ASEPTIC PROCESSING & STERILE PROCESSES

June 26 - 29, 2006 • NH Grand Krasnapolsky • Amsterdam, the Netherlands

Industry's Largest and Most Comprehensive Aseptic Processing Event

Hear Industry Experts From:

- Eli Lilly and Company
- Bayer Healthcare
- BIOQUELL
- Mar Cor Purification
- ISS Corporation
- Genentech, Inc.
- Baxter Pharmaceutical Solutions, LLC
- Vectech Pharmaceutical Consultants
- Technovation Systems Inc
- STERIS
- PharmSupply, Inc.
- World Heart, Inc.
- Validation Technologies, Inc.
- Clean Modules Ltd.
- GETINGE La Calhene
- International Lancer
- Shield Medicare Ltd.
- Lighthouse Worldwide Solutions
- Fresenius Product Partnering
- Facility Monitoring System

Featuring 10 Hands-On Stations Demonstrating Various Stages Of The Aseptic & Sterile Lifecycle

SPONSORED BY:

Shield Medicare · MF · ACCUGENIX

SUPPORTING PUBLICATIONS:

IVT Institute of Validation Technology · Journal of Validation Technology · Journal of GXP Compliance · Pharmaceutical Technology Europe www.ptemagazine.com · BioPharm International The Science & Business of BioPharmaceuticals

Monday, June 26, 2006
Pre-Conference Half-Day Workshops

7:30 AM – Conference Registration and Continental Breakfast

interactive Workshop A 8:30 AM – 12:00 PM
Developing an Effective Cleaning Validation Master Plan (CVMP) – A Case Study

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

I. Validation
- Defining the task
- Do's and don'ts
- 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
- Table of contents
- Critical sections
- Related documents
- Protocols and reports

V. Maintaining Validation
- Coping with change
- When to revalidate
- Streamlining

VI. Interactive Exercise:
Attendees will form teams and develop brief sections of a CVMP. An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

interactive Workshop B 8:30 AM – 12:00 PM
Energy Efficient Cleanroom Design for Pharma, Biotech, Medical Devices and Life Sciences

Raj Jaisinghani, President and CEO, Technovation Systems, Inc.

I. Review of ISO 14644, FDA cGMP and EU Guidelines
- Pressure
- Filter velocity
- Air changes per hour
- DQ/IQ/OQ and other guideline requirements
- Current draft guidelines

II. Master Plan
- Validation overview
- Design activities
- Build activities
- Develop user requirements: User specifications, validation and monitoring requirements, process requirements and cost compromises

III. Developing Design Specifications
- Translate user requirements into engineering design keeping ISO 1444-1, and cGMP, cGTP, and GXP guidelines in mind

IV. Airflow Rate Design
- Review of methods
- Dilution model
- Transient analysis, and computational fluid dynamics

V. Energy Efficient Air Conditioning and Air Handling Design
- Cost for conventional central air handling
- Cost for conventional distributed air handling with ACU bypass

VI. Environmental Monitoring
- Control set points alarms
- Actions and alert levels with energy considerations
- Actions and alert levels with cost considerations

VII. Interactive Exercise:
Requirements and design development with audience participation and speaker feedback on cost impact: audience fulfills role of end user, speaker fulfills role of design/build firm. Develop airflow rate requirement using Transient Model Analysis for various class cleanrooms with different processes.

interactive Workshop C 8:30 AM – 12:00 PM
Sterility Failure Investigation

Hope Deckard, Microbiology Process Laboratory Supervisor, Baxter Pharmaceutical Solutions LLC

I. Regulations
- MHRA, USP, 21CFR and FDA recommendations

II. Sterility Failure
- Lab investigation
- Facility investigation
- Bracketing
- Finding the root cause

III. Case Study Examples
- Laboratory failure
- Stability batch sterility failure
- Sterility failure

IV. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

Monday, June 26, 2006
Pre-Conference Half-Day Workshops

interactive Workshop D 8:30 AM – 12:00 PM

Utilizing Root Cause Analysis (RCA) and Corrective and Preventative Actions (CAPA) in Environmental Monitoring (EM)

J. Kirby Farrington, Ph.D. (RM/SM), Research Advisor-Microbiology, Eli Lilly and Company

I. FDA, EMCA, IMB and Other Regulatory Expectations
- Learn what is in the various regulations and guidelines
- Learn what an inspector will want to see

II. FDA's Science Based and Risk Approach to Environmental Control Issues
- Review the various publications outlining the new approach and program
- Participate in a discussion of what aspects of this approach applies to EM

III. The Basics of Establishing a Risk Based EM Program
- Hazard Analysis and Critical Control Points (HACCP)

IV. A Root Cause Analysis (RCA) of an EM Excursion
- The difference between probable and definitive root cause
- Methods useful in investigations
- What is the difference between an Out-of-Specification (OOS) and RCA?
- What is the end point of an investigation?

V. Corrective and Preventative Actions (CAPA)
- The relationship between RCA and CAPA
- In this case the chicken (RCA) comes before the egg (CAPA)
- Do not forget to show the preventative actions were effective

VI. Interactive Exercise:

The instructor will supply RCA and CAPA case studies involving aseptic manufacturing operations as well as non-sterile. The attendees are encouraged to bring examples. It is requested that any attendee-supplied examples be in power point and on a CD disk to facilitate display and audience viewing.

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

Monday, June 26, 2006
Main Conference General Sessions

12:00 PM – Main Conference Registration

1:00 PM

Chairperson's Opening Remarks

1:15 PM

Overview of the Design for Pharmaceutical, Biotech and Life Sciences Cleanrooms

Raj Jaisinghani, President and CEO, Technovation Systems, Inc.

An overview of the design/build process will be presented with special considerations for cGMP, cGTP, and GXP requirements.
- Impact of new cGMP and other FDA related requirements on design specifications
- DQ and IQ/OQ plans at design phase
- Construction protocols and project management
- Development of design specifications based on user specifications and the impact of user specifications on initial and operating costs

2:00 PM

Exploring the Benefits of Establishing a Hazard Analysis and Critical Control Point (HACCP) Philosophy in an 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.
- Cost benefit of early compliance
- Documentation for compliance
- The role of validation
- QA as a major player on the HACCP team

2:45 PM

From Training to Behavioral - Key for Asepsis

Dr. Thomas H. Agrait, I.E., Validation & Regulatory Team Director, ISS Corp.

This session focuses on the role of the training component for underpinning the level of competencies of the employees and associates to deliver an aseptic product.
- Historic signs
- Review cGMP of aseptic preparation
- Determine individual roles limits and referral systems
- Employee empowerment
- Raise an aseptic mind

3:30 PM – Refreshment Break

Monday, June 26, 2006
Main Conference General Sessions

3:45 PM
Design of an Environmental Monitoring Program to Meet the Requirements of the New Aseptic Processing Guidance

Jeanne Moldenhauer, Pharma Consultant, Vectech Pharmaceutical Consultants, Inc.

Issuance of the 2004 Aseptic Processing Guidance by FDA has clearly defined expectations of an environmental monitoring program. This discussion will talk about how one can address these issues with an existing system, as well as how to design a new system to meet these requirements. Additionally, it will discuss the types of inspection observations typically seen in an inspection of the environmental monitoring system.

- Learn current FDA expectations for an environmental monitoring program
- Understand the differences in expectations between the U.S. and other countries
- Determine how to update your program to meet these requirements
- Consider how to perform an assessment of existing systems to meet these requirements
- Decide what other resources are available for your use

4:30 PM
Microbial Contaminants – the USP "Specified Organisms" and the FDA "Objectionable Organisms"

Scott Sutton, Ph.D., Pharma Consultant, Vectech Pharmaceutical Consultants, Inc.

With the discussions of the harmonized microbial limits tests complete and the finalized chapter going into effect, it is useful to pause and compare the expectations and role of the compendia with those of FDA. Recommendations will be made on the manner in which to conduct risk analysis on the microorganisms found in non-sterile products.

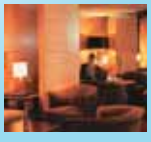
- Historical basis
- Objectionable organisms
- Index organisms
- Current divergent set of concerns

5:15 PM – Close of Day One

HOTEL INFORMATION

NH Grand Hotel Krasnapolsky
Dam 9
1012 JS Amsterdam, The Netherlands
Telephone: +31-20-554-9111
Fax: +31-20-622-8607
Website: www.nh-hotels.com

Call the hotel directly at the above number and mention IVT to receive the reduced room rate.



