



**INFORMATIVE
SESSIONS ON:**

- **Annex 1**
- **HACCP**

Environmental Monitoring

August 23-25, 2006 • Washington DC

HEAR FROM INDUSTRY EXPERTS

Including a Former FDA official and over 20 Pharmaceutical/Biotechnology Manufacturing and Allied Companies including:

- AAC Consulting Group
- Applied Biosystems
- Arion Water, Inc.
- Biolog, Inc
- Compliance Software Solutions Corporation
- Edgington Associates
- Johnson & Johnson (GPSG North America)
- Microrite Inc.
- Monsanto Company
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Create Your Own Conference: Choose from New Advanced Sessions

- Microbiology Methods Used for EM and the Impact of Method Variability
- Evaluation of Microbial Identification Methods for Pharmaceutical Manufacturing – A Practical Approach
- An Overview of Methods for the Identification of Filamentous Fungi
- Challenges and Considerations when Implementing an Electronic EM Data Management System
- Bacterial Identification in EM

Environmental Monitoring • Wednesday, August 23, 2006

Pre-Conference Half-Day Workshops

7:30 AM – Conference Registration and Continental Breakfast

Interactive Workshop A 8:30 AM – 12:00 PM **Establishing a New EM Program “A Complex System Simplified”**

Ziva Abraham, President, Microrite, Inc.

I. Terminology and Classification Schemes to Establish An Effective EM Program

- Understanding definitions of the terms related to EM to avoid misinterpretations
- Selecting a classification scheme by knowing the commonalities and differences in US, ISO and EU classification schemes
- Learning how FDA’s guidance on Aseptic Processing can also help in establishing an effective and scientifically sound EM Program

II. Choosing and Evaluating Sampling Sites, Equipment and Establishing Sampling Schedules for new EM Programs

- Establishing a sampling plan with sampling sites that can provide relevant data
- Establishing what and why criteria’s are critical for evaluating total particulate and viable air counters and microbial identification systems
- Learning the basics for establishing monitoring frequency
- Discovering when and why to characterize isolates recovered during monitoring

III. Key Elements of EM Procedures

- Discovering effective document sampling plans and frequency of monitoring
- Understanding the key elements of the Test Report for data interpretation

- Learning about EM scheduling
- Understanding the concept of tracking and trending EM data

IV. Understanding the Impact of Out of Limit and Out of Trend Results

- Learning how to track and trend EM data to use it as a measure for evaluating the controlled environment and assessing risk to product
- Writing periodic EM summary reports that will allow assessing facility condition at a glance
- Using the summary reports to evaluate cleaning procedures and personnel gowning procedures
- Conducting and reporting investigations related to EM excursions

V. Interactive Exercise

Using example of documentation errors in EM Test Report, attendees will create a Test Report where testing parameters can be appropriately documented to avoid mistakes. Attendees will then compare and contrast the test report they develop with the audience.

Participants will take home the following bonus information:

Template for compiling EM Summary Report which will include sections that are important in evaluating the controlled environment on a regular basis

Interactive Workshop B 8:30 AM – 12:00 PM **Water System Design- A Continuous Ambient Operation without Sanitization (Part 1)**

Bob Livingston, CTO, Arion Water, Inc.

I. Water System Design is Better than Sanitization Strategy

- Learn why ambient temperature Purified water systems are associated with microbiological problems and how to avoid problems
- Learn Purified Water System Design options with proven microbiological control approaches that work
- Learn sanitization approaches that do and do not work

II. WFI Design, Purified Design and HP Purified Designs

- Fundamental differences
- Regulatory expectations
- Product Water Quality problems and differences

III. Pretreatment Design

- Avoiding Chemical Additions
- Microbial control without sanitization
- Simplified Design for RO feed water preconditioning

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IV. Reverse Osmosis Design

- Proper design for microbio control
- Avoiding sanitization and membrane cleaning
- Single pass vs. Double pass or EDI/CDI designs

V. Post Treatment Design

- Storage Considerations and Tank Designs
- Economically Processing Water to Ultra High Purity
- Ambient temp operation without sanitization
- Design myths that aren't helpful including, Single stage centrifugal pumps, Stainless Steel, Hot water sanitizations, Spray balls and Sanitary Design

Participants will take home the following bonus information:

- Water System Design Basis Template (User Requirements Document Worksheet)
- A comprehensive worksheet addressing all the design assumptions required to initiate a validated water system design

Interactive Workshop C 8:30 AM – 12:00 PM
The Cleanroom Design/Build Process and End User, QC/QA Role in the Process

Raj Jaisinghani, PE, President, Technovation Systems, Inc.

