

MICROBIAL CONTAMINATION CONTROL A HOLISTIC APPROACH

May 15th & 16th, 2012 BIOCOM-San Diego, CA microrite, inc.

MICROBIAL CONTAMINATION CONTROL A HOLISTIC APPROACH

This in depth 2 day course will cover many microbial contamination related topics including:

DAY 1

Understanding Microbial Contamination

- Internal and external sources, types and quantity of Microbial contamination(bacterial and fungal)
- Cleanroom Microbiology –Bacterial and fungal contamination and their proliferation methods
- Types of human borne contaminations that can compromise aseptic operations

Facility Design Issues

- The importance of adequate air flows, and pressure differentials considering the nature of operation
- Appropriate cleanroom materials to effectively control contamination
- Understanding personnel flow and materials flows in a multi product facility

Gowning

- Understanding the rationale behind gowning
- Qualifying personnel for gowning
- Types of gowns and what to look for

Hoods and Incubators

- Important points to consider when working in Laminar Flow Hoods or Biological Safety Cabinets

Aseptic Techniques

- Do's and don'ts when performing aseptic inside hood for conducting cell manipulations
- Consequences of improper transfer methods and not following aseptic techniques during cell manipulations

Process Related Microbial Contamination

- Raw Materials as a source of contamination
- Evaluating and measuring contamination in utilities
- Establishing critical control points in process and setting acceptance criteria
- Common process failures that can contribute to microbial contamination
- Understanding cleaning validation and effects of product or microbial cross contamination

Housekeeping rules

- General every day cleaning around the lab
- Wipedown of items going into the lab
- Wipedown of surfaces/centrifuges/spills/end of day cleaning
- Managing outside cleaning personnel

Laboratory Operations

- Laboratory design and flow
- Laboratory cleaning
- Good laboratory practices

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DAY 2

Monitoring and Combating Microbial Contamination

- Discussion on the various cleanroom classification schemes and environment monitoring regulations and guidances
- Qualification of cleanrooms-important points to consider and common errors
- Using a risk based approach how to establish a meaningful environmental monitoring program
 - Number of sites using regulatory guidance and risk based approach
 - Discussion on choice and evaluation of equipment for environmental monitoring
 - Frequency of monitoring
- Microbial Identification, when it is necessary and why-how to identify objectionable microorganisms
- Challenges in establishing validity of microbial identification
- Importance of trending data to assess risk to product
- Establishing user requirements for electronic environmental monitoring systems
- Discussion on phenotypic and genotypic microbial identification systems
- Overview of the key components of EM Summary Reports
- Environmental Monitoring related investigations; what and where to look for?
- Case studies and discussion on HACCP principles to investigate excursions and assess risk
- Discussion on current FDA 483 observations on environmental monitoring and data trending

Disinfectant Choice, Qualification and Disinfection Program

- Disinfectants commonly used in the industry; modes, efficacy and toxicity
- Understanding testing for manufacturers and industry
- Disinfectant Qualification
 - Discussion on current industry trend for qualifying disinfectants-What is expected from regulatory agencies and who is required to perform such studies
 - Tools to develop an effective disinfectant qualification program
 - Common challenges in drafting and executing Disinfectant Qualification protocols
- Commonly observed deficiencies in Disinfectant Qualification studies that may lead to contamination or FDA observations
- Cleaning procedures-points to consider when choosing disinfectants, establishing rotation of disinfectants, frequency of cleaning, flow of cleaning, and choosing right cleaning supplies considering the criticality of the surfaces to be cleaned
- Challenges in Cleaning-Understand the natures of surfaces and the role of supplies
- Know the importance of chemical kill and physical removal of contamination
- Discussion of FDA 483s related to disinfection and disinfectant qualification