Tuesday, June 27, 2006
Main Conference 90-Minute Sessions

7:30 AM – Continental Breakfast

Interactive Session 1 8:30 AM – 10:00 AM
Use of a Comparability Protocol to Make Changes to Your Aseptic Facility

Jeanne Moldenhauer, Pharma Consultant, Vectech Pharmaceutical Consultants, Inc.

I. FDA Guidance on Comparability Protocols
- Learn what the FDA guidance requires for comparability protocols
- Learn how to use this guidance to support a change to an aseptic facility
- Gain insight into how to generate the data needed for the comparability protocol

II. Case Study 1: Qualifying a New Facility
- Designing an approach
- Meeting with FDA
- Submission of the protocol
- FDA outcomes

III. Case Study 2: Qualifying an Addition to an Existing Facility
- Designing an approach
- Meeting with FDA, should a pre-meeting be held?
- Submission of the protocol
- FDA outcomes

IV. Interactive Exercise:

The group will discuss different types of changes that might be made to an aseptic facility and then propose strategies for implementing these changes. The strategies proposed will be discussed and evaluated with the whole group. Each participant will receive a copy of the Comparability Protocol Guidance from the FDA. A list of other useful documents will also be provided, e.g., identification of FDA presentations on this topic.

Interactive Session 2 8:30 AM – 10:00 AM
Comparison of the FDA, EU, and Canada GMP Regulations with Respect to Aseptic Processing

Mitchell Tse, CQE, CQM, CQA, QA Validation Manager, Bayer Healthcare
Thomas P. James, Senior Quality Assurance Specialist, Bayer Healthcare

I. Manufacturing in and for a Global Market
- Understanding which guidelines apply to you
- What regulations are out there?
- Requirements versus guidelines
- New EU Annex 1 and FDA aseptic guideline

II. Highlights of Different Regulations
- HVAC requirements
- Environmental monitoring requirements
- Personnel training and qualification
- Cleaning requirements
- Sterilization and depyrogenation requirements
- Capping and container closure requirements
- Media fill requirements

III. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have. Additionally, a table will be provided to summarize the requirements of the different regulatory agencies.

Interactive Session 3 8:30 AM – 10:00 AM
Trouble Shooting Water Systems
J. Kirby Farrington, Ph.D. (RM/SM), Research Advisor-Microbiology, Eli Lilly and Company

I. Common Water System Problems
- Possible results
- Possible causes
- Investigation techniques
- Remedies for problems
- Preventative actions
- Alternative occupation options

II. Microbial contamination
- Possible results
- Possible causes
- Investigation techniques
- Remedies for problems
- Preventative actions

III. TOC/Conductivity Issues
- Possible results
- Possible causes
- Investigation techniques
- Remedies for problems
- Preventative actions

IV. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

Interactive Session 4 8:30 AM – 10:00 AM
Garment Characteristics and Cleanliness Evaluation
Raj Jaisinghani, President and CEO, Technovation Systems, Inc.

I. Review of Garment/Material Evaluation Methods
- Significance of garment cleanliness - why a garment needs to be processed in a cleanroom better than the cleanroom where the garment is to be used
- Garment/Material particle cleanliness methods – Helmke Drum and Body box – why these methods do not correlate
- Review of garment/material bio-burden measurement
- Methods specific detailed review of IEST-RP-CC003.3 – details of conducting such a test

II. Calibration of a Body Box
- Challenges in Body box design and importance of calibration
- Difficulties in obtaining meaningful samples from a Body box and the importance of the calibration factor
- Calibration method of Body box – learn about how to periodically calibrate the Body box and to interpret calibration results
- Results of two calibrations

III. Body Box Test Results on Garments
- Results for a well-cleaned and cleanroom packaged garment
- Results for a not so well-cleaned garment
- Results for a low particle emission well-cleaned garment material

IV. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

10:00 AM – 10:30 AM Refreshment Break

Interactive Session 5 10:30 AM – 12:00 PM
Establishing a Sterility Testing Program
Manpreet Bal, Senior Quality Assurance Specialist, Bayer Healthcare

I. Establishing a Program
- Testing environment: the conventional sterility test suite vs. sterility test isolators
- Environmental monitoring test methods
- Training of laboratory personnel

II. Test Methodologies and Requirements
- Media and incubation conditions
- Method validation – bacteriostasis and fungistasis
- Harmonization amongst USP, EP and JP

III. Interactive Exercise:
Participants will have an interactive question and answer period. This will be followed by an opportunity to design sterility tests and validation test plans.

Interactive Session 6 10:30 AM – 12:00 PM
Validation Discrepancy Investigation and Root Cause Analysis
Mitchell Tse, CQE, CQM, CQA, QA Validation Manager, Bayer Healthcare

I. Basics of Validation Discrepancies
- Investigation of validation discrepancies
- When can a validation discrepancy have potential product impact?
- Impact or no impact?
- Invalid vs. failed
- When to resume validation work when a discrepancy occurs

II. Investigating Your Validation Discrepancy
- Gathering facts
- Interviewing as soon as possible
- Finding causes vs. symptoms

III. Root Cause Analysis
- Makeup of investigation team
- Cause analysis tools
- Adequate documentation
- Corrective action

IV. Interactive Exercise:
Examples of validation discrepancies will be presented, and the group will brainstorm together to investigate these issues.

Tuesday, June 27, 2006
Main Conference 90-Minute Sessions

interactive Session 7 10:30 AM – 12:00 PM
Designing and Implementing an Effective Cleaning and Disinfection Program

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

I. How to Ensure Your Cleaning and Disinfection Program is Robust
- Disinfectant regulations
- Manufacturer's regulations
- Pharmaceutical, biotech regulations and medical device
- "Real world" examples of cleaning and disinfection programs
- Increasing awareness of elements that make cleaning and disinfection successful

II. Troubleshooting Problems Related to Cleaning and Disinfection
- Contact time
- Dilution rates
- Application
- Corrosion or the porosity of substrates

III. Safety Related to Application and Application Techniques of Disinfectants
- Safety of the concentrated disinfectant vs. the use dilution
- Application of disinfectant products in cleanrooms and controlled areas
- Frequency of application

IV. The Elements of a Successful Disinfectant Validation
- Regulations
- Testing

V. Interactive Exercise:
Groups will outline a cleaning and disinfection protocol that is appropriate for an aseptic filling suite.

interactive Session 8 10:30 AM – 12:00 PM
Microbiological Method Validation vs. Suitability

J. Kirby Farrington, Ph.D. (RM/SM), Research Advisor-Microbiology, Eli Lilly and Company

I. Review of Method Validation Requirements
- FDA
- EP

II. Review of Method Capabilities
- Plate count procedures
- Microbial limits tests
- Anaerobes
- Identification systems

III. Is There a Discrepancy Between Method Capability and Regulatory Expectations?
- Discrepancies
- Use of Hazard Analysis and Critical Control Point (HACCP)

IV. Interactive Exercise:
Participants will explore experiences with regulatory agencies regarding microbiological methods and specifications.

12:00 PM - Lunch

Tuesday, June 27, 2006
Main Conference General Sessions

1:00 PM
Chairperson's Opening Remarks

1:15 PM
Honing in on the Microbial Evaluation of Controlled Environments - USP <1116>

Hope Deckard, Microbiology Process Laboratory Supervisor, Baxter Pharmaceutical Solutions LLC

This presentation provides an overview of the microbial evaluation processes beginning with examining the controlled environments and facilities and ending with exploring FDA monitoring programs.
- Facility capability
- USP <1116>
- EM program attributes
- FDA favorite monitoring programs

2:00 PM
How Media Fill Investigations Have Evolved in Response to Regulatory Guidance

Carolyn Broughton, Ph.D., Senior Manager, Microbiology, Genentech, Inc.

