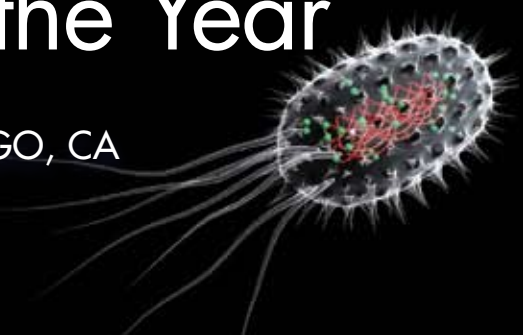


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NOVEMBER 6-8, 2007 • U.S. GRANT HOTEL • SAN DIEGO, CA



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SESSION HIGHLIGHTS:

- **CASE STUDY: How to Get Same-Day Sterility Test Approval**
Gary Gressett, MBA, Senior Manager, Corporate QA, Alcon Laboratories
- **CASE STUDY: Validation & Regulatory Approval of Sterility Testing with a Rapid Microbial Detection Method**
Ann Warford, DrPH, ABMM, QA Product Manager, Media/Fermentation, Microbiology/Virology SME, Bayer Healthcare
- **SPECIAL FEATURE: Half-Day Environmental Monitoring Focus Session**
By Eli Lilly, Novatek, Accugenix, and Genentech

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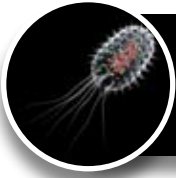
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Microbiology Event of the Year

TUESDAY, NOVEMBER 6, 2007

7:30 AM – Conference Registration and Continental Breakfast

8:30 AM - 12:00 PM
GENERAL SESSIONS

8:30 AM – Chairperson's Opening Remarks

8:35 AM - 9:15 AM

Laboratory Inspection Trends- What You Need to Know Before Your Next Audit

Peter G. Amanatides, M.S. - Director of Quality, Site Support, DSM Pharmaceuticals, Inc.

This talk will focus on inspection trends and techniques used by investigators to evaluate the state of compliance within laboratories, focusing primarily on microbiological laboratories. We will review common laboratory observations and what can be done to avoid these in your laboratories. The focus of the discussion will be on preparing the laboratory, presenting the laboratory, and interacting with investigators.

- Understand how auditors conduct an inspection of the laboratory
- Learn how to best prepare the facility, personnel, and yourself for your next inspection
- Understand the critical areas of concern for auditors related to laboratories
- Assist in prioritization of audit risk

9:15 AM - 10:00 AM

Use of the Bactec 9240 for Sterility Testing of In-process Fermenter rFactor VIII Cells and Fermenter Media Samples: Validation and Regulatory Approval

Ann L. Warford, DrPH, ABMM, QA Product Manager, Media/Fermentation, Microbiology/Virology SME, Bayer HealthCare

The Bactec 9240 microbial detection system was validated in order to implement a daily monitoring system for the continuously perfused and harvested rFVIII producing fermenters and the fermenter media with a rapid microbial detection method. The Bactec 9240 (Becton-Dickinson, Sparks, MD) is a CDRH type I detection method approved by the FDA in 1992. It is an automated, continuously monitored culture system used for rapid, sensitive detection of microbes in blood and other cellular body fluids. The application of the Bactec 9240 for mammalian cells and media is similar.

The Bactec system was compared to the 14-day USP sterility test method since Bactec replaced the twice weekly USP sterility testing of the fermenters.

- The validation was performed according to the guidelines of the PDA Technical Report No. 33 evaluating repeatability precision, specificity, limit of detection, sample suitability and system suitability and passed recommended acceptance criteria
- Regulatory submission was made and approval received - EMEA, FDA, Canada, Australia, New Zealand, and several other agencies world-wide
- Bactec 7-day Sterility for Fermenter samples (cellular) and 4-day Sterility for Fermenter media sample testing were implemented in Summer 2004 successfully
- Regulatory agency questions and hindsight- lessons learned from this process for improved future rapid microbiology validations & submissions:
 - Prevalidation steps
 - Vendor participation and support
 - Selection of local site specific microbes
 - Number of replicates
 - Robustness protocol

10:00 AM - 10:30 AM – Exhibit Viewing and Refreshment Break

10:30 AM - 11:15 AM Risk Assessment Tools for Pharma Assessing and Managing Risk

Herb Anthony, B.S. Chemistry, QA Senior Training Manager, MedImmune Inc.