I. DQ/IQ/OQ and Project Management

- Development of DQ/IQ and OQ during the Design/Build Process
- DQ as a foundation for the entire Cleanroom Validation process
- Process Integration issues in the Design/Build process
- Importance qualifications of a Design/Build Company

II. cGMP Guidelines

- Filter face velocity and air exchange rates
- Room pressures and pressure differentials
- Temperature and RH requirements
- Airlock and other entry/buffer zone requirements
- Isolation and cross contamination prevention requirements

III. Interactive Development of Cost Effective EM & Control Specifications

- Room Pressure
- Make Up/Exhaust air & Leakage
- RH and Temperature
- Cost Impacts of Environmental parameters

IV. Basics of Cleanroom and Airflow Design Methods

- Airflow Design cost impacts
- Airflow Design methods
- Energy implications using computer airflow modeling techniques

V. New Energy Efficient Air Handling Methods and Technology

- Distributed (Optimized Bypass) versus Central air handling
- Low Pressure Drop Bactericidal Filters for energy efficiency and low bio burden
- Other energy savings methods
- Examples and analysis of Energy and Cost Savings using the above methods

Participants will take home the following bonus information:

- Project Specification Development Worksheet
- Free Computer Airflow Analysis Submittal Form
- Airflow Design Publications:
 - 1. Control and Monitoring of Bioburden in a Biotech/Pharmaceutical Cleanrooms, *Institute of Validation Technology Journal*, August 2000
By Raj Jaisinghani, Technovation; Greg Smith, Encelle Corp, and Gerald Macedo, MedPharmex,
 - 2. ENERGY EFFICIENT LOW OPERATING COST CLEANROOM AIRFLOW DESIGN by Raj Jaisinghani, Paper presented at IEST's ESTECH 2003 Conference, Phoenix, AZ May 18-21, 2003

Interactive Workshop D 8:30 AM – 12:00 PM
Principles of EM for Isolator Systems

Edith Lewis-Rogers, Former FDA; Partner, SMHW Associates, LLC



I. Introduction to Isolators

- What are the general types of isolators?
- How does the type of isolator determine monitoring issues?

II. Positions of Regulatory Authorities

- What FDA guidance documents are available?
- What EMEA annexes provide guidance?
- What government/industry organizations have generated positions?

III. Purchasing Isolators

- What involvement should the Microbiology/Quality Assurance staff have in the decision to purchase an isolator?
- What recommendations can be made about the customization of the unit for expected product usages?

**Wednesday, August 23, 2006
Pre-Conference Half-Day Workshops**

IV. Commissioning/Qualifying and Validating Isolators

- How to determine the high risk areas of isolators?
- What requirements should be met during the commissioning/qualifying stage?
- What requirements need to be met to approve the isolator at validation?

V. Special Monitoring Issues of Isolators

- Learning the key issues in air, surface and product sampling
- Learn the key personnel risks due to difficulties in access

VI. Interactive Exercise

- Using three case studies from pharmaceutical and biotechnology companies, participants will review these cases to develop an action plans to address isolator EM issues. Attendees will compare and contrast these plans with other workshop attendees

Participants will take home the following Bonus Information:

- An updated compiled list of regulatory references

12:00 PM – Lunch for Pre-Conference Workshop Participants

**Wednesday, August 23, 2006
Main Conference General Sessions**

12:00 PM – Main Conference Registration

1:00 PM

Chairperson's Opening Remarks

1:15 PM

Establishing an EM Program

Marsha Hardiman, Manager Microbiology, Johnson & Johnson (GPSG North America)

This session will address how to establish an EM (EM) Program for aseptic, non-sterile and/or medical device manufacturing environments. A review of standards, guidelines, and regulations will be discussed. Sample site rationale, sampling frequency, and sampling methods and instruments will be discussed. Creating a validation protocol to address sampling, as well as sample handling, sample incubation, and data analysis will be covered. Tips will be provided on how to establish alert and action limits and performing statistical data trending.

- Learn how to establish a risk-based EM Program to allow for the collection of meaningful data
- Understand how to create and execute a protocol to establish a baseline EM Program
- Learn how to establish appropriate alert and action limits for your EM Program
- Learn how to investigate responses to alert and action level excursions
- Gain knowledge in performing statistical data trend analysis

2:00 PM

Application of Genetic-Based Methods for Microbial EM Programs

James L. Bruce, Product Manager, Applied Markets Division, Applied Biosystems

With the emergence of genetic based methods it is important to understand the theory and application of these methods for routine environmental programs. By providing new levels of accuracy and reproducibility over traditional compendial test, these methods have been proven to be valuable tools in understanding microbial populations. This session will review genetic-based methodologies used for microbial detection, microbial identification and strain level characterization programs and routine QC testing.