Procedures addressing discrepancies in the manufacture of Current Good Manufacturing Practices (cGMP) material have become more formalized. This session focuses on media fill investigations within discrepancy management systems.
- Establishing standard policies for assessing, tracking and trending discrepancies
- Defining roles and responsibilities for investigations: Quality and manufacturing
- Developing the study plan and interpreting data
- Determining corrective and preventive actions
- Assessing impact of discrepancy on product quality

2:45 PM
Sanitization Techniques for Cleanrooms and Controlled Areas

Jim Polarine, MA, Technical Service Specialist, STERIS Corporation

This presentation will provide a background on antimicrobial regulations, technologies, and applications for cleanrooms. Additionally, key areas of disinfectant and sterilant chemistries and applications will be addressed. Common questions about the use of antimicrobial products in cleanrooms will be covered.
- Learn the most common chemistries used in cleanrooms
- Review "real world" examples of sanitization applications
- Determine how to apply sanitization products effectively
- Understand regulations affecting the use of antimicrobial products in cleanrooms

3:30 PM – Refreshment Break

Tuesday, June 27, 2006
Main Conference General Sessions

3:45 PM
Preparation of Pharmaceutical Waters
John J. Vajda BS, Vice President, Manufacturing, World Heart, Inc.

There are multiple types of water preparations described in the USP. This session will focus on preparation of WFI grade water but equally apply these methods for Purified Water. The focus will be on specific treatments and removal of impurities.

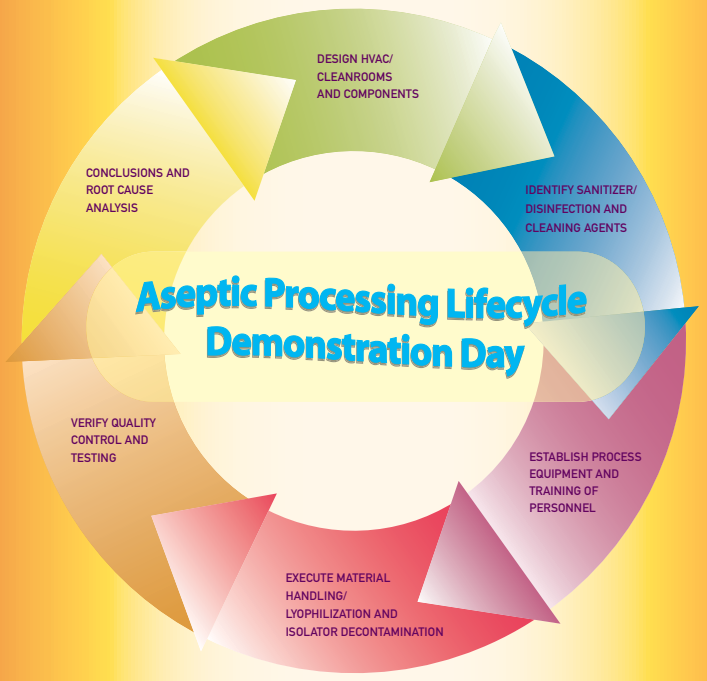
- Exploring the background of pharmaceutical waters
- Planning treatments for pharmaceutical waters
- Determining ion removal
- Establishing bacterial control
- Understanding the appropriate procedures

4:30 PM
Comparison of Microbial Identification Methods – Practical Approach
Scott Sutton, Ph.D., Pharma Consultant, Vectech Pharmaceutical Consultants

A review of the microbial identification methods that are available to support compendial testing will be presented to describe the state of the art within the pharmaceutical industry. Emphasis will be given to the preliminary screening of microbial isolates for cellular morphology, staining, and diagnostic biochemical reactions to either characterize the microorganisms or support decisions for using different microbial identification schema and the rapid microbial identification methods that are available. The relative advantages of phenotypic and genotypic microbial identification methods will be discussed within the context of practical laboratory limitations and current regulatory guidance.

- Screening of microbial isolates
- Biochemical reactions
- Phenotypic vs. genotypic microbial identification methods
- Limitations

5:15 PM - Close of Day Two



10 Hands-On Stations Demonstrating Various Stages Of The Aseptic & Sterile Lifecycle.

IMPORTANT! Due to the nature of the demonstrations, we kindly ask that all attendees be punctual. Please arrive by 8:30 AM. All stations will demonstrate on this schedule:

9:30 AM – 10:00 AM

10:05 AM – 10:35 AM

10:40 AM – 11:10 AM

11:10 AM – 11:40 AM – Refreshment Break

11:40 AM – 12:10 PM

12:15 PM – 12:45 PM

12:45 PM – 2:00 PM – Lunch

2:00 PM – 2:30 PM

2:35 PM – 3:05 PM

3:05 PM – 3:35 PM – Refreshment Break

3:35 PM – 4:05 PM

4:10 PM – 4:40 PM

4:45 PM – 5:15 PM

5:20 – Cocktail Reception

Aseptic & Sterilization Demonstration Day
Wednesday, June, 28, 2006 • Amsterdam, the Netherlands

FEATURING 10 STATIONS DEMONSTRATING VARIOUS STAGES OF THE ASEPTIC/STERILE LIFECYCLE

Demonstration Station 1

Modular Cleanrooms – The Fast, Easy and Clean Solution for any Clean Requirement

John Robinson, Managing Director, Clean Modules Ltd.

This demonstration provides an overview of possibilities and opportunities of cleanrooms and its components, designed and constructed on a modular approach. It shows how, based on customer's needs, the process from designing until validation takes place and which standards need to be taken into consideration.

I. Modular Cleanrooms vs. Conventional Cleanrooms
- General requirements for cleanrooms
- Standard ISO 14644 – Requirements and convenient cleanroom classes
- About the modular approach

II. The Process – From the Enquiry to the Validation
- Modular cleanrooms in the pharmaceutical industry
- Construction and validation
- Maintenance and service

III. Equipment and Components
- Panels, filters, windows, doors, etc.
- Transfer systems, change areas, air showers, etc.
- Isolators, laminar flow cabinets, etc.

IV. Examples
- NIBSC - Modular cleanroom
- Glan Clywd - Two-storied module
- University of Kiel - Cleanroom unit in a container

Demonstration Station 2

Dry Fogging as a New Technology to Disinfect Cleanrooms

Dominique Leclercq, Regional Sales Manager, Mar Cor Purification

Europe is preparing a new Biocide Directive and the use of carcinogenic or mutagenic chemicals such as Formaldehyde and Phenols is going to be limited very soon.

The Pharmaceutical industry is now investigating ways to find sporicidal substitutes to those particular chemicals that often validated for cleanroom disinfections.

- Hydrogen Peroxide/Per acetic Acid Based Chemicals and Properties
- Pharmaceutical Manufacturer's Requirements
- Available on the Market
- Efficiency Compared to Current Products
- Possible Applications
- HP/PAA Technology for Cleanroom Airborne Disinfection

Demonstration Station 3
Driving Forces of cGMP Cleaning

Geraldine Defrocourt, Validation Manager, GETINGE La Calhene
Miquel Lozano, GMP Washers Product Manager, Lancer France
Karel Rietveld, GMP Washing Specialist, Lancer Netherlands

Proper cGMP cleaning procedures for an adequate washing of pieces of equipment used for aseptic processing to be ready for further manufacturing steps in case of mono or cross contamination. You can see on our demonstration station that adapted baskets are necessary to cover quantitative and qualitative needs leading to controllable results complying with regulations.