I. Quality Risk Management Process

- Establishing a Team
- Responsibilities
- Defining the Problem
- Scoring

II. Assessment Tools

- FMEA (severity, occurrence, detectability)
- Process Mapping
- Process Mapping Exercise

III. Risk Review

- Establishing acceptance criteria
- Determining if Root Cause was established
- Monitoring and reviewing events

IV. Interactive Exercise:

Participants will create a process map using information given to them as well as brainstorming.

11:15 AM - 12:00 PM

Taking the Mystery out of Media Runs

Robert J. Pallo, BA, MA., Manager, Pharmaceutical Sciences Operations, Fill and Finish Operations, Allergan

This talk will educate attendees on how to design a media run, determining the number and frequency of runs, and determining media run durations and run sizes. We will also discuss:

- Line speeds and container sizes -What are the pitfalls of slow speeds vs fast speeds? What if your line typically produces a variety of fill sizes?
- A word about media- anaerobes and aerobes and special circumstances (like nitrogen blanketing)
- What should be incubated- reject units? Cosmetic defects?
- Learn what the results mean: what constitutes a problem? What should you do if you have a positive?

12:00 PM - 1:30 PM – Exhibit Viewing and Lunch

1:30 PM - 2:15 PM

Investigation of Sterility Test Failures

Jeanne Moldenhauer, Vice President, Excellent Pharma Consulting

Sterility test failures happen at a very low rate of occurrence. As such, many companies do not formalize the procedures used to perform the investigation, nor do they develop a level of expertise in this type of investigation. Areas of discussion include:

- An overview of the types of considerations to be made in performing this type of investigation
- Case studies from a variety of real-life investigations
- How some of these investigations have been assessed by regulatory investigators

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Microbiology Event of the Year

TUESDAY, NOVEMBER 6, 2007 & WEDNESDAY, NOVEMBER 7, 2008



WEDNESDAY, NOVEMBER 7, 2008

Special Half-Day Focus on Environmental Monitoring

2:15 PM - 3:00 PM

Microbiological Services – An Overview of Typical Laboratory Testing

Clifford Bailey, Senior Microbiologist, Sterility Assurance Group, Eli Lilly and Company

Key types of testing will be discussed such as compendial testing, testing performed to support routine manufacturing operations, and testing performed to support the laboratory operations.

- Routinely performed lab tests and the tests required to support them
- Key regulatory elements of lab operation
- Build quality into lab operations

3:00 PM - 3:30 PM – Exhibit Viewing and Refreshment Break

3:30 PM - 4:15 PM

Growth Promotion of Microbiological Media (How to Re-Invent the Wheel and Keep Your Regulatory Group Happy)

Rick Jakober, Vice President Laboratory Services, Perritt Laboratories, Inc.

- Harmonized growth promotion requirements in USP and EP
- Traditional growth promotion before harmonization
- Compendial requirements for media after harmonization
- An overview of cultures, culture storage, and low-level inoculum (in-house and commercial options)

4:15 PM - 5:30 PM

Bacterial Endotoxin Testing Using LAL Methods

Jacqueline Hansen, Ph.D., Manager – QC Microbial Science & Technology, Wyeth Biotech

This presentation will provide an overview of current endotoxin testing methods that utilize the Limulus Amoebocyte Lysate (LAL) reagents, including: gel clot, kinetic turbidimetric, and kinetic chromogenic methods. Key concepts of performing and validating an LAL assay will be discussed, with the overall benefits of the presentation to include:

- Similarities and differences between the LAL test methods
- How to structure a validation protocol for endotoxin testing using an LAL method
- Regulations for endotoxin test methods

5:30 PM – 6:30 PM

Networking Cocktail Reception



7:15 AM – Continental Breakfast

8:00 AM - 9:00 AM

Developing an Effective Environmental Monitoring Program and Meeting Regulatory Requirements

Aaron Hubbell, Bioprocess Research and Development Biologist, Eli Lilly and Co.