- Learn the theory of PCR and Real-Time
- Learn about molecular typing techniques
- Learn the principles of DNA sequencing and analysis
- Gain a better understanding on how to apply genetic-based methods for microbial detection, identification and characterization

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2:45 PM

The New Draft of Annex 1: What Does it Mean for Me?

Mike Edgington M.Sc, CEO, Edgington Associates BV Sassenheim, the Netherlands

Although the European Authorities would not like to admit it there are some "anomalies" in the current version of Annex 1 which give a questionable benefit to absolute compliance. The proposed new draft of Annex 1 published on 11 November 2005 by the European Commission goes a long way towards correcting those anomalies and comes closer to the FDA Aseptic Processing Guide.

I. The Current Version of Annex 1

- Legal status
- The Errors and impossibilities
- Interpretation by European Inspectors (cultural differences)

II. The Draft of Annex 1

- Establishing the differences and correcting the errors
- Cleanroom classification
- Non-viable particle monitoring
- New draft Annex 1 versus FDA aseptic processing guide
- The similarities and differences
- Establishing what you have to do

3:30 PM – Refreshment Break

3:45 PM

Non-Viable Particle Counting

Mark Hallworth, Pharmaceutical Manager, Particles Measuring Systems

This session will review the non-viable particle counting regulations as defined by the European and FDA GMP Guidelines. It will cover aspects such as legislation, portable monitoring, automated monitoring, GMP required reports and review sample point selection and placement. With completely automated systems, a significant amount of data is generated, the session shows how to turn data into release information and prove control over the environment. Participants will establish the following:

- Direction of the ECcGMP revisions to Annex 1
- How to establish and maintain a monitoring program
- Selecting suitable instrumentation that addresses both the portable and continuous monitoring

4:30 PM

Exploring the Benefits of Establishing a Hazard Analysis and Critical Control Point (HACCP) Philosophy in a Early Stage Pharmaceutical Environment

John J. Vajda, BS, Vice President, Manufacturing, World Heart, Inc.

In the pharmaceutical industry, especially in early stage companies, establishing a HACCP program can make the difference between failure and success. An effective program can not only save money, but also reduce "time to market" which is critical for a company's survival. Incorporating the QA/QC functions into the HACCP early on can smooth the way to compliance. This session will focus on a new way of looking at HACCP.

- Establishing cost benefit of early compliance
- Assessing Documentation for compliance
- Establishing the role of validation
- Discussing quality assurance (QA) as a major player on the HACCP team

5:15 PM – End of Day One

**5:30 PM – 6:30 PM
Networking
Cocktail Reception**



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7:30 AM – Continental Breakfast

7:30 AM – Interactive
Breakfast Session

**Minimize Regulatory Risk:
Meeting FDA Requirements**

Edith Lewis-Rogers, Former FDA; Partner,
SMHW Associates, LLC



This session will address the current FDA EM requirements. With CDER's emphasis on risk based inspections, sterile products are incurring increased attention and as a result so are EM. CBER continues to expect strong EM programs for biologics. The presentation will highlight areas that should receive additional attention to assure compliance.

- Review CDER's current risk-based approach to inspections
- Learn the current expectations for EM results
- Learn the expectation for investigations
- Learn about current compliance actions being taken by FDA including Warning Letters

Interactive Workshop E 8:30 AM-12:00 PM

An Approach to In-Depth Root Cause Analysis and CAPA for Adverse EM Results and Sterility Test Positives

Betty Seawell, PhD., Director QA/QC, Monsanto Company

I. Sterility Assurance and Aseptic Processing – Brief Overview

- Discussing an overview of sterility assurance and how it is achieved for an aseptic process
- Reviewing typical environmental surveillance programs
- Reviewing recommendations found in the 2004 Guidance for Industry – Sterile Drug Products produced by Aseptic Processing – Current Good Manufacturing Practice

II. Adverse EM and Sterility Testing Results

- Gaining knowledge of what potential adverse results may be obtained in various surveillance programs, including individual events and adverse trends.
- Discussing an overview of sterility testing, including its benefits and potential shortfalls.
- Discussing potential laboratory and operational contributions to adverse results
- Developing a check-list to aide in root-cause analysis
- Using a process map approach to root cause analysis

III. Failure Mode and Effect Analysis

- Understanding the basic elements of an FMEA
- Learning the basics of the FMEA process
- Learning how to define an FMEA Team

- Understanding how to assess the results of an FMEA

IV. Interactive Exercise

FMEA and how it can be used improve an approach to environmental surveillance and effective corrective and preventive actions

- Using a case study, attendees will assess the results of an FMEA and learn how to set priorities and execute activities designed to improve sterility assurance