I. The Role of the Parts Washer in the Cleaning Lifecycle
- System requirements
- Mechanical action

II. Parts Washing Applications
- Determining what parts are conducive to automated washing
- Limitations of automated parts washing
- Common parts washing applications

III. Inventory System Design
- What data is required for proper inventory system design
- How to optimize load patterns
- Important factors in proper inventory system design
- Ergonomics
- Loading
- Cross-functionality

Demonstration Station 4
Cleaning and Disinfection Techniques for Aseptic Processing

Karen Rossington, Marketing Manager, Shield Medicare Ltd

I.Cleaning and Disinfection
- Definitions
- What is contamination?
- Where does contamination come from?
- Affect on transfer disinfection for aseptic processing

II. Factors Affecting Transfer Disinfection
- Particles generated
- Affect of poor liquid transfer disinfection protocols
- Correct methods for liquid transfer disinfection

III. Aims of Cleaning
- Different products available
- When and how to clean
- Benefits of wiping

IV. Application of Disinfectants
- When and how
- Different disinfectants available
- Guidance from GMP
- Validation

Demonstration Station 5
The DPTE-BetaBag® System

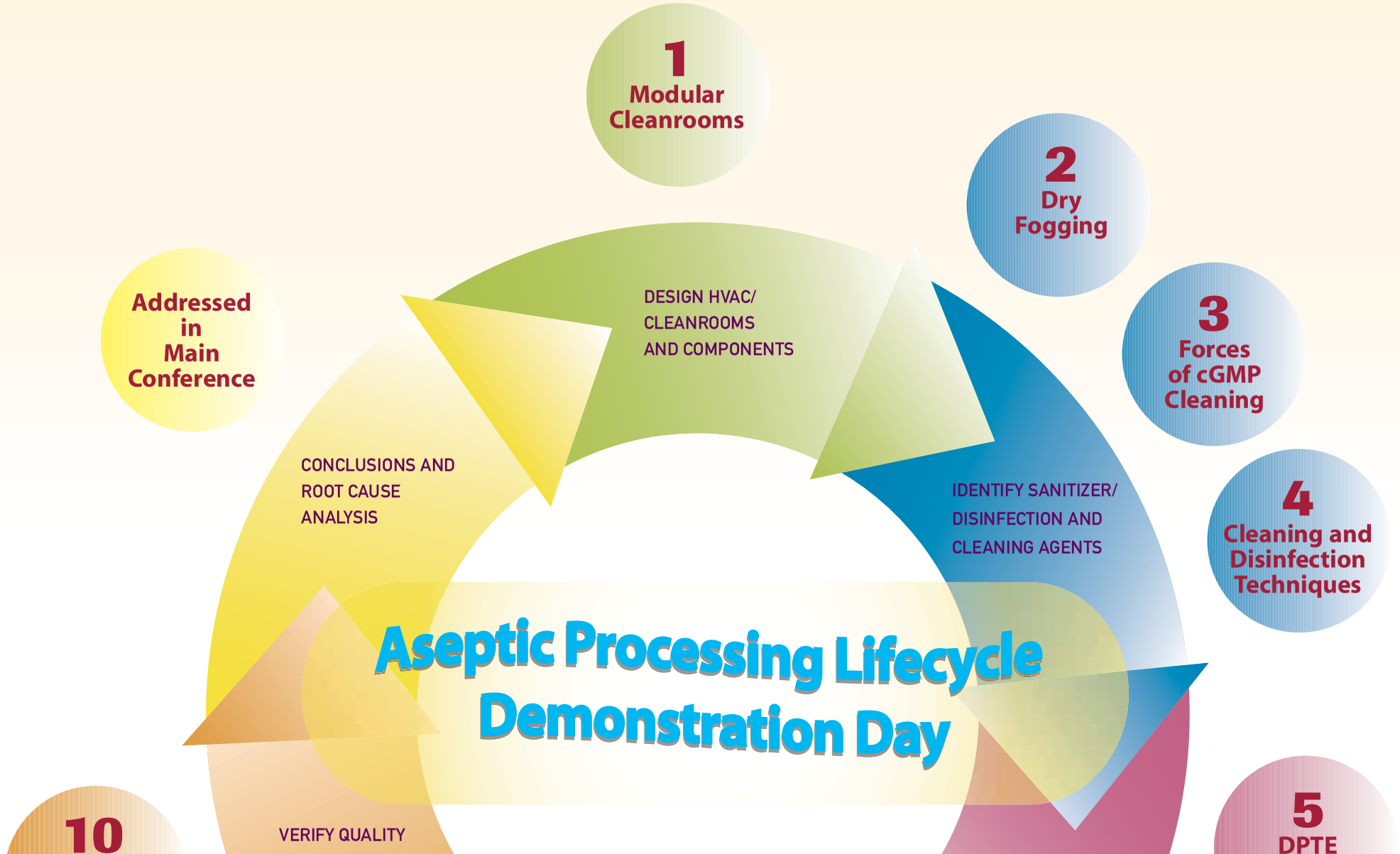
Didier Meyer, Marketing Manager, GETINGE La Calhene
Brigitte Lechiffre, Technical Sales Engineer, GETINGE La Calhene

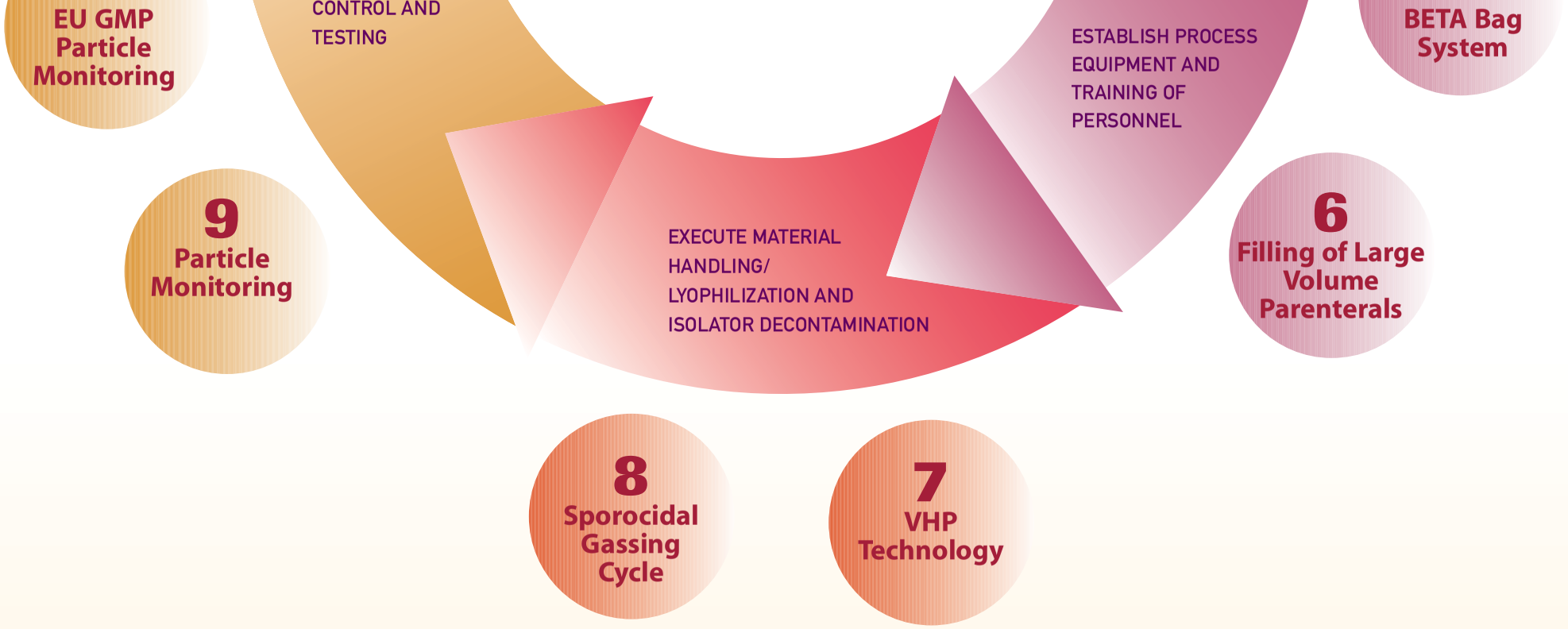
This demonstration will explore rapid transfer and dispensing of sterile closures, sterile powder and sterile liquid with disposable DPTE-BetaBag® System to an APA or a RABS or an isolator. The main benefits of this system are to avoid any cross contamination between the product, the operators and the environment. This allows individuals to deal not only with fragile product but also with also highly toxic product. With the "hands on" demo unit you will have the opportunity to try the system by yourself.