What is environmental monitoring? What are the regulatory requirements? How do I develop my program? What if I don't do aseptic processing – do I still need an EM program? What sorts of tests and equipment should I use? How do I ensure that my program maintains compliance? What can I expect during a regulatory inspection of my environmental monitoring program?

This introductory session will answer all of these questions and more as attendees are given an overview of how to develop an effective and compliant environmental monitoring program. This session will cover the following areas:

- Regulatory expectations for an environmental monitoring program including FDA and EU considerations
- Aseptic vs. non-aseptic programs
- Risk-based program development: Tests, action levels, sample locations, sampling frequency
- Selecting test equipment
- Qualifying the program
- Easing the transition between qualification and routine monitoring
- Routine program surveillance: maintaining compliance and robustness
- Recent inspectional trends and hot topics
- References and resources

9:00 AM-9:45 AM

Challenges in Implementing an Electronic Environmental Monitoring Data Management System

Susan B. Cleary, Associate Director of Product Development, Novatek International

This presentation will discuss how to overcome the major challenges when implementing electronic environmental monitoring systems focusing on the management of data to control compliance and the facility. Understand what it takes to be successful

and overcome the pitfalls which can extend timelines and cost thousands of dollars. Learn what should be included in these systems and what critical factors are needed to ensure success. Areas to discuss include:

- Selecting the right system: software (OTS, customized, configurable, hybrid), GAMP validation (software categories, hybrid), vendor audit
- Pilot System: training, configuration, control log, UAT
- Validation including 21 CFR part 11: documentation, SOPs, IQ/OQ/PQ, risk assessment
- EM reporting: individual reports, statistics, report package

9:45 AM - 10:00 AM – Refreshment Break

10:00 AM-10:45 AM

Designing a Comprehensive, Genetics-based Microbial Identification Program for the QC Microbiology Laboratory

Grace Thornhill, Ph.D., Director of Scientific Development, Accugenix, Inc.

This presentation will discuss how sequencing, combined with strain-typing, make for a comprehensive microbial identification program that meets the regulatory, technical and business needs of the Microbiology laboratory. Additional topics of discussion will include the polyphasic approach to identification as well as the impact of limiting genotypic identification to failure investigations only.

- Discuss the key components required to implement a successful microbial identification program
- Understand the difference between microbial identification and microbial characterization
- Explore the perception that genetics-based methods are "overkill" for the pharmaceutical Microbiology lab

10:45 AM-11:30 AM

Establishing a Personnel Monitoring Program

Clifford Bailey, Senior Microbiologist, Sterility Assurance Group, Eli Lilly and Company

In this session, participants will gain awareness of all of the key elements for



Microbiology Event of the Year

WEDNESDAY, NOVEMBER 7, 2007

Special Half-Day Focus on Environmental Monitoring

a sound personnel monitoring program including: certification, routine monitoring, and de-certification. We will also cover:

- Regulatory requirements
- Why the evaluation of personnel plays a key part in the development of quality cleanrooms
- Points to consider in the design of a gowning room
- Gowns: disposable vs. reusable

11:30 AM - 12:15 PM

Investigations of Environmental Excursions

Carole Genovesi, Senior Manager, Environmental QC, Genentech, Inc.

This presentation will discuss the rationale for an environmental monitoring program, including definitions and limitations of the monitoring methods. Various procedures for the investigation of Alert and Action Limit excursions will be evaluated in relation to the limitations of the methods, possible impact on the manufacturing environment or product, and process simulation (media fill) results.

