

CHALLENGES IN MICROBIAL IDENTIFICATION

Who should attend: Microbiologists performing, and reviewing microbial identification, and Quality Assurance and Quality Management personnel responsible for disposition final product and performing quality and product reviews

Benefit from the experts' extensive experience in Bacterial and Fungal Identification

Participate in the only comprehensive course that will discuss conventional methods, automated phenotypic and genotypic systems and validation issues with ample case studies to emphasize the value of the polyphasic approach

Understand why knowledge of classification and special features are important in morphological Fungal Identification, and comparing preparation to pictures in reference texts may often lead to incorrect identification

DAY 1 –16 October, 2008

BACTERIAL IDENTIFICATION

- Brief history of bacterial identification, beginning from gram stain to modern automated systems
- Role selective and differential media may play as confirmatory tests
- Gram staining and ancillary tests to help confirm results obtained by automated systems
- Understanding why knowledge of conventional microbiology, presumptive and confirmatory test methods may help in scrutinizing and confirming identifications obtained using automated systems
- Case studies to show how accepting results from automated systems without confirmation can influence product disposition
- Overview of Phenotypic Microbial Identification Systems
- Evolution of the phenotypic systems over the past decades, technology and modes of operation
- Important points to consider when identifying microbial isolates using phenotypic systems
- Accepting phenotypic microbial ID results - what one must look for
- Validation of phenotypic systems
- Case studies related to misidentifications-what can go wrong
- Overview of genetic (DNA) based systems e.g. PCR, sequencing. Comparison of genetic and phenotypic-pros and cons
- DNA sequencing as it pertains to identification of organisms
- Applications to Microbiology-advancement of Phylogenetics/Taxonomy
- DNA Sequence databases-public vs industrial (validated)
- Comparison of commercial systems/platforms
- Short methodology of the DNA sequencing process to obtain a target sequence and Genetic ID
- How one obtains a match to a database
- Data editing and acceptance criteria issues for cGMP including overview of validation issues
- Pitfalls with over-reliance on purely genetic based ID-here significant case studies (bacterial as well as fungal) will be shown
- Brief overview on Microarrays

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DAY 2 –17 October, 2008

FUNGAL IDENTIFICATION

Identification of Fungi remains a challenge that requires both art and technical expertise. The art of macroscopic and microscopic examination to identify fungi is slowly declining, yet it is very important to learn it as the databases of automated systems whether phenotypic or genotypic may contain many fungal species, are far from being comprehensive for all the fungi found in the environment. This workshop will provide an opportunity to learn the best practices for classical identification methods first-hand from experts along with current molecular methods available. Using reference texts and digital images learn the distinguishing characteristics used for classical identification. Understand the polyphasic approach to gain confidence in fungal identification.

- Pitfalls with over-reliance on purely genetic based Fungal IDs
- Overview of clinical classification fungi to understand risk to product
- Learn about the common sources of fungi found in cleanrooms
- Classification Keys to be used in macroscopic and microscopic Identification
- Step by step identification by macroscopic and microscopic examination using numerous reference test books and classification keys
- Importance of knowing anamorphs and teleomorphs
- Learn about the common errors in fungal identification – how one stage of one fungus can look like another stage of some other fungus- comparing samples to pictures in text books can be misleading
- Correct use of reference materials- when and how to use reference text
- Learn about the pitfalls in both microscopic examination and automated methods
- Practice fungal identification using high quality digital pictures using the classification, keys and techniques learned in this course
- Case studies on how wrong IDs can lead to loss of product or disposition of product with an objectionable fungus can lead to product recalls

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ABOUT THE PRESENTERS

***Dr. Jaspreet Sidhu** is currently the Vice President for Business Development and Pharmaceutical Microbiology at Molecular Epidemiology, Inc. Lake Forest Park, WA. He has served as the Principal Scientist/Laboratory Research Director at the University of Washington, Seattle, WA. He has also worked as a Post Doctoral Fellow, Visiting Scientist and Senior Research Scientist at the University of Washington, Seattle, WA. He received his PhD in Biochemistry from Brunel University and Max-Planck Institute for Biophysical Chemistry, in Goettingen, Germany. He has been an active member of Regulatory Affairs Professionals Society, Parenteral Drug Association, and the International Society for Pharmaceutical Engineering*

