

MASTERING THE SCIENCE OF

Process Validation

SYMPOSIUM

December 5 – 7, 2006 • Marriott Mission Valley • San Diego, California

This Year's **Must-Attend** Process Validation Event

Providing Powerful Tools to Improve Validating Pharmaceutical, Biotechnology, and Medical Device Processes

Analyze
Real Life
Situations

CASE
STUDY

through interactive
CASE STUDIES—

topics ranging from
Process Validation Basics
to Tips for a Successful
Internal Auditing Program

In-depth Coverage on Process Analytical Technology (PAT)

PAT — A GMP Tool You Can Use

Discover an Alternative to a Traditional Approach

**Generation of Process Understanding for Execution of
PAT and Manufacturing Excellence Initiatives**

Determining PAT Standards /Best Practice and Where to Find Them

ADDITIONAL BENEFIT!

SAME VENUE! SAME DATES!

Free Access to IVT's **Equipment
Qualification & System
Validation** Conference!



MEDIA PARTNERS

**GMP
TRENDS, INC.**

**Pharmaceutical
Review**



PRESENTED BY

**Journal of
VALIDATION
TECHNOLOGY**

**Journal of
GXP
Compliance**

**Pharmaceutical
Technology**

BioPharm
INTERNATIONAL
The Science