- Rationale for Environmental Monitoring
- Definitions of alert and action levels
- Regulatory observations for EM
- Responses to alerts and actions/risk assessments
- Relation of EM to media fills

12:15 PM - 1:00 PM – Exhibit Viewing and Lunch

1:45 PM - 5:00 PM

Group Excursion to Balboa Park

Join your colleagues for a 10-minute ride via motorcoach from the hotel to Balboa Park- the nation's largest urban cultural park. Home to 15 major museums, renowned performing arts venues, beautiful gardens and the San Diego Zoo, the Park has an ever-changing calendar of museum exhibitions, plays, musicals, concerts, and classes. And, of course, unique shopping, restaurants and casual outdoor dining. (See www.balboapark.org)



6:30 PM – Cocktail Reception



7:30 PM - 9:00 PM – Awards Dinner and Keynote Speaker

Evening Awards Dinner for the MICROBIOLOGIST OF THE YEAR 2007!

DINNER KEYNOTE ADDRESS:

Making Changes in Microbiology Easier Through Corporate Networking

Jeanne Moldenhauer, Ph.D., Vice President, Excellent Pharma Consulting

There is a new trend in implementation of rapid microbiological methods in pharmaceutical facilities. Companies are working together to try to achieve a common goal:

- Implementation of a new methodology
- The consortium approach to rapid method implementation
- The benefits of using a consortium
- Success stories and failures
- Food for thought

LAST YEARS AWARD RECIPIENT



Shown at left is **IVT's MICROBIOLOGIST OF THE YEAR 2006: Michael Miller, Ph.D., Senior Research Fellow, Manufacturing Science and Technology, Eli Lilly and Company** with **Phil Houle, IVT Microbiology Conference Producer.**

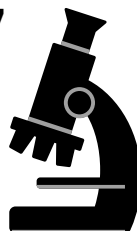
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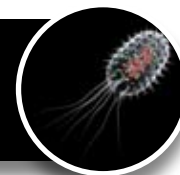
- Microbiological advances • Dedication to industry
- Achievements in microbiology • Industry contribution



IVT's awards program is designed to recognize and honor industry's most talented microbiology professionals. Join your fellow industry colleagues at this evening gala to welcome and congratulate this year's nominee for **IVT's MICROBIOLOGIST OF THE YEAR 2007 AWARD!** A cocktail reception will begin the festivities followed by a sumptuous dinner and awards ceremony.

Microbiology Event of the Year

THURSDAY, NOVEMBER 8, 2007



7:45 AM – Continental Breakfast

8:30 AM - 10:00 AM
SESSIONS 1-3

INTERACTIVE SESSION 1

Selection of Microbiological Methods for Purified Water Analysis

Rick Jakober, Vice President Laboratory Services, Perritt Laboratories, Inc.

This presentation will give attendees an overview of the different types of microbiological methods used to test water systems. Attendees will learn to develop a qualification process that will allow them to determine the optimal microbiological method for their water system.

I. Microbiological Regulations for Pharmaceutical Water

- USP and EP– current requirements
- Guidance documents and sources
- Regulatory expectations

II. Microbiological Qualification of a Water System

- What are we monitoring for?
- Selection of media
- Membrane filtration vs. pour plate
- Volume, incubation time, and temperature

III. Microbiological Monitoring

- Initial monitoring (OQ)
- Routine monitoring (PQ and beyond)
- Microbial identification
- Setting microbial specifications

IV. Interactive Exercise

Participants will discuss selected microbial monitoring regimens and analyze optimal microbial recovery strategies.

INTERACTIVE SESSION 2

Error Proofing: Eliminating Errors Before They Happen

Herb Anthony, B.S. Chemistry, QA Senior Training Manager, MedImmune Inc.