Lucia Clontz is Director of Microbiology at Diosynth Biotechnology, a division of Schering-Plough, located at the Research Triangle Park, in NC. Lucia has expertise in pharmaceutical microbiology and for more than 20 years has managed numerous validation projects, established quality systems for microbiology laboratories, and participated in compliance audits. In her previous position as consultant and director of regulatory compliance at Serentec Inc., Lucia helped clients find effective and practical solutions for microbiology issues associated with facilities, processes, and laboratories. Lucia has B.S. degrees in Chemistry, with a minor in Chemical Engineering and in Marine Sciences. She also holds a Master of Science degree in Microbial Biotechnology and a graduate certificate in Molecular Biotechnology, both from the North Carolina State University. Lucia is a member of the Parenteral Drug Association (PDA) and a cofounder of the Pharmaceutical Microbiology Forum (PMF) and the Biofilm Networking Group (BNG).

***Ziva Abraham** has over 25 years of academic, research, clinical and industrial experience in Microbiology, and Quality Assurance. She has trained personnel from various industries in microbiology techniques and methods. Ziva has received her Master's Degree in Microbiology and has conducted research on developing Microbial Insecticides. She has established clinical laboratory systems in Israel, and Microrite, Inc. a consulting company based in San Jose, CA that helps Pharmaceutical, Medical Device, and Biotechnology Companies. Microrite focuses on helping companies with contamination control, microbiological quality control for sterile and non-sterile manufacturing, and Quality Assurance. Ziva has also developed "BACTISPELL" a microbiology spellchecker to spell check genus and species names of microbes and other microbiology related terms. She is a member of PDA, ISPE, AAMI, and PMF and is an active mentor for graduate students at Stanford University working through the American Woman in Science Organization (AWIS). She is involved in Expanding Your Horizons, a program through the Math and Scientific Network to educate young girls about careers in science. Ziva serves on the editorial board of Pharmaceutical Microbiology Forum (PMF) Newsletter*

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SCHEDULE AND VENUE

16 and 17 October, 2008

Hilton North Raleigh

3415 Wake Forest Rd
Raleigh NC 27609

PROGRAM

Day 1 (16 October, 2008): Registration and Light -Breakfast	8.00 AM to 8.30 AM
History of Microbiology, Gram Staining and Media Types, and Conventional Methods	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Presumptive Identification and Confirmatory Tests	10.15 AM to 11.00 PM
Phenotypic Microbial Identification Systems	11.00AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Phenotypic Microbial Identification Systems and Validation	1.00 PM to 2.00 PM
<i>Questions and Answers</i>	2.00 PM to 2.15 PM
Genotypic Microbial Identification Systems	2.15 PM to 3.00 PM
Break	3.00 PM to 3.15 PM
Genotypic Systems for Bacterial Identification and Importance of Polyphasic Approach	3.15 PM to 4.15 PM
<i>Questions and Answers</i>	4.30 PM to 4.45 PM
Day 2 (17 October, 2008): Registration and Light -Breakfast	8.00 AM to 8.30 AM
Genotypic Systems for Fungal Identification and Polyphasic Approach	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Classification Schemes and understanding key features of each Class	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
Grouping by hyphae and sporulation patterns and using Identification Keys	1.00 PM to 2.30 PM
<i>Questions and Answers</i>	2.30 PM to 2.45 PM
Coffee Break	2.45 PM to 3.00 PM
Practice Identification using digital images and case studies	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 Code) _____ Facsimile: (Area Code) _____

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Fees: Day1: \$900.00 (US) Day 2: \$900 (US) Both Days: \$1750 (US)

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

Additional Attendees:	Choose 1,2, or both days			Day 1	Day 2	Both Days
Last Name:	First Name:	Title:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Last Name:	First Name:	Title:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Last Name:	First Name:	Title:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Cancellation Policy: Your notice of cancellation must be received in writing by facsimile or email 10 working days prior to seminar date. Fax: 408-445-1236 Email: sales@microrite.com or info@microrite.com

A 10% cancellation fee is applicable for credit card payments

Accommodation: Seminar attendees requiring hotel accommodation should contact Hilton North Raleigh, 3415 Wake Forest Rd, Raleigh NC 27609 Tel: 1-919-872-2323

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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>

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Card Number:

Expiration(Month/Year):

Name on Card:

Amount (US Dollars):

Signature:

Name of Attendee(s)

**City and Date of
Seminar**