- Inlet of Pre-sterilised Items such as Filling Components into a Filling Line
- Inlet of Sterile Equipment into a Filling Line
- Inlet of Various Types of Semi-finished Product Packed in a Primary Packaging = DPTE BetaBag® Deals as Secondary Packaging
- Inlet of Monitoring Items such as Petri-dishes
- Evacuation of Waste
- Outlet of Production Samples for Microbiological Tests
- Outlet and Storage of Semi-finished Products
- Outlet or Inlet + Transportation + Storage of a Product such as Semi-finished Products

Aseptic & Sterilization Demonstration Day
Wednesday, June, 28, 2006 • Amsterdam, the Netherlands

FEATURING 10 STATIONS DEMONSTRATING VARIOUS STAGES OF THE ASEPTIC/STERILE LIFECYCLE





IVT
INSTITUTE OF VALIDATION TECHNOLOGY®

www.ivthome.com

IMPORTANT! Due to the nature of the demonstrations, we kindly ask that all attendees be punctual. Please arrive by 8:30 AM. All stations will demonstrate on this schedule:

8:30 AM – Continental Breakfast
9:00 AM – Demo Day Introduction
9:30 AM – 10:00 AM
10:05 AM – 10:35 AM
10:40 AM – 11:10 AM

Refreshment Break:
11:10 AM – 11:40 AM
11:40 AM – 12:10 PM
12:15 PM – 12:45 PM

Luncheon:
12:45 PM – 2:00 PM
2:00 PM – 2:30 PM
2:35 PM – 3:05 PM

Refreshment Break:
3:05 PM – 3:35 PM
3:35 PM – 4:05 PM
4:10 PM – 4:40 PM
4:45 PM – 5:15 PM
5:20 – Cocktail Reception

Demonstration Station 6

Aseptic Filling of Large Volume Parenterals – Stringent Requirements and Flexibility

Dr. Peter Kajtna,
Director, Pharmaceutical Projects,
Fresenius Kabi Austria

This presentation discusses an isolator protected aseptic filling process of pre-sterilized bags of large volume parenterals. The main focus of this equipment is to fill temperature sensitive solutions for infusions in bags of 50 ml up to 2000 ml. This semiautomatic line is flexible in changing the bag volume without affecting the sterile environment. Bag-materials can be varied according to the specific requirements of the products since the variable closing process (welding) of the filling tube allows handling with a lot of different materials. The contribution will cover strategies to combine the stringent requirements of aseptic processing of large volume parenterals with the flexibility required by a contract manufacturer.

I. Preconditioning of Primary Packaging
- Sterilization of bags by irradiation

II. Preconditioning of the Aseptic Equipment
- Sterilization of the isolator with H2O2
- Handling of sterile bags - material flow

III. Filling Concept
- Sterile filtration of the product
- The filling device
- The filling procedure
- The welding - HF or temperature

IV. Overwrapping Process
- Bags that are overwrapped in the cleanroom

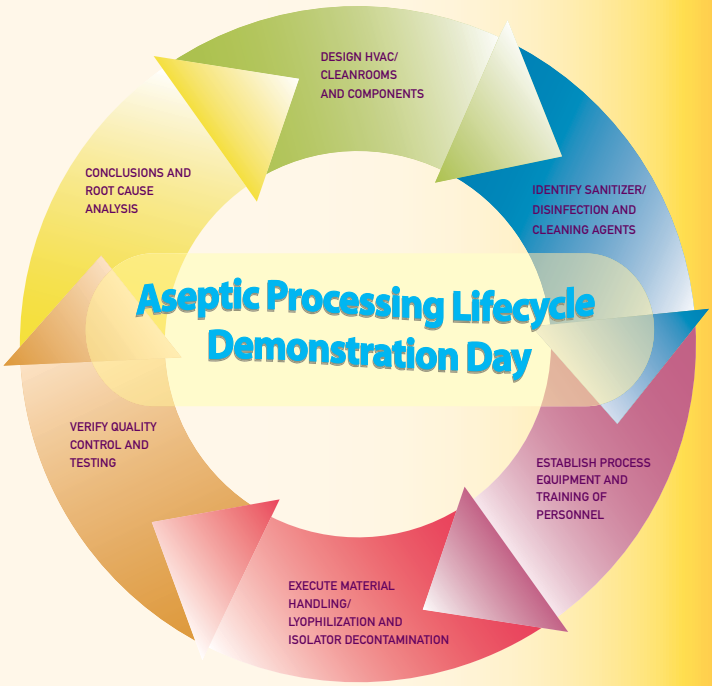
Demonstration Station 7

The Use of Vaporized Hydrogen Peroxide (VHP) Systems for Aseptic Manufacturing and Area Decontamination

Murray Nicholson - Application Development Manager, International, STERIS Limited, United Kingdom
Brian Jeffries – Pharmaceutical Solutions Engineer, Envair Limited, United Kingdom

The demonstration will provide an overview of decontamination technologies used within the pharmaceutical industry and the increasing use of vaporized hydrogen peroxide to provide solutions for aseptic production areas and enclosure applications. The presentation will be support by Envair Limited, who will provide examples of engineering design solutions of how VHP can be integrated.

- Aseptic Filling Lines
- Isolator Systems
- Pass Through Chambers
- Pass Through Hatches
- Cleanrooms



Small Group Round Robin Format Maximizes Interaction and Hands-On Learning!

Demonstration Station 8
Optimization of Hydrogen Peroxide, Sporicidal Gassing Processes, for Bio-decontamination of Aseptic Processing Separative Devices

James L Drinkwater, Process and Validation Director, Bioquell UK

Hydrogen peroxide vapor is a condensable gas that needs special considerations to fully optimize both efficacy for 6log [Kill] reduction in bio-contamination, and efficiency in cycle time. This demonstration considers key principles for system configuration, strategies that increase the speed of bio-contamination 'kill' and methods to reduce the gas residual removal stage (the longest part of any cycle).

I. Isolators
- Optimum system configuration
- Management of HEPA filter bio-decontamination

II. Restricted Access Barriers (RABS)
- Closed gassed RABS option
- Room gassed RABS option
- Key advantages of in-place feeder bowl – feed tracks 6log bio-decontamination

III. Cleanrooms
- Mobile system for room sporicidal gassing
- Remote gas generator system with fixed vapor delivery systems
- Sporicidal process regimes for room gassing

Demonstration Station 9
Particle Monitoring in Pharmaceutical Cleanrooms

Martin Derks, Operations Manager, Lighthouse Worldwide Solutions Benelux BV

Environmental monitoring is an important aspect of regulatory and quality control in the production of pharmaceuticals. The manufacturing environment must be controlled and monitored during the production of drugs.

I. A Compliant Monitoring System
- The regulation
- Critical terminology
- Sample locations; Risk analysis
- Where to monitor

II. Regulatory Attitude to Facility Monitoring
- Project lifecycle development and validation
- 21 CFR part 11
- Validation document

III. Process Analytical Technology (PAT)
- Monitoring for compliance
- Reporting
- Using the measurement data

IV. Classifications
- Levels and limits
- Action plans

Demonstration Station 10
Developing a Compliant Continuous Particle Monitoring System

Tim Russell, Director, Facility Monitoring Systems Ltd

This demonstration provides an overview of continuous particle monitoring of critical environments, the regulatory guidance (EU GMP Annex 1 and cGMP) and the hardware/software that are used to achieve compliance. The monitoring of other environmental parameters such as room pressure and temperature will also be demonstrated.

I. Interpretation of Regulatory Guidance
- EU GMP Annex 1
- FDA cGMP
- 21 CFR Part II and critical monitoring

II. Sampling Techniques
- Continuous point of use particle counters
- Manifold particle counting systems
- Advantages and disadvantages

III. Sampling Locations
- Identifying where to monitor in Grade A areas
- Understanding particle counting for the surrounding Grade B areas
- Implementing continuous room differential pressure monitoring

IV. Monitoring Software
- Determining levels and limits – the 5 micron sampling issue
- Ensuring data integrity and system robustness

Thursday, June 29, 2006
Half-Day Interactive Workshops

7:30 AM – Continental Breakfast

Interactive Workshop E 8:30 AM – 12:00 PM
Cleanroom Design, Operations, Training and Validation for Aseptic Processing

David Vincent, CEO, Validation Technologies

I. Controlling the Working Environment: Cleanroom and Processing Fundamentals
- Defining and attaining an aseptic state
- People in an aseptic area
- Aseptic techniques
- Environmental particles, microorganisms, and pyrogen behaviors
- General product requirements
- Complexity of aseptic processing approaches

II. Practical Introduction to the Cleanroom
- Excelling an aseptic environment
- FDA and cGMP implications
- Employee hygiene and aseptic gowning
- Air filtering
- General requirements
- Requirements for critical areas and controlled areas

III. Uses for Controlled Area and Critical Area
- High Efficiency Particulate Air Filter (HEPA) function
- Air quality: air changes, pressure differentials, and airflows
- Environmental controls: temperature control