I. What is Error Proofing?

- General definition
- Poka-Yoke (POH-kah YOH-kay)
- Zero Quality Control (ZQC)
- Structured approach to quality

II. Why Do It?

- Defects that occur during one operation in a manufacturing or business process do not get passed on:
 - So that immediate action can be taken

- to resolve the situation
- To eliminate incorrect actions
- Minimize process variability

III. Sources of Errors

- Human
- Measurement
- Methods/procedures
- Materials
- Machines
- Environmental conditions

IV. 7-Step Problem-Solving Model

- Describe the problem
- Describe the current process
- Identify the root cause(s)
- Develop a solution and action plan
- Implement the solution
- Review and evaluate the results
- Reflect and act on findings

III. Interactive Exercise

Participants will analyze an error-filled procedure and use the tools learned in the training to rid it of errors.

INTERACTIVE SESSION 3

Contamination Control for Pharmaceutical, Biotech, and Medical Device Cleanrooms

Carole Genovesi, Senior Manager, Environmental Quality Control, Genentech, Inc.

I. Effective Contamination Control Program

- Training operators and managers
- Awareness of bioburden contributors
- Action plans to address contamination

II. Molds, Yeasts, Viruses, Prions, Vegetative Bacteria, & Spore Forming Bacteria

- Action plans to address excursions
- Correct products to control organisms
- Preventing future excursions

III. Guidelines Related to Bioburden Control

- USP 29 NF-24 General Chapter <1072>
- New Aseptic Processing guidelines (2004)
- ISO guidance documents (ISO 14698)
- IEST Guidance Documents
- Other current guidance and trends

IV. Interactive Exercises

Real world excursion exercises to assess and determine the root cause.

10:00 AM - 10:30 AM – Exhibit Viewing and Refreshment Break

10:30 AM - 12:00 PM
SESSIONS 4-6

INTERACTIVE SESSION 4

Impact and Changes in the New Harmonized Microbial Limits Tests

Marc Glogovsky, S.M. (NRM), Sr. Business Development Manager, EMD Chemicals

I. Enumeration Methods

- Methods for determination of CFU in non-sterile products
- Growth promotion methods and recovery requirements
- Suitability of counting methods
- Sterility & Negative control assessment
- Available analysis methods of non-sterile products

II. Tests for Specific Organisms

- Discussion of monograph requirements
- Group formerly known as “Fab Four” is now “Super Seven”
- Selection of culture media, addition and subtraction of new/old media
- Growth promotion and qualitative properties of culture media
- Flow charts of new harmonized microbiological assays

III. Microbiological Attributes

- Brief overview of nature, use, application, and microbiological properties of products

IV. Interactive Exercise:

Participants will view all new media for harmonized MLT tests. Participants will be able to discuss requirements of new harmonized tests as it pertains to their products. Objectionable organisms will be evaluated and discussed for non-sterile preparations and products.

INTERACTIVE SESSION 5

Biological Indicators- Use and Abuse

Russ Nyberg, BS, BSED, MS, Director of Tech Support/ Biological Indicators, Raven Labs

I. Biological Indicators and Abuse

- Commonly used BI's and their intended use
- The Certificate of Analysis, 'intended use' testing performed by BI manufacturers
- Presentation of various examples of how some BI's are commonly being misused in various applications- emphasis is on Steam Sterilization



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THURSDAY, NOVEMBER 8, 2007

II. Specialty or Alternative BI's

- "Non-traditional" BI's will be presented and discussed
- Use of this type of BI may be more applicable to validation work where small lumens or tight areas need to be tested for BI lethality

III. Interactive Session

Group will apply information from above sessions to suggest proper BI use for "unique" validation situations and identify BI abuse in presented situations.

INTERACTIVE SESSION 6

Genotypic and Phenotypic Microbial Identification Systems: An Attempt to Compare Apples and Oranges

Grace Thornhill, Ph.D., Director of Scientific Development, Accugenix, Inc.

An in-depth comparison of the most commonly used microbial identification systems will be presented. How each system is suited to addressing the increasingly complex microbial investigations now routinely expected by the regulatory agencies will be emphasized. A review of current literature on the performance of selected identification systems will be offered.

I. Components of an Effective Microbial Investigation

- Regulatory expectations for performance of microbial investigations
- What questions should be asked and answered?
- What is the role that microbial ID plays in an investigation?

