <input type="checkbox"/> Env. Monitoring | <input type="checkbox"/> Laboratory |

Confirmation: Written confirmation will be sent to you once payment is received. **Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made any time. If you are pre registering as a substitute attendee, indicate in the registration form. Should you be unable to attend, please inform us in writing prior to 10 days and a credit voucher will be awarded which is applicable to a training course one year from date of issue. Event **Cancellation:** ECHO reserves the right to modify the material or instructor without notice or to cancel the event. If the event must be cancelled, registrant will be notified as soon as possible and will receive a full refund of fees paid. ECHO cannot be responsible for airfare penalties or other cost incurred due to a cancellation. Course enrollment is limited for the benefits of all attendees; this necessitates early registration.