Participants Will Take Home The Following Bonus Information:

- Example Check list and Process Map
- Case Study FMEA on Sterility Assurance

Interactive Workshop F 8:30 AM-12:00 PM

Microbial Control for Regulated Manufacturing Facilities: Application and Validation Issues

Jim Polarine Jr., MA, Technical Service Specialist, STERIS Corporation

I. Regulatory Expectations

- Current FDA and EMEA standards
- Evaluating real-world examples from industry
- Assessing whether or not your limits are appropriate for your manufacturing environment and down stream processing

II. Equipment and Facilities Design and Operational Issues Affecting Microbial Control

- How the design of equipment and facility impacts contamination control
- Cleaning versus sanitization-how effective cleaning programs can eliminate the need for sanitization steps
- Study examples from other facilities

III. Sampling and Setting Limits

- The sources of microorganisms
- Evaluating selection of worst-case sample points
- Sampling techniques for inaccessible areas
- The most common approaches to setting limits

IV. Components of the Cleaning Validation Protocol

- Elements of the cleaning validation protocol
- Examples of cleaning validation protocols

V. Interactive Exercise

This session will cover information on microbial control and validation issues with equipment and processing areas. Attendees will be asked to review information from real facilities (Pharmaceutical and Biotech) and to determine actions required in the development of validation protocols.

ADVANCED SESSION

Interactive Workshop G 8:30 AM-12:00 PM

Microbiology Methods Used for EM and the Impact of Method Variability

Scott Sutton, PhD, Vectech Pharmaceutical Consultants

I. Current Methods Used for EM

- Learning about the different viable air monitoring methods available
- Examining surface sampling methods and how to demonstrate recovery efficiencies
- Evaluating water testing methods both from a practical perspective (media, sample volumes, collection methods) and theoretical (why bother?)

II. Variability in the Methods

- Reviewing work on accuracy in microbiological test methods for enumeration
- Evaluating the effect of multiple samplings
- Discussing the differences among microbial identification systems

III. Opportunities for Implementation of Rapid Methods

- Discussing the appropriate implementation of different rapid enumeration methods in microbiology
- Evaluating the appropriate level of microbial identification in support of an EM program

IV. Interactive Exercise: Determining the Uncertainty

Using a model EM program, participants will evaluate the uncertainty in the measurements and their reproducibility. Participants will then develop a "scientifically rational" alternate program.

Participants Will Take Home The Following Bonus Information:

The toolkit will contain a copy of the FDA 2004 Aseptic Processing Guidance Document, a limited number of relevant review articles, and a copy of USP Chapter "<1227> Validation of Microbial Recovery from Pharmacopeial Articles" and the worksheet from the interactive exercise.

Interactive Workshop H 8:30 AM-12:00 PM

Case Study: Developing an Effective Cleaning Validation Master Plan (CVMP)

John J. Vajda, BS, Vice President, Manufacturing, World Heart, Inc.

I. Validation

- Defining the task
- Establishing the pros and cons of validation
- Basic documents

II. The Validation Team

- Participants
- Leadership
- Basic tasks for the team

III. Gaining Support

- Getting support from management
- Presenting your plan
- Avoiding politics

IV. Forming Elements of a CVMP

- Using the table of contents
- Critical sections
- Related documents
- Protocols and reports

V. Maintaining Validation

- Coping with change
- Establishing when it's necessary to revalidate
- Streamlining

VI. Interactive Exercise

Attendees will form teams and develop brief sections of a CVMP. Critique and Q&A will follow

12:00 PM – Luncheon

Interactive Session 1 1:30 PM – 3:00 PM
Are Disposables Meeting the Requirements of Your EM Program?



Edith Lewis-Rogers, Former FDA; Partner, SMHW Associates, LLC

I. Cross Contamination

- How does the reduced risk of cross contamination influence firm's choice to use disposables?
- How have EM decisions factored into the choice to use disposables?

II. Current Industry and Regulatory Involvement on EM of Production Using Disposables

- What microbiological and particulates issues are being addressed by the suppliers of disposables?
- What positions have been taken by EMEA and FDA to date on disposables relative to EM?

III. EM Issues

- Learn keys to disposable supplier selection
- Learn essentials in incoming approvals for disposables
- Learn key issues in qualification/validation
- Learn essentials in routine monitoring

IV. Interactive Exercises

- Case studies will be provided on a number of EM issues related to disposables. Groups will determine appropriate follow-up activities to resolve the issues.

Participants will take home the following Bonus Information:

A bibliography of suggested reading materials

ADVANCED SESSION

Interactive Session 2 1:30 PM – 3:00 PM
An Overview of Methods for the Identification of Filamentous Fungi

Stacy O. Montgomery, Ph.D. Director, Global Marketing, Biolog Inc.