II. What is a Genotype? What is a Phenotype?

- Some basic definitions
- Are genotypic methods more accurate than phenotypic methods?

III. Phenotypic and Genotypic Microbial ID Systems: A Review

- Attributes of a Microbial ID system: Accuracy, repeatability, and data base coverage
- Review of MicroSeq, MIDI, Vitek 2 Compaq, Biolog
- Review of RiboPrinter, Diversilab

IV. Overview of Current Literature

- Four papers comparing different ID systems will be reviewed

V. Interactive Exercise: A Mock Investigation

Participants will use data from three different microbial ID systems to perform an investigation of a sterility failure.

12:00 PM - 1:00 PM – Exhibit Viewing and Lunch

1:00 PM - 2:30 PM
SESSIONS 7-9

INTERACTIVE SESSION 7 ▶ CASE STUDY A Case Study: How To Get Same-Day Sterility Test Approval

Gary Gressett MBA, Sr. Mgr., Corporate QA, Alcon Laboratories Inc.

I. Sterility Test Results the Same Day – A Case Study

- What is a sterility test and how long does it take to detect microorganisms?
- How do you construct a protocol to approve a one day test for sterility?
- Establishing acceptance criteria for a new instrument and microbiological methods
- Working team dynamics within QA, Mfg, Reg. Affairs, and Research – what happens in real life?
- Strategic approach to product and process selection using risk based analysis and ROI models to justify your project to management
- Real examples of manufacturing benefits and laboratory challenges experienced during the project up to FDA approval

II. Thinking "Outside the Box" for Rapid Micro Method Applications

- Evaluation of rapid methods for applications such as Inprocess Bioburden, system utilities, and Isolate identification
- How do you get started? Do you need a contract lab or consulting partner?
- Breaking barriers in perceptions of the need to continue classical micro methods, such as "That's the way we have always done it" or "What do we do if we find something?"
- Ongoing evaluation of continuous improvement projects in Microbiology

III. Interactive Exercise

Participants will consider the elements in their own laboratories, discuss where they can see improvements in their processes, and benefit from each other's experiences.

INTERACTIVE SESSION 8

Harmonized Compendial Microbiological Qualification for Non-Sterile Pharmaceuticals

Rick Jakober, Vice President Laboratory Services, Perritt Laboratories, Inc.

With harmonization looming in the US, EU and Japan, new pharmaceutical products will need to be qualified using these new methods, and many existing products will need to be re-qualified to meet the latest susa method requirements. This presentation will give attendees an overview of those requirements, discuss qualification of the harmonized methods, and map out a re-qualification strategy for existing products.

I. Overview of USP, EP and JP Harmonized Methods

- USP, JP, and EP – current requirements
- Guidance documents and sources
- Regulatory expectations

II. Microbiological Qualification using the Harmonized Methods

- Monographs and development of specification
- Qualification methods
- Suitability of the Counting Method
- Suitability of the Test Method
- What to do if it doesn't work

III. Re-qualification Strategy

- Master list of products and raw materials
- Criticality of materials
- Timeline

IV. Interactive Exercise

Participants will be given list of raw materials and products and determine master list and timeline for re-qualification of those materials.

SESSION 9

Prefiltration Bioburden

Clifford Bailey, Senior Microbiologist, Sterility Assurance Group, Eli Lilly and Company

I. What is Bioburden?

II. Review of Regulatory Requirements

- FDA
- USP
- EU

Microbiology Event of the Year

THURSDAY, NOVEMBER 8, 2007



III. Looking at the Total Picture When Developing a Bioburden Program

- Understanding your vendor and their abilities
- Shipping needs
- Storage requirements
- Dispensing

IV. Qualification of Bioburden Testing

- Growth promotions
- Sampling procedures (sterile vs. non-sterile sampling environments)
- How much do we test?