IV. Cleanroom Technology Standards
- Applicable regulations and guidelines
- Design criteria and maintenance programs
- Environmental control, cleaning, and sanitization programs
- General aspects of process analysis
- Filter integrity, decontamination time, and contamination curves
- Cleaning and sanitation methodology and validation

V. Cleanroom Monitoring
- Operator qualification
- Reasons to monitor cleanrooms
- Microbial monitoring

VI. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

Interactive Workshop F 8:30 AM – 12:00 PM
Testing for Biopharmaceuticals - Strategies and Case Studies

Stephan O. Krause, Ph.D., Manager, QC Analytical Services and Compendial Liaison,
Hematology and Cardiology, Bayer HealthCare LLC

I. Introduction and Overview
- Terminology and principles of the Analytical Method (AM) life cycle
- Development and validation elements
- Current guidance documents
- Process flow maps of Analytical Method Development (AMD)/Analytical Method Verification (AMV) and their extensions

II. Validation Aspects: Documenting Evidence that Test Methods are Suitable for Their Intended Use
- What constitutes a good AMV
- Points to consider during AMD
- Beyond the requirements for ICH Q2A and Q2B guidelines
- AMV execution matrix
- Acceptance criteria

III. Validation Extensions - Interactive Case Studies
- Analytical Method (Suitability) Verification (AMSV) per USP draft chapter <1226>
- Analytical Method Comparability (AMC) for method replacements
- Analytical Method Transfer/Maintenance/Component Equivalency (AMT)/(AMM)/(AMCE)
- Validation extension acceptance criteria

IV. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquires they may have.

Interactive Workshop G 8:30 AM – 12:00 PM
Validation and Monitoring of Aseptic Processing: Media Fills and Sterility Testing

Carolyn Broughton, Ph.D., Senior Manager, Microbiology, Genentech, Inc.

I. Sterility Testing
- Compendial requirements
- Limitations of the method
- Interpretation of results

II. Process Simulation Runs (Media Fills)
- Guidance: EU Annex 1, FDA's aseptic guidance
- Media fill study design
- Worst case conditions
- Interventions
- Incubation and examination of units

III. Discrepancy Systems
- Policies, roles and responsibilities
- Documentation

IV. Sterility and Media Fill Failure Investigations
- Facility: Cleaning and monitoring
- Equipment: Sanitization and sterilization
- Personnel: Training and qualification
- Interpretation of data
- Corrective and preventive actions

V. Interactive Exercise:
The group will analyze data from a failed media fill, develop an investigation plan and propose corrective actions.

interactive Workshop H 8:30 AM – 12:00 PM
Qualification of a Lyophilizer and Associated Validations
Thomas P. James, Senior Quality Assurance Specialist, Bayer HealthCare

I. Considerations Before Qualifying a New or Modified Lyophilizer
- Exploring new processes for a new lyophilizer
- Determining processes for a new lyophilizer
- Existing lyophilizers modifications
- Gaining wisdom from the production floor

II. Process Development
- Selecting components
- Examining process control automation and methodology
- Delivering a usable system to the customer and operators

III. Qualification Activities for a New or Modified Lyophilizer
- User requirements: understand your customers' needs
- Design considerations: understand your engineers' needs
- FAT/SAT
- Turn-over package
- Hardware Installation Qualification (IQ)
- Software I/O Qualification
- Equipment IQ and OQ
- Temperature mapping

IV. Regulations for Validation of Processes Impacted by a New or Modified Lyophilizer
- Cleaning validation
- Sterilization validation
- Environmental monitoring
- Process validation
- Container closure
- Incorporation into process simulation
- Submitting changes to regulatory agencies
- Re-validation

V. Interactive Exercise:
A packet will be provided to support the presentation with key points from practical experience to support qualifying and maintaining a lyophilization process. A question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

12:00 PM – Luncheon

interactive Session 9 1:30 PM – 3:00 PM
Validation Master Plan (VMP) – Light House for the Regulatory Seas
Dr. Thomas H. Agrait, I.E., Validation & Regulatory Team Director, ISS Corp.

I. VMP – The Entire Validation Effort
- Guiding company personnel in validation activities
- Demonstrating to FDA personnel company's commitment to action
- Satisfying other stakeholders of company's commitment to quality
- Addressing 21 CFR Part 11 gaps

II. The Structured View
- The regulatory requirements
- Critical areas identification ending in FDA 483 and warning letters
- CFR 211 details
- Typical format review - IOPQ

III. Interactive Exercise:
The content of this seminar will assist participants as a framework to integrate engineering, construction, and validation projects. A question and answer period will provide an opportunity to clarify any inquiries they may have.

interactive Session 10 1:30 PM – 3:00 PM
Steam Sterilizer Qualification
Mitchell Tse, CQE, CQM, CQA, QA Validation Manager, Bayer Healthcare

The majority of materials entering a filling suite is through the steam sterilizer. Whether validating a new steam sterilizer, adding/modifying a load for an existing sterilizer, or revalidating a sterilizer, understanding the work is critical. This presentation will focus on the validation of the steam sterilizer and sterilization loads for use in an aseptic filling suite.

I. Steam Sterilization Background
- Types of sterilization methods
- Reasons to steam sterilize
- Regulations and guidelines that describe steam sterilization
- Sterility Assurance Level (SAL)
- Overkill method vs. bioburden based method

II. Validation of the Steam Sterilizer
- User requirements
- Factory acceptance testing/site acceptance testing
- Commissioning/Engineering checkout
- Installation Qualification (IQ)
- Hardware/Software IQ and Operation Qualification (OQ)
- Operation Qualification (OQ)
- Process development of sterilization loads
- Performance qualification of sterilization loads
- Revalidation and change control

III. Other Critical Steps Associated with a Steam Sterilizer Validation Process
- Utilities - Clean steam/Purified water
- Biological indicator qualification
- Evaluation of micro-organisms in environment
- Data monitoring and recording

IV. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have. Additionally, recent issues with steam sterilizer validation will be presented and discussed.

Interactive Session 11 1:30 PM – 3:00 PM
Validation of Terminal Sterilization Processes
Joseph Tyler, CMC Consultant

I. Regulatory Guidance Documents
- Introduction
- Examination

II. Terminal Sterilization Validation Approach
- Overkill
- Bioburden

III. Validation Protocol
- Elements
- Strategies

IV. Validation Execution and Report

V. Interactive Exercise:
Attendees will have the opportunity to participate in calculating a terminal sterilization cycle. An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

Interactive Session 12 1:30 PM – 3:00 PM
Qualifying a Compartment Washer
Thomas P. James, Senior Quality Assurance Specialist, Bayer HealthCare

I. User Requirements: What Actually Happens on the Production Floor?
- Selecting the equipment
- Designing your pattern load & rack
- Determining your compartment washer
- Developing a robust cleaning cycle

II. What Should my Role be in Equipment Development – Isn't that an Engineer's Job???
- Understanding how the software control works
- Exploring basic inputs and outputs
- Information that is required after a cycle is complete
- Determining what to look for at an FAT/SAT
- Understanding the importance of an installation qualification
- Exploring spray coverage

III. Development and Performance Qualification
- Understanding the design of experiment
- Deciding when and what to validate
- Optimizing the performance qualification timeline
- Training

IV. Interactive Exercise:
Attendees will gather requirements for validating a new compartment or cabinet washer. We will discuss how to identify the most logical grouping of the equipment based on material, equipment, and people flow. We will also develop a design of experiment for a new cleaning process to optimize quality, value, and speed. Participants will select a compartment washer that meets your needs and is safe for your operators and determine how to deliver a new compartment or cabinet washer that your customer actually thinks is an improvement to his/her equipment preparation process.

3:00 PM – Refreshment Break

Interactive Session 13 3:30 PM – 5:00 PM
HVAC and Energy Monitoring: Modeling by Process Analytical Technology (PAT)
Dr. Thomas H. Agrait, I.E., Validation & Regulatory Team Director, ISS Corp.

