

Biofilm Conference 2009

This is the third public event sponsored by the Biofilm Networking Group (BNG). Aimed at the pharmaceutical professional, the event will cover the basics of biofilms, including their harmful effects on pharmaceutical manufacturing.

When:
November 10th 2009

Where:
Biomanufacturing Training and Education Center (BTEC)
850 Oval Drive - Centennial Campus
North Carolina State University
Raleigh, NC 27695-7928

Control by Design[®]: Preventing Microbial Contamination and Biofilms

Meeting Agenda

8:00 - 8:30	Registration and Continental Breakfast
8:30 - 9:00	Introduction: Control by Design[®] Concept - Lucia Clontz, M.S.
9:00 - 9:45	Process Risk Assessments - Christopher Moore
9:45 - 10:30	Risk Assessment: Objectional Organisms - Frank Settineri
10:30 - 10:45	Break
10:45 - 11:30	Contamination Control Regulatory Update - Kalavati Suvarna, Ph.D. (FDA)
11:30 - 12:15	Rapid Detection Methods for Process Control - Michael J. Miller, Ph.D.
12:15 - 13:15	Lunch
13:15 - 13:45	Technology Update: Anti-Biofilm Agents - Christian Melander, Ph.D.
13:45 - 14:00	Workshop Assignments
14:00 - 17:30	Workshops

Meeting Information

Who Should Attend?

Professionals responsible for any aspect of microbial control, including QA, QC, RA, Validation, Engineering, product development scientists and cleaning validation experts.

Learning Objectives:

- Expand the fundamental aspects of biofilms as applied to pharmaceuticals
- Recognize the tools available to manage, control & prevent biofilms
- Understand the regulatory and business implications of equipment biofouling

Cost: \$475.00; BNG members pay \$375.00. Call for pricing for university faculty and government employees. Registration form: www.sci-nc.com

For more information, contact:

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Speaker Bios
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REGISTRATION IS LIMITED TO 50 PARTICIPANTS!

About Our Speakers

Our speakers include:

Lucia Clontz, M.S.

is the Director of Microbiology at Diosynth Biotechnology. Lucia is co-founder of the Biofilm Networking Group. 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. She has successfully developed innovative approaches to the application of microbiology in pharmaceuticals and is a well regarded instructor, presenter and author in the area of pharmaceutical microbiology. Lucia has consulted and taught pharmaceutical microbiology topics worldwide.

Our FDA Speaker:

Kalavati Suvarna, Ph.D., is a Microbiologist in the Biotech Manufacturing Team within the Division of Manufacturing & Product Quality (DMPQ), Office of Compliance, in the Center for Drug Evaluation and Research (CDER). In this position, she is responsible for the review of biologic license applications (BLA) and pre-approval inspections of manufacturing sites associated with BLAs. She is also currently Acting as Associate Director for Regulatory Science in DMPQ. Prior to joining the Office of Compliance, she was a Senior Clinical Microbiology Reviewer in CDER. She received her Ph.D. from Northern Illinois University in August 1994 and worked in the drug discovery area in both academic and pharmaceutical settings prior to joining the FDA.

Chris Moore

has a BS in Medical Technology from Georgia State University and an MBA from North Carolina State University. For over eight years, Chris Moore has been a member of Diosynth Biotechnology, a contract biotechnology manufacturing company engaged in the development, scale up and manufacture of clinical and commercial products for various clients. Chris's current role as Manager of Downstream Process Sciences includes monitoring process cleaning, equipment design and selection, and process control supporting purification strategies that help prevent contamination. Chris has also worked in various positions in Quality Assurance, including validation support.

Michael J. Miller, Ph.D.

is an internationally recognized microbiologist and subject matter expert in pharmaceutical microbiology, Process Analytical Technology (PAT), isolator design and qualification, and the due diligence, validation, registration and implementation of rapid microbiological methods. Currently, Dr. Miller is the President of Microbiology Consultants, LLC. In this position, he is responsible for providing microbiology, regulatory and quality solutions for the pharmaceutical and biopharmaceutical industries. Over the past 20 years, Dr. Miller has held numerous R&D, manufacturing, quality, consulting and business development leadership roles at Johnson & Johnson, Eli Lilly and Company, Bausch & Lomb, and Pharmaceutical Systems, Inc.

Frank Settineri

is the founder and President of Veracorp LLC, a consulting firm that specializes in providing pharmaceutical, biotech, medical device and startup companies with the essential advice they need to keep their businesses running efficiently and within regulatory guidelines. He has helped companies and clients solve manufacturing problems, respond to 483s, warning letters and consent decrees, build and grow their businesses, assemble their infrastructure and train their employees. He has directed laboratories, manufacturing sites, quality assurance, quality control and sales departments, has traveled the world outsourcing API and finished product manufacturers, and developed strategies with senior management teams. He is a frequent speaker for PDA, PMF and Compliance Online, particularly on topics related to aseptic processing, microbiology and training. He works both independently and collaborates with partners, depending on the scope of each project.

Christian Melander, Ph.D.

received a B.S. in Chemistry, with departmental honors, from UC Davis and a Ph.D. in Organic Chemistry, supported by an NIH chemistry and biology-training grant. Dr. Melander is an Assistant Professor at North Carolina State University (NCSU), in the Department of Chemistry, and is co-founder of Agile Sciences, a company that develops compounds that can disperse biofilms. These compounds have applications in the areas of medicine, agriculture, and industry. Agile Sciences' proprietary compound, Agilyte(tm), is able to prevent biofilm formation and re-sensitize multi-drug resistant bacteria to the effects of conventional antibiotics. Agilyte™ is the first example of a non-bactericidal small molecule that inhibits and disperses biofilms across bacterial order, class, and phylum. Other potential applications for this product include prevention of biofilms in filtration systems and medical devices. Agile Sciences' founders have won a University of North Carolina General Administration Competitiveness Grant for continuing work on anti-biofilm agents showing that there is significant perceived promise in the technology.