

Understanding Cleaning Validation, Principles, Planning, Execution and Data Analysis

Cleaning procedures must strictly follow carefully established and validated methods. Learn from those who perform cleaning validation on a day to day basis for a variety of industries.

Who should attend: Process, Validation and Quality Personnel

This course will:

Provide guidance on issues and topics related to cleaning validation, techniques for establishing cleaning validation plans and programs, verifying the effectiveness of the cleaning procedure for removal of production residues, degradation byproducts, preservatives, excipients, and cleaning agents as well as the control of potential microbial contaminants. Risk management approaches are also addressed relative to mitigating risk associated with cross-contamination of active ingredients.

SEMINAR ON CLEANING VALIDATION

- Cleaning Validation Principles
- Master Planning – Developing an effective roadmap for instituting and maintaining a cleaning and cleaning validation program, including tips on how to clearly identify:
 - Strategy
 - Analytical techniques and methods
 - Cleaning methods
 - Cleaning processes
- Process Mapping
- Integrating Risk Management Principles
- Worst case Residue
- Supporting Studies
 - Recovery Study
 - Degradation Studies
 - Cleaning studies
- Recovery Studies
 - Analyst variability
 - Using different recovery matrices
 - Swab techniques (multiple directions / multiple swabs)
- Analysis of recovery data
 - Recovery
 - LOD / LOQ

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ABOUT THE PRESENTER

“Keith Bader is the Director of Technical and Quality Services at Hyde Engineering + Consulting, Keith is responsible for the implementation of quality and validation standards for Hyde Engineering + Consulting on a corporate wide basis. Keith has worked on equipment ranging from stand-alone unit operations such as CIP and Ultrafiltration skids, to entire process trains. Prior to joining Hyde, Keith was a Research Engineer at TDA Research in Wheatridge Colorado where he was responsible for the synthesis and testing of novel catalysts, and advanced ceramic composites. All of the work at TDA was funded by various government agencies, including NASA, DOE, and the EPA, through the SBIR program. Keith earned his bachelors degree in Chemical Engineering from the University of Colorado at Boulder in 1995.”

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SCHEDULE AND VENUE

September 14, 2009

**Microrite Training Center
2338 B Walsh Avenue
Santa Clara, CA**

PROGRAM

Registration and Light -Breakfast	8.00 AM to 8.30 AM
Cleaning Validation Principles	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Master Planning	10.15 AM to 11.00 AM
Process Mapping	11.00 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Integrating Risk Management Principles and Residue Issues	1.00 PM to 2.30 PM
Break	2.45 PM to 3.00 PM
Recovery Studies and Data Analysis	3.00 PM to 4.30 PM
<i>Questions and Answers</i>	4.30 PM to 4.45 PM

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REGISTRATION FORM

Personal Information of One Registrant

Last Name: Mr. Ms. Dr. First Name: _____
 Title: _____ Organization: _____
 Mailing Address: _____
 Telephone: (Area _____ Facsimile: (Area Code) _____
 Email: _____

Fees: \$900.00

This fee includes breakfast, lunch, break and handouts

Group Discount: 10% discount for each attendee when 4 or more attendees register for any one seminar

Additional Attendees:					
Last		First		Title	
Last		First		Title	
Last		First		Title	
Last		First		Title	

Method of Payment: Check, Credit Card or Purchase Order
Fax : 408-445-1236

Checks payable to Microrite, Inc.
5019, New Trier Avenue
San Jose, CA 95136

Confirmation of registration will be sent via email if payment is made by check or PO. For credit card payment on website, a payment receipt will be considered as confirmation of registration. For credit card information faxed to Microrite an email confirmation will be sent with a copy of payment receipt. Please call 408-445-0507 in due time if confirmation is not received after payment.

Cancellation Policy: Your notice of cancellation must be received by in writing by letter, facsimile or email 10 working days prior to the Seminar date. Fax: 408-445-1236 Email: sales@microrite.com or info@microrite.com. A 10% cancellation fee is applicable for credit card payments

SUGGESTED AIRPORT AND HOTELS

Closest Airport

Norman Y. Mineta San Jose International Airport (SJC)
1732 N 1st St # 600
San Jose, CA 95112
Distance from Microrite Training Center
Estimated Driving Time: 9 minutes Estimated Distance: 4.77 miles

Accommodations

Biltmore Hotel and Suites

2151 Laurelwood Road
Santa Clara, CA 95054
408-988-8411
0.96 miles away from Microrite Training Center

Microrite's discounted rates will apply to this hotel.

Standard Garden Room: Rate \$109.00 per night, KING or QQ

Tower Suite: Rate \$129.00 per night, QUEEN w/ sofa Sleeper

Executive Tower Suite: Rate \$ 149.00 per night, QUEEN w/ sofa

Hotel services will include pick-up and drop off, to and from San Jose International Airport and Microrite's Training Center and Shopping within 5 miles of radius from Hotel.

Breakfast and internet access is free of cost at the hotel. Mention "MICRORITE" when reserving room to receive the discounted rate.

Other Suggested Area Hotels

Holiday Inn Express 1700 El Camino Real

Santa Clara, CA 95050
877-410-6681
1.35 miles away from Microrite Training Center

Hawthorn Suites-Santa Clara

2455 El Camino Real
Santa Clara, CA 95051
408-241-0514
1.19 miles away from Microrite Training Center

Howard Johnson

2499 El Camino Real
Santa Clara, CA 95051
408-244-9610
1.19 miles away from Microrite Training Center

Embassy Suites

2885 Lakeside Drive
Santa Clara, CA 95054
408-496-6400
1.19 miles away from Microrite Training Center

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Business name: _____

CREDIT CARD INFORMATION

Credit Card Payment may be made on the Micro rite's website-

<http://www.microrite.com>

Or this form may be faxed to 408-445-1236

Choose one:

VISA

Master Card

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Card Holder's Name

Address of Card Holder

Please note Company Address if it is a Corporate Card and
Personal Address if Personal Card

Street

City

Zip Code

Country

Contact Phone Number

Card Number:

Expiration(Month/Year):

Name on Card:

Amount (US Dollars):

Signature:

Name of Attendee(s)

City and Date of Seminar