I. Reasons for Energy Monitoring
- Energy end use
- Specific technology assessment
- Savings
- Building diagnostics

II. Protocols for Performance Monitoring
- Retrofit monitoring
- New construction retrofit

III. Common Monitoring Issues
- Planning
- Implementation and verification
- Data analysis & reporting

IV. HVAC / Energy Monitoring and PAT Merge: Projects Design and Implementation Steps
- Methodology for design
- Project goals and objectives Identification
- Building characteristics design
- Data products and project output
- Monitoring design approach
- Specify data analysis procedures
- Specify field data monitoring points
- Resolve data product accuracies
- Specify verification and quality assurance procedures
- Specify recording and data exchange formats

V. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

Thursday, June 29, 2006
Post-Conference 90-Minute Sessions

interactive Session 14 3:30 PM – 5:00 PM
Validation of Environmental Monitoring Methods: Surface and Air Monitoring

Manpreet Bal, Senior Quality Assurance Specialist, Bayer Healthcare

I. Background on Surface Monitoring
- Validation of contact plates
- Validation of swabs

II. Background on Air Monitoring
- Qualification of settling plates
- Qualification of viable air samplers
- Qualification of particle samplers

III. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

interactive Session 15 3:30 PM – 5:00 PM
Preparing for a FDA Pre-Approval Inspection at a Sterile Product Manufacturing Site

Joseph Tyler, CMC Consultant

I. FDA Guidance Documents
- What the FDA will use to guide the inspection
- Safety of product when preparing for a pre-approval inspection
- Procedures

II. Microbiological Control
- Facility
- Utilities
- Environmental control
- Control of components and materials
- Personnel
- Sterilization operations
- Media fills and process simulations
- Laboratory operations

III. Interactive Exercise:
The participants will develop a checklist incorporating the elements from section II of the presentation to use for conducting audits to prepare for an FDA pre-approval inspection.

interactive Session 16 3:30 PM – 5:00 PM
Current Regulatory Trends in Aseptic Processing of Sterile Drug Products

David W. Vincent, CEO, Validation Technologies, Inc.

I. Building and Facilities
- Background – Regulatory and technical
- Critical area - Class 100 (ISO 5)
- Supporting clean areas
- Clean area separation
- Air filtration
- Design

II. Personnel Training, Qualification and Monitoring
- Personnel
- Laboratory personnel
- Monitoring program

III. Components and Container/Closures
- Components
- Containers/closures

IV. Validation of Aseptic Processing and Sterilization 21
- Process simulations
- Filtration efficacy
- Sterilization of equipment and container and closures

V. Laboratory Controls
- Environmental monitoring
- Microbiological media and identification
- Pre-filtration bio-burden
- Alternate microbiological test methods
- Particle monitoring

VI. Sterility Testing
- Choice of methods
- Media
- Personnel
- Sampling and incubation
- Investigation of sterility positives
- Batch record review: Process control documentation

VII. Interactive Exercise:
An interactive question and answer period will provide attendees an opportunity to clarify any inquiries they may have.

5:00 PM – Close of Conference

Thank you

A Very Special Thank You to Technical Advisors ***Hope Deckard****, Microbiology Process Laboratory Supervisor, Baxter Pharmaceutical Solutions LLC. and* ***J. Kirby Farrington****, Ph.D., Research Advisor – Microbiology, Eli Lilly and Company.*

IVT's ASEPTIC/STERILE PROCESSES EVENT
June 26 – 29, 2006 • Amsterdam, the Netherlands

Monday, June 26, 2006

7:30 AM – Registration and Continental Breakfast

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

WORKSHOP A
Developing an Effective CVMP – A Case Study

WORKSHOP B
Energy Efficient Cleanroom Design

WORKSHOP C
Sterility Failure Investigation

WORKSHOP D
Utilizing RCA and CAPA in EM

12:00 – Lunch for Workshop A, B, C, D Participants

12:00 – Main Conference Registration

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

1:00 PM
Chairperson's Opening Remarks

1:15 PM
Overview of the Design for Cleanrooms

2:00 PM
Exploring the Benefits of Establishing a HACCP Philosophy in an Early Stage Pharmaceutical Environment

2:45 PM
From Training to Behavioral - Key for Asepsis

3:30 PM – Refreshment Break

3:45 PM
Design of an EM Program

4:30 PM
Microbial Contaminants – the USP "Specified Organisms" and the FDA "Objectionable Organisms"

Tuesday, June 27, 2006

7:30 AM – Continental Breakfast

8:30 AM – 10:00 AM
90-Minute Interactive Sessions – 1, 2, 3, 4

SESSION 1
Use of a Comparability Protocol to Make Changes to Your Aseptic Facility

SESSION 2
Comparison of the FDA, EU, and Canada GMP Regulations

SESSION 3
Trouble Shooting Water Systems

SESSION 4
Garment Characteristics and Cleanliness Evaluation

10:00 AM – Refreshment Break

10:30 AM – 12:00 PM
90-Minute Interactive Sessions 5, 6, 7, 8

SESSION 5
Establishing a Sterility Testing Program

SESSION 6
Validation Discrepancy Investigation and RCA

SESSION 7
Designing and Implementing an Effective Cleaning and Disinfection Program

SESSION 8
Microbiological Method Validation vs. Suitability

12:00 PM – Lunch

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

1:00 PM
Chairperson's Opening Remarks

1:15 PM
Honing in on the Microbial Evaluation of Controlled Environments – USP <1116>

2:00 PM
How Media Fill Investigations Have Evolved in Response to Regulatory Guidance

2:45 PM
Sanitization Techniques for Cleanrooms and Controlled Areas

3:30 PM – Refreshment Break

3:45 PM
Preparation of Pharmaceutical Waters

4:30 PM
Comparison of Microbial Identification Methods – Practical Approach

Wednesday, June 28, 2006

Aseptic Lifecycle Demonstration Day

8:30 AM – Continental Breakfast

9:15 AM
Demo Day Introduction

9:30 AM – 10:00 AM
10:05 AM – 10:35 AM
10:40 AM – 11:10 AM
11:10 AM – 11:40 AM – Break
11:40 AM – 12:10 PM
12:15 PM – 12:45 PM
12:45 PM – 2:00 PM – Lunch
2:00 PM – 2:30 PM
2:35 PM – 3:05 PM
3:05 PM – 3:35 PM – Break
3:35 PM – 4:05 PM
4:10 PM – 4:40 PM
4:45 PM – 5:15 PM

5:20 PM
Cocktail Reception

DEMONSTRATION STATION 1
Modular Cleanrooms

DEMONSTRATION STATION 2
Dry Fogging

DEMONSTRATION STATION 3
Driving Forces of cGMP Cleaning

DEMONSTRATION STATION 4
Cleaning and Disinfection Techniques

DEMONSTRATION STATION 5
The DPTE-BetaBag® System

DEMONSTRATION STATION 6
Aseptic Filling of Large Volume Parenterals

DEMONSTRATION STATION 7
The Use VHP Systems

DEMONSTRATION STATION 8
Sporicidal Gassing Processes

DEMONSTRATION STATION 9
Particle Monitoring

DEMONSTRATION STATION 10
EU GMP Particle Monitoring System

Thursday, June 29, 2006

7:30 AM – Continental Breakfast

8:30 AM – 12:00 PM
Half-Day Workshops E, F, G, H

WORKSHOP E
Cleanroom Design, Operations, Training and Validation for Aseptic Processing

WORKSHOP F
Testing for Biopharmaceuticals - Strategies and Case Studies

WORKSHOP G
Validation and Monitoring of Aseptic Processing: Media Fills and Sterility Testing

WORKSHOP H
Qualification of a Lyophilizer and Associated Validations

12:00 – Lunch

1:30 PM – 3:00 PM
Post-Conference 90-Minute Interactive Sessions 9, 10, 11, 12

SESSION 9
VMP - Light House for the Regulatory Seas

SESSION 10
Steam Sterilizer Qualification

SESSION 11
Validation of Terminal Sterilization Processes

SESSION 12
Qualifying a Compartment Washer

3:00 PM – Refreshment Break

3:30 PM – 5:00 PM
Post Conference 90-Minute Interactive Sessions 13, 14, 15, 16

SESSION 13
HVAC and Energy Monitoring: Modeling by PAT

SESSION 14
Validation of Environmental Monitoring Methods: Surface and Air Monitoring

SESSION 15
Preparing for a FDA Pre-Approval Inspection at a Sterile Product Manufacturing Site

SESSION 16
Current Regulatory Trends

Aseptic Processing & Sterile Processes • June 26 – 29, 2006 • Amsterdam, the Netherlands

Complete this registration form, include payment in U.S. funds, and send to:
Advanstar/Institute of Validation Technology • PO Box 6004, Duluth, MN 55806-6004
888.524.9922 (U.S. only) or 218.723.9130 (U.S. or international) • Fax: 218.723.9308 • E-mail: Registration@ivthome.com • www.ivthome.com

For hotel information see page 4.