I. Importance of Filamentous Fungi in Many Fields

- Diversity of beneficial processes they carry out
- Production of novel bioactive metabolites as well as their ability to cause serious disease

II. The Identification of Fungal Contaminants

- Aging population and increase in the numbers of immuno-compromised individuals
- Organisms that were once considered harmless saprophytes have now been shown to be the etiological agent of disease

III. Examining the Basics of Fungal Classification and Systematics

- Reviewing the enormous diversity of the fungal world

IV. Analyzing the Major Methods for the Identification of Filamentous Fungi

- Classical macroscopic and microscopic morphology
- Biolog Carbon Source Utilization
- MicroSeq rRNA gene sequencing

Interactive Session 3 1:30 PM – 3:00 PM
EM Performance Qualification

Mike Edgington, M.Sc CEO Edgington Associates, BV Sassenheim the Netherlands.

I. FDA and International Requirements

- EM Regulation
- The Aseptic Processing Guide
- EU GMP Annex's 1, 2, 5, and 17
- ISO 14644-1-7 and 14698
- What is relevant

II. How to Design an EMPQ

- Use of HACCP to identify potential hot spots
- To grid or not to grid
- Writing the protocol
- Execution of the study

III. Using the Results to Define Future EM Programs

- Initial program
- Annual review to cover seasonal variation
- Ruthless reduce sample locations to only those that give control data
- More is not better

IV. Interactive Exercise: Developing Documents

Using a case study from a vaccine production facility, attendees will develop concepts for the EMPQ protocol. Concepts will include control and tracking.

Participants will take home the following information:

Sample SOP's designed from the EMPQ (IV above)

3:00 PM - 3:30 PM – Refreshment Break

ADVANCED SESSION

Interactive Session 4 3:30 PM – 5:00 PM

Bacterial Identification in EM

Scott Sutton, PhD, Vectech Pharmaceutical Consultants

I. Reviewing the Microbial Identification Methods that are Available to Support EM

- Gram Staining, the standard method basic to microbial identification, will be reviewed with emphasis on quality control of the operation
- Phenotypic Methods will be discussed in terms of different technologies involved and currently available to the QC microbiology lab
- Genotypic Methods available to the pharmaceutical QC microbiology lab will be reviewed

II. Evaluating the Relative Advantages of Phenotypic and Genotypic Microbial Identification Methods

- The different methods will be evaluated for the appropriateness of the technology in terms of cost, technical expertise required, value to the EM program, and value in an investigation.
- A basic User Requirement Document will be introduced

III. Interactive Exercise: Developing User Requirements

The participants will develop a preliminary User Requirement document (as a small group exercise) for different applications of microbial identification technologies in support of EM. These will then be presented and discussed in the group as a whole

Participants will take home the following bonus information:

A copy of the FDA 2004 Aseptic Processing Guidance Document, a limited number of relevant review articles, and a copy of the article "Microbial Identification in the Pharmaceutical Industry" by Sutton, S.V.W. and A.M. Cundell. Pharm Forum. 2004

Interactive Session 5 3:30 PM – 5:00 PM

Effective Elements of a Successful Disinfectant Validation Program

Jim Polarine Jr., MA, Technical Service Specialist, STERIS Corporation

I. How to Ensure Your Disinfectant Validation Program is a Success

- Learn disinfectant testing methodologies
- Review "real world" examples of disinfectant efficacy tests
- Increase awareness of pitfalls encountered during testing

II. Troubleshooting Problems Related to Disinfectant Efficacy Testing

- Problems associated with porosity of substrates
- Neutralizers that are toxic to cells
- Recovery steps that give problematic results

III. Regulatory Guidelines Related to Disinfectant Validation

- USP <1072> informational chapter
- New Aseptic Processing guidelines
- ISO guidance documents

IV. Interactive Exercise: Troubleshooting a Protocol

Participants will be given a disinfectant validation protocol and asked to troubleshoot the documents for possible flaws. There will be an analysis and discussion of the protocols with a focus on improvements.

Interactive Session 6 3:30 PM – 5:00 PM

Risk Based Approaches in EM

Mike Edgington, M.Sc, CEO Edgington Associates, BV Sassenheim the Netherlands

I. What's Risk and How do we Identify it?

- Risk analysis; when is the product really at risk
- Process risks, personnel risks

II. Hazard Analysis at Critical Control Points (HACCP) Approach

- Building the HACCP Team
- Who should be included team
- Get out of the office and look
- Designing the EM program

III. Using Data to Control the Risk?

- Convert data into knowledge
- Using knowledge to eliminate problems
- Avoid the additional monitoring approach
- More is not better
- Trending, annual review
- Be ruthless limit the EM sample locations to those that give controlling data

IV. Interactive Exercise

- Environmental Monitoring (EM) gone MAD !
- Attendees will comment on the scope of an actual EM program to determine whether it is valuable information or over kill.

