

**Cleaning Validation Swab Recovery Studies and Analysis
A HANDS-ON WORKSHOP**

BTEC, Raleigh, NC

April 08 and 09, 2010

Most cleaning validation programs must rely on data from direct surface swab samples backed by a surface swab recovery study. This workshop provides a thorough demonstration of what information can be extracted from a surface swab recovery study for maximum leverage in a cleaning and cleaning validation program. Learn from those who perform cleaning validation studies on a day to day basis in a variety of industries.

Who should attend: Validation, Process and Quality Personnel

This course will provide:

The course addresses the fundamentals of a sound cleaning validation strategy, and the benefits of using a rapid, non-specific analytical method to determine cleaning process efficacy. The available technologies for Total Organic Carbon (TOC) will be discussed in the context of cleaning validation and surface swab recovery studies. Subsequently, the factors that may contribute to variability in a recovery study will be addressed. Among these are the surface swabs, the extraction matrix, characteristics of production equipment materials of construction, sampling techniques, and the characteristics of the production residues.

Participants will gain an understanding of the necessary controls required for a defensible study, as well as interpretation and analysis of swab recovery data. The Hands-on approach of this workshop also allows participants to gain direct experience setting up an effective cleaning validation study by going through a systematic approach to cleaning validation. Students will participate in laboratory activities to determine swab recovery data by sampling soiled coupons and analyzing the extracted residues using a state-of-the-art TOC analyzer.

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DAY 1- April 08, 2010

Lecture

- Overview of Cleaning Validation and TOC Technology (analyzer validation and method validation)
- Recovery Studies – structure and intricacies
- Classroom Discussion of Recovery Study Data Analysis
 - Expected recoveries – what is acceptable?
 - Standards for recovery performance

Laboratory

- Hands on Preparation of Spiking Solutions and Coupons
 - Preparation of solutions – demonstration of analyst variability three individuals to prepare a 750 ppb TOC solution
- Learn how to use the TOC analyzer for cleaning validation studies
- Run suitability samples

DAY 2 - April 09, 2010

Laboratory

- Hands on recovery study sampling (in the lab)
- Preparation and Analysis of samples
- Data analysis: Presentation, statistical analysis, and interpretation of swab data
- Recommendations for adjusting study based on results

This training will be performed in a laboratory setting. TOC analyzer, coupons, laptops, and all materials needed for the hands on training will be provided by Microrite.

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

microrite, inc.

Practical Series Seminars and Workshops

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

April 08 and 09 , 2010

BTEC
 Golden LEAF Biomanufacturing Training &
 Education Center North Carolina State
 University Centennial Campus
 Campus Box 7928 Raleigh, NC 27695-7928

PROGRAM

DAY 1- April 08, 2010: Registration and Light –Breakfast	8.00 AM to 8.30 AM
Overview of Cleaning Validation and TOC Technology (analyzer validation and method validation)	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Recovery Studies – structure and intricacies	10.15 AM to 11.45 PM
Classroom Discussion of Recovery Study Data Analysis Expected recoveries – what is acceptable? Standards for recovery performance	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Hands on Preparation of Spiking Solutions and Coupons	1.00 PM to 2.30 PM
Break	2.45 PM to 3.00 PM
Using the TOC analyzer / suitability samples /	3.00 PM to 4.30 PM
<i>Questions and Answers</i>	4.30 PM to 4.45 PM
DAY 2- April 09, 2010: Light -Breakfast	8.00 AM to 8.30 AM
Hands on Recovery Study Sampling (in the lab)	8.30 AM to 9.00 AM
<i>Questions and Answers / Load Samples for Analysis</i>	9.00 AM to 10.00 AM
Break (Begin Analysis of samples)	10.00 AM to 10.15 AM
Data analysis discussion – Statistical analysis of the data. What do the results look like and how to interpret them.	10.15 AM to 11.45 PM
<i>Questions and Answers</i>	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Hands on Analysis of Data	1.00 PM to 2.30 PM
Discussion – and presentation of the data	2.30 PM to 3.00 PM
Coffee Break	3.00 PM to 3.15 PM
Recommendations for adjusting study based on results	3.00 PM to 4.30 PM



Practical Series Seminars and Workshops

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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: \$2300.00

This fee includes breakfast, lunch, break , workshop handouts and all materials needed for

Group Discount: 10% discount for each attendee when 4 or more attendees register for then workshop

Additional Attendees:					
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

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List of Hotels near BTEC

Holiday Inn Brownstone Dt NC Raleigh

1707 Hillsborough Street
Raleigh, NC 27605 US
Phone: (919)-828-0811
No shuttle service- 3.5 miles from BTEC - University shuttle available near hotel

Ramada Raleigh-Blue Ridge

1520 Blue Ridge Road
Raleigh, NC US 27607
Phone: (919)-832-4100
Airport Shuttle not available-University Shuttle near Hotel

Clarion Hotel State Capital

320 Hillsborough Street
Raleigh, NC US 27603 1786
Phone: (919) 832-0501
No Airport or University (BTEC) Shuttle service available

Sheraton Raleigh Hotel

421 South Salisbury Street
Raleigh, NC US 27601
Phone: (919) 834-9900
No Airport or University (BTEC) Shuttle service available

Raleigh Marriott City Center

501 Fayetteville Street
Raleigh, NC US 27601
Phone: (919) 833-1120
No Airport or University (BTEC) Shuttle service available

Marriott Raleigh Crabtree Valley

4500 Marriott Drive,
Raleigh, NC 27612
Phone: (919) 781-7000
Shuttle services to and from airport-4 miles from BTEC-No shuttle service available to BTEC

Embassy Suites Raleigh - Crabtree

4700 Creedmoor Road
Raleigh, NC 27612 US
Phone - (919) 782-9708
Shuttle services to and from airport-5 miles from BTEC-No shuttle service available to BTEC

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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

American Express

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 _____