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VENUE AND CONFERENCE AGENDA	
May 15 th & 16 th , 2012	BIOCOM 4510 Executive Drive, Plaza 7 San Diego, California 92121
PROGRAM	
May 15, 2012 Registration and Light Breakfast	8.00 AM to 8.30 AM
Understanding Microbial Contamination	8.30 AM to 10.30 AM
Break	10:30 AM to 10.45 AM
Facility Design Issues, Gowning and Hoods	10.30 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Aseptic Techniques	1.00 PM to 1.45 PM
Process Related Microbial Contamination	1.45 PM to 2.30 PM
Break	2.30 PM to 2.45 PM
House Keeping Rules	2.45 PM to 3.00 PM
Laboratory Operations	3.00 PM to 4.00 PM
Q&A and Discussions	4.00 PM to 4.30 PM
May 16, 2012	
Light Breakfast	8.00 AM to 8.30 AM
Discussion on Day 1 Identification Issues	8.30 AM to 9.00 AM
Environmental Monitoring	9.00 AM to 10.15 AM
Break	10.15 AM to 10.30 AM
Environmental Monitoring (continued)	10.30 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Disinfectant Choice and Disinfectant Qualification	1.00 PM to 3.00 PM
Break	3.00 PM to 3.15 PM
Disinfection Program/Cleaning Procedures	3.15 PM to 4.00 PM
Wrap-Up Questions and answers	4.00 PM to 4.30 PM

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REGISTRATION FORM

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Personal Information of One Registrant		
Last Name: Mr. Ms. Dr.		First Name:
Title:		Organization:
Mailing Address:		
Telephone:		
Email:		
Fee: \$1,800.00 per attendee (Includes 2 day seminar fee, breakfast, lunch, break for all days, and course material)		
Additional Attendees		
First Name:	Last Name:	Title:
First Name:	Last Name:	Title:
First Name:	Last Name:	Title:
First Name:	Last Name:	Title:
<p>Method of Payment: Credit Card and Check payments only. Attendees can register and make payments on Microrite's website-www.microrite.com or complete this form and fax to 408-445-1236. Check payments must be cleared before the seminar date. If you have any questions regarding payment methods feel free to contact Microrite at 408-445-0507 or send your enquiry to info@microrite.com.</p> <p>Confirmation of registration will be sent via email. 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.</p> <p>Accommodation: Microrite suggests Embassy Suites San Diego-La Jolla at 4550 La Jolla Village Drive, San Diego, CA if you need sleeping rooms for this event. The hotel is half a block from BioCom. Shuttle will be available from the hotel to BioCom if needed. Kindly contact the hotel directly at:</p> <p>Embassy Suites San Diego - La Jolla 4550 La Jolla Village Drive, San Diego, California, United States 92122 Tel: 1-858-453-0400 Fax: 1-858-453-4226</p>		

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Address of Card Holder:	<i>Enter firm address for corporate card or personal address for personal card</i>		
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City:			
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Card Number:			
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Amount (US Dollars):			
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Prudential is able to provide national or international cleanroom laundry and apparel service programs. PCS remains committed to satisfying our customers' evolving requirements. PCS maintains state of the art ISO Class 3 cleanroom garment processing services throughout the United States and Malaysia.



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VWR International, LLC, headquartered in Radnor, Pennsylvania, is a global laboratory supply and distribution company with worldwide sales in excess of \$3.6 billion in 2010. VWR enables the advancement of the world's most critical research through the distribution of a highly diversified product line to most of the world's top pharmaceutical and biotech companies, as well as industrial, educational and governmental organizations. With 150 years of industry experience, VWR offers a well-established distribution network that reaches thousands of specialized labs and facilities spanning the globe. VWR has over 7,000 associates around the world working to streamline the way researchers across North America, Europe, and Asia stock and maintain their labs. In addition, VWR further supports its customers by providing onsite services, storeroom management, product procurement, supply chain systems integration and technical services. For more information on VWR, phone 1-800-932-5000, visit www.vwr.com, or write, VWR International, LLC, 100 Matsonford Road, Building 1, Suite 200, P.O. Box 6660, Radnor, PA 19087.