Participants will take home the following information:

A key point checklist on how to establish an EM program based on risk assessment.

7:30 AM – Continental Breakfast

7:30 AM – Interactive Breakfast Session

Identifying EM Trends

Betty Seawell, PhD., Director QA/QC,
Monsanto Company



This session will address an approach to trending EM results obtained in various surveillance programs. Potential sources of concern will be highlighted. Recommendations shared with ways to enhance trending program to improve the ability to detect potential shifts in patterns of both numbers of excursions and the potential causes of excursions. The need to adjust alert and action levels based upon trending results will be discussed.

- See some examples of trending EM results
- Discuss interpretation of various trending patterns
- Gain insight into what might be an indication of an adverse trend
- Discuss what the FDA recommends on setting alert and action limits based upon trends

Interactive Session 7 8:30 AM – 10:00 AM

Microbial Detection Using Real-Time PCR and MicroSeq® DNA Sequencing for Microbial Identification

James L. Bruce, Product Manager, Applied Markets Division, Applied Biosystems

I. Real-Time PCR for Microbial Detection

- Learn the theory of real-time PCR
- Learn how to use AB Real-time PCR system and analysis
- Learn about the analysis software

II. PCR and DNA Sequencing

- Learn the theory of PCR
- Learn the theory of DNA sequencing and application for microbial identification
- Learn about phylogenetics

III. MicroSeq® Microbial Identification System

- Hands-on simple work flow exercise of the MicroSeq® system
- Learn about sample types and how to prepare samples for PCR and DNA sequencing
- Learn about the MicroSeq® identification kits
- Learn the easy steps to operate thermal cyclers
- Learn the theory and operation of DNA sequencer systems

IV. Gain Hands-on Experience of the MicroSeq® Software Analysis Program

- Learn the process of automated sequence analysis and identification
- Gain an understanding and theory behind data quality measurements (Quality Scoring)
- Learn how to build custom libraries
- Create custom reports
- Learn how to import and export data
- Learn about tracking and trending using the MicroSeq® software
- Review identification reports and discuss data interpretation

ADVANCED SESSION

Interactive Session 8 8:30 AM – 10:00 AM

Evaluation of Microbial Identification Methods for Pharmaceutical Manufacturing – a Practical Approach

Stacy O. Montgomery, Ph.D., Director, Global Marketing, Biolog Inc.

I. Identification of Microbial Contaminants

- Critical aspects of EM and Quality Assurance programs.

II. Choosing Methods

- Profound impacts on a company's ability to ensure products are manufactured in a state of environmental control, as well as ability to investigate root cause in the event of product contamination.

III. Basic Technology Behind Major Commercial Identification Systems Including:

- Phenotypic Systems (bioMerieux Vitek and Vitek 2 Compact, MIDI Sherlock, Biolog MicroStation and OmniLog)
- Genotypic Systems (Applied Biosystems MicroSeq DuPont Qualicon RiboPrinter)

IV. Exploring Evaluation Criteria Necessary to Determine Appropriate ID System for Your Laboratory and Level of Throughput

- Accuracy, Reproducibility, Cost of Platform, Cost per Sample, Automation, Time to Result, Ease of Use, Ease of Interpretation
- Reviewing the importance of Microbial Identification databases including "why and how" to grow your own
- Reviewing the recent FDA Aseptic Processing Guidance and what impact it may have on your choice of identification methods
- Reviewing the differences between species level identification vs. strain level characterization.

Friday, August 25, 2006
Post-Conference 90-Minute Sessions

- Determining when strain characterization is necessary and discuss current available methods

Interactive Session 9 8:30 AM – 10:00 AM
Understanding Both 21 CFR Part 11 (FDA) and Annex 11 (EU)

Fred Kazarian, Project Manager, Novatek International

I. FDA and International Requirements

- Understanding what 21 CFR Part 11 regulations mean
- Understanding what Annex 11 regulations mean
- Learn what 21 CFR Part 11 requirements mean in terms of software features
- Learn what Annex 11 requirements mean in terms of software features

II. Difference Between Annex 11 and Part 11

- Which requirements overlap?
- Which requirements conflict?

III. Commonalities Between Annex 11 and Part 11

- Making a system work for both the FDA and the EU
- What goes into an inter-site compliant system?
- Effect of time zones on audit trails and user logs

IV. Interactive Exercise

10:00 AM - 10:30 AM – Refreshment Break

ADVANCED SESSION

Interactive Session 10 10:30 AM – 12:00 PM
Challenges and Considerations When Implementing an Electronic EM Data Management System.

