

**Cleaning Validation Swab Recovery Studies and Analysis**

**A HANDS-ON WORKSHOP**

**14, and 15 September 2009**

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.

## DAY 1

### 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

### 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 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 and 15, 2009**

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

**PROGRAM**

<b>Day 1 (September 14, 2009):</b> 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
<b>Day 2 (September 15, 2009):</b> 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

**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:					
<b>Last</b>		<b>First</b>		<b>Title</b>	
<b>Last</b>		<b>First</b>		<b>Title</b>	
<b>Last</b>		<b>First</b>		<b>Title</b>	
<b>Last</b>		<b>First</b>		<b>Title</b>	

**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](mailto:sales@microrite.com) or [info@microrite.com](mailto: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

Business name: \_\_\_\_\_

**CREDIT CARD INFORMATION**

Credit Card Payment may be made on the Microrite'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 \_\_\_\_\_