REGISTER ONLINE AT:
http://www.ivthome.com

Monday, June 26, 2006
Pre-Conference Half-Day Interactive Workshops
8:30 AM – 12:00 PM ..... $795 USD
A ☐ B ☐ C ☐ D ☐ (Choose one)

☐ **Monday - Tuesday, June 26-27, 2006**
MAIN CONFERENCE: General Sessions and Inclusive 90-Minute Interactive Sessions: .....$1995 USD

Monday General Sessions: 1:00 PM – 5:15 PM

Tuesday Interactive Sessions:
8:30 AM – 10:00 AM
1 ☐ 2 ☐ 3 ☐ 4 ☐ (Choose one)
10:30 AM – 12:00 PM
5 ☐ 6 ☐ 7 ☐ 8 ☐ (Choose one)

Tuesday General Sessions: 1:00 PM – 5:15 PM

☐ **Wednesday June 28, 2006**
Aseptic Processing Lifecycle Demonstration Day
8:30 AM – 5:20 PM: .....$995 USD

Thursday, June 29, 2006
Half-Day Interactive Workshops
8:30 AM – 12:00 PM.....$795 USD
E ☐ F ☐ G ☐ H ☐ (Choose one)

Thursday, June 29, 2006
Post-Conference 90-Minute Interactive Sessions
1:30 PM – 3:00 PM.....$495 USD
9 ☐ 10 ☐ 11 ☐ 12 ☐ (Choose one)

3:30 PM – 5:00 PM.....$495 USD
13 ☐ 14 ☐ 15 ☐ 16 ☐ (Choose one)

☐ **The Ultimate Passport $2795 USD**

SAVE $2775

Attend the entire event at this best value price. The Passport Includes:

- Conference Workbooks with All Available Presentations
- Pre-Conference Workshop on Monday
- Main Conference Monday through Tuesday
- Two Post-Conference 90-Minute Sessions
- Networking Cocktail Reception
- 10 Hands-On Demonstrations on Wednesday

Passport registrants must check the boxes of the workshops and sessions that they wish to attend!

✸ **Multiple Registrations:** Send three attendees and the fourth is FREE!
✸ **Early Bird Discount:** Register early and send in payment before May 1, 2006 and receive a **10% discount**!

Method of Payment: Please note that payment is required in advance of the conference. Please make checks (in U.S. funds drawn on a U.S. bank) payable to IVT/Advanstar Communications. Confirmation of your registration will be sent. Full payment must accompany registration form. Registrations received without payment will not be processed.
Cancellations/Substitutions: Your registration form may be transferred to a member of your organization at any time. Requests for cancellations (by mail or fax) must be received by June 12, 2006 in order to receive credit for attending another IVT event. Please be aware that cancellations will not be accepted after that date. All cancellations are subject to a $325.00 processing fee. IVT reserves the right to cancel an event. IVT is not responsible for any airfare, hotel, or other costs incurred by registrants. Speakers subject to change without notice.

Federal Tax ID # 592757389

You **MUST** mark the sessions and workshops you will be attending. Fax, E-mail, Mail, Call, or Check the Website Today. Payment is required at time of registration. **Registration Form:** Print Clearly or Attach Business Card.

Customer ID:

Enter Customer ID from Mail Panel ➧:

Name FIRST _____ LAST _____

Title: _____

Organization: _____

Mailing Address: _____

City: _____

State: _____ ZIP/Postal Code: _____

Country: _____

Telephone: ( ) _____

Fax: ( ) _____

E-mail: _____
Please include for confirmation of registration. Allow three days for processing.

Payment method: ☐ VISA ☐ MC ☐ AMEX ☐ Check *Payable to Advanstar/IVT*

Credit Card #: _____

Exp. Date: _____

Cardholder's Name (PLEASE PRINT): _____

Signature: _____

COST TOTALS: ASEPTIC PROCESSING & STERILE PROCESSES

Monday, June 26, 2006 Pre-Conference Half-Day Interactive Workshops A – D	$795 USD	$ _____
Monday – Tuesday, June 26-27, 2006 Main Conference & 90-Minute Interactive Sessions 1-8	$1995 USD	$ _____
Wednesday, June 28, 2006 Demonstration Day	$995 USD	$ _____
Thursday, June 29, 2006 Half-Day Interactive Workshops E – H	$795 USD	$ _____
Thursday, June 29, 2006 Post-Conference 90-Minute Interactive Sessions 9 – 12	$495 USD	$ _____
90-Minute Interactive Sessions 13 – 16	$495 USD	$ _____
OR **The Ultimate Passport**	$2795 USD	$ _____
SUB TOTAL		$ _____
✸ **Early Bird Discount - 10%**		$ _____
TOTAL Enclosed		$ _____

#889706

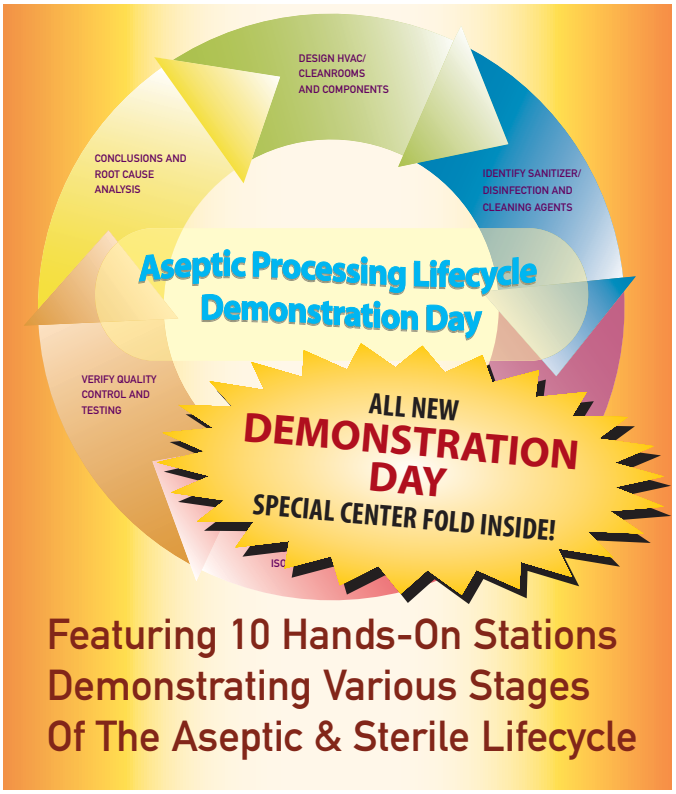
ASEPTIC PROCESSING & STERILE PROCESSES

June 26 - 29, 2006 • NH Grand Krasnapolsky • Amsterdam, the Netherlands

Industry's Largest and Most Comprehensive Aseptic Processing Event

Hear Industry Experts From:

- Eli Lilly and Company
- Bayer Healthcare
- BIOQUELL
- Mar Cor Purification
- ISS Corporation
- Genentech, Inc.
- Baxter Pharmaceutical Solutions, LLC
- Vectech Pharmaceutical Consultants
- Technovation Systems, Inc
- STERIS
- PharmSupply, Inc.
- World Heart, Inc.
- Validation Technologies, Inc.
- Clean Modules Ltd.
- GETINGE La Calhene
- International Lancer
- Shield Medicare Ltd.
- Lighthouse Worldwide Solutions
- Fresenius Product Partnering
- Facility Monitoring System



Featuring 10 Hands-On Stations Demonstrating Various Stages Of The Aseptic & Sterile Lifecycle

IVT
INSTITUTE OF VALIDATION TECHNOLOGY®

PO Box 6296
Duluth, MN 55806-6296
USA

Customer ID:

If addressee is no longer at this address, please forward to:

- Method Validation/Development
- Validation Manager
- Quality Assurance/Quality Control
- Research and Development
- Analytical Development Manager
- Analytical Chemists

ADVANSTAR COMMUNICATIONS