George M. Levinson, President, Compliance Software Solutions Corp

I. Automating an EM Program

- Understanding and defining the key elements of a documented environmental control program
- Gaining insight into industry trends, regulatory requirements and current compliance challenges faced by manufacturers
- Determining system requirements, and understand the needs of end-users and management

II. Trending, Reporting and Analyzing the Data

- Learning the benefits of trending data
- Recognizing what the trends are telling you
- Understanding the graphing tools and what you need to know about them

III. Selecting the Right Environmental Data Management System

- Understanding the criteria for selecting a suitable software program solution
- Learning about automation options, and their respective strengths and weaknesses
- Creating vendor selection criteria and audit requirements
- Determining what documentation will be needed
- Defining training needs and resources

IV. Implementation and Validation of Your Solution Option

- Understanding license and maintenance / support of your software
- Configuring the software now, and in the future
- Reviewing the impact that 21 CFR Part 11 has on your decision to automate
- Knowing what is needed to perform the IQ, OQ, and PQ
- Learning what to look for in security options

Interactive Session 11 10:30 AM – 12:00 PM

Case Studies: Pharmaceutical Water Systems: Design, Operation, Validation and Instrumentation

Al Hewing, Director Validation Compliance, AAC Consulting Group

I. Types of Water Systems

- Discuss PW and WFI water systems
- Briefly chat about their specifications and usage

II. Design and Operation of Water Systems

- Talk about operation of water treatment equipment
- Look at water treatment issues such as welding, passivation, rouging, aggressive water
- Chat about distribution loop equipment and operation

III. Validation

- Discuss relationship of specifications to validation
- Delineate requirements for IQ, OQ and PQ

IV. Water System Monitoring

- Discuss grab sampling versus on-line monitoring
- Learn about laboratory testing issues (USP, calibration tolerance)
- Discuss on-line conductivity, pH and TOC

V. Case Studies

- Discuss on-line instrument data storage
- Evaluate sample point placement
- Learn about RO normalization basics

Friday, August 25, 2006
Post-Conference 90-Minute Sessions

- Focus on Pseudomonas control

VI. Interactive Exercise

- Using actual pressure, flow, TDS and temperature data, attendees will normalize a reverse osmosis system, deciding when the system should be chemically cleaned

Interactive Session 12 10:30 AM – 12:00 PM

Storage and Distribution Loop Design- Rouging, Biofilm and Microbial Status and Sampling (Part 2)

Bob Livingston, Chief Technical Officer, Arion Water, Inc.

I. The Relationship Between Higher Water Quality and Microbial Control

- Water quality that may be utilized to control microbiological proliferation continuously without sanitization
- Improving Purified water quality facilitates wider applications, such as laboratory, research, pilot plant Water Qualities
- Confusing Regulatory Quality Requirements with much higher OBTAINABLE water qualities
- WFI/HP (Highly Purified) / Purified

II. Distribution Loop Design Options and Their Impact on Microbial Status

- Learn why materials of construction should not impact microbial activity
- Understand why flow velocity does not impact microbial activity
- Selecting Use Point configurations and important relationships between pipe sizing, water usage and number

- & size of Use Points and its impact on microbio fluctuations
- Learn Sample valve design configuration options and do's and don'ts of proper utilization of hoses

III. Microbiological Profiling of the Distribution System and Corrective Action for Out of Specification Anomalies

- Sampling strategies for differentiating the microbio
- quality of the product water vs. water in distribution vs. the use points
- Case studies detailing why hot water sanitizations do not solve microbial problem
- Proper distribution design that will prevent microbiological proliferation without sanitization
- Evaluating sanitization strategies and their surprising microbiological results

IV. Distribution Loop Materials of Construction

- Establishing why plastic is becoming the cGMP choice for Purified Water distribution loops
- Pro's and con's of 316 Stainless Steel vs. polymeric plastics
- Causes of rouge, measuring the extent of rouge, the need to passivate and prevention methods to avoid passivation

Participants will take home the following bonus info.