V. Setting Alert/Action Level

- What constitutes how we set our specifications
- Limits vs. levels

VI. When Do You Reject a Product?

2:30 PM - 3:00 PM – Exhibit Viewing and Refreshment Break

3:00 PM - 4:30 PM
SESSIONS 10-12

INTERACTIVE SESSION 10

Biological Indicators- Population Verification, 'Do's and Don'ts' for Traditional and Unique BI types.

Russ Nyberg, BS, BSEd., MS, Director of Tech Support/ Biological Indicators, Raven Labs

I. Problems to Avoid When Attempting In-House Population Verification Testing

- A review of USP Procedure, Viable Spore Count
- In-coming inspection acceptance criteria and population specifications
- Population VS resistance, importance in validation
- Common errors that can reduce your end result by as much as 1 Log or more
- Population assay procedure for metal BI carriers and unique or non-traditional BI's

II. Population Assay Interactive Exercise

- Using population assay equipment, a demonstration of a population assay emphasizing "Do's and Don'ts" will be performed. Demonstration equipment will be given to someone in the attending group from a drawing at session conclusion.

INTERACTIVE SESSION 11

Benefit From Real-Time Microbiology Results: Get Proactive

Pascal Yvon, Pharm.D., M.B.A., AES – Chemunex, Inc., C.E.O.

The detection of microbial contaminants during key steps in the pharmaceutical manufacturing process is critical to product efficacy and profitability. For example, cleanrooms are constantly challenged by potential contaminants in the air, on surfaces and on personnel. Efficient detection must combine speed, sensitivity, and accuracy, without compromise. Learn how to review the benefits of implementing a rapid method in your organization and present them to upper management.

I. How Long Does it Take to Get Traditional Microbiology Results? What is the Impact?

- It takes days and weeks to get results with traditional microbiology
- Getting the results after days or weeks impacts companies' productivity

II. What Does Rapid Methods Mean? What Technologies are Available?

- Rapid methods technologies will be introduced

III. What are the Benefits of Implementing a Rapid Method? Where Can it be Implemented?

- The benefits of using a rapid method will be presented

IV. Interactive Exercise

Participants will analyze real-life situations and define the benefits of implementing a rapid method in their company.

INTERACTIVE SESSION 12 ► CASE STUDY

A Rapid and Non-Destructive Method for Enumerating Microbial Contamination of Biopharmaceutical Manufacturing Processes: Technology to Successful Implementation

Don Straus, Ph.D., VP Research, Rapid Micro Biosystems

David Jones, Ph.D., Director of Technical Services, Rapid Micro Biosystems

Julie Schwedok, Ph.D., Principal Scientist, Rapid Micro Biosystems

Deb Brusini, VP Product Management, Rapid Micro Biosystems

I. Rapid Enumeration Technology – Replacing the Human Eye with Digital Imaging

- The spectrum of available rapid micro tests and deciding what is appropriate for your facility
- Growth Direct technology - the integration of imaging, software, and microbial growth - design principles that preserve all the benefits of culture without the detractors
- Automated detection and analysis in action via video
- Growth Direct performance for all the common micro applications

II. Case Studies of Key Biopharmaceutical Applications

- Testing of cell culture derived products
- Mycoplasma testing application
- "Real-life" example approach to the implementation of broad-based, multi-site rapid micro in a biopharmaceutical company

III. Validating a Rapid Micro System to Replace Culture

- Successful validation strategies for rapid microbiology methods
- Validation strategy and implementation with Growth Direct – the straightforward approach
- Current experiences of validation in action

IV. Interactive Session: Translating the Benefits of Rapid, Automated Testing into Dollars Saved for Your Company; Demonstrating a Solid Return on Investment

- Using selected case studies and an interactive tool, the attendee will learn how to develop the cost justification and return on investment for implementation of a rapid micro system from all angles. The attendee will learn how the cost benefit of the purchase will impact the whole production facility and organization rather than just the micro lab.

4:30 PM – End of conference

Thank You

The Institute of Validation Technology would like to thank the following Technical Advisor for her insight on this program:

*JEANNE MOLDENHAUER,
Excellent Pharma Consulting*

Institute of Validation Technology

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