Take home appropriate Water Sampling SOP's and rinsing recommendations and sample preservation techniques for Bacteria samples, Endotoxin samples, TOC samples, Ion analysis and Metals analysis

12:00 PM – Close of Conference

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Environmental Monitoring (At-A-Glance)

August 23-25, 2006 – Washington DC

WEDNESDAY, AUGUST 23, 2006

7:30 AM – Conference Registration & Continental Breakfast

Pre-Conference Half-Day Workshops A-D 8:30 AM – 12:00 PM

WORKSHOP A (Abraham)

Establishing A New EM Program "A Complex System Simplified"

WORKSHOP B (Livingston)

Water System Design - A Continuous Ambient Operation without Sanitization (Part1)

WORKSHOP C (Jaisinghani)

The Cleanroom Design/Build Process and End User, QC/QA Role in the Process

WORKSHOP D (Lewis-Rogers)

Principles of EM For Isolator Systems



12:00 – Lunch for Pre-Conference Workshop Participants

12:00 – Main Conference Registration

Main Conference General Sessions 1:00 PM – 5:15 PM

1:00 PM Chairperson's Welcome

1:15 PM (Hardiman)
Establishing an EM Program

2:00 PM (Bruce)
Application of Genetic-Based Methods for Microbial EM Programs

2:45 PM (Edgington)
The New Draft Of Annex 1, What Does It Mean For Me?

3:30 PM Refreshment Break

3:45 PM (Hallworth)
Non-Viable Particle Counting

4:30 PM (Vajda)
Exploring the Benefits of Establishing a Hazard Analysis and Critical Control Point (HACCP) Philosophy in a Early Stage Pharmaceutical Environment

5:30 PM – 6:30 PM Networking Cocktail Reception



THURSDAY, AUGUST 24, 2006

7:30 AM – Continental Breakfast

7:30 AM (Lewis-Rogers)
Interactive Breakfast Session-
Minimizing Regulatory Risk:
Meeting FDA Requirements



Main Conference Half-Day Workshops E-H 8:30 AM – 12:00 PM

WORKSHOP E (Seawell)

An Approach to In-Depth Root Cause Analysis and CAPA for Adverse EM Result and Sterility Test Positives

WORKSHOP F (Polarine)

Microbial Control for Regulated Manufacturing Facilities: Application and Validation Issues

WORKSHOP G (Sutton) (ADVANCED SESSION)

Microbial Methods Used For EM and the Impact of Method Variability

WORKSHOP H (Vajda)

Case Study: Developing an Effective Cleaning Validation Master Plan (CVMP)

12:00 – Luncheon

Main-Conference 90-Minute Sessions 1:30 PM – 3:00 PM

SESSION 1 (Lewis-Rogers)
Are Disposables Meeting The Requirements Of Your EM Program?



SESSION 2 (Montgomery) (ADVANCED SESSION)
An Overview of Methods for the Identification of Filamentous Fungi

SESSION 3 (Edgington)
EM Performance Qualification

3:00 PM – 3:30 PM Refreshment Break

Main-Conference 90-Minute Sessions 3:30 PM – 5:00 PM

SESSION 4 (Sutton) (ADVANCED SESSION)
Bacterial Identification in EM

SESSION 5 (Polarine)
Effective Elements of a Successful Disinfectant Validation Program

SESSION 6 (Edgington)
Risk Based Approaches in EM

5:00 PM – Close of Day Two

FRIDAY, AUGUST 25, 2006

7:30 AM – Continental Breakfast

7:30 AM (Seawell)
Interactive Breakfast Session
Identifying EM Trends



Post-Conference 90-Minute Sessions 7-9 8:30 AM – 10:00 AM

SESSION 7 (Bruce)

Microbial Detection Using Real-Time PCR and MicroSeq® DNA Sequencing for Microbial Identification

SESSION 8 (Montgomery) (ADVANCED SESSION)

Evaluation of Microbial Identification Methods for Pharmaceutical Manufacturing- A Practical Approach

SESSION 9 (Kazarian)

Understanding Both 21 CFR Part 11 (FDA) and Annex 11 (EU)

10:00 AM – 10:30 AM Refreshment Break

Post-Conference 90-Minute Sessions 10-12 10:30 AM – 12:00 PM

SESSION 10 (Levinson) (ADVANCED SESSION)

Challenges and Considerations when Implementing an Electronic Environmental Monitoring Data Management System

SESSION 11 (Hewing)

Case Studies: Pharmaceutical Water Systems: Design, Operation, Validation and Instrumentation

SESSION 12 (Livingston)

Distribution Loop Design, Microbial Status and Sampling of Pharmaceutical Water Systems

12:00 PM – Close of Conference

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Thursday, August 24, 2006

Interactive Breakfast 7:30 AM (please check box if you plan to attend)

Main Conference Half-Day Interactive Workshops:

8:30 AM – 12:00 PM

E F G (ADVANCED SESSION) H (Choose one)

Main Conference 90-Minute Interactive Sessions

1:30 PM – 3:00 PM

1 2 (ADVANCED SESSION) 3 (Choose one)

3:30 PM – 5:00 PM

4 (ADVANCED SESSION) 5 6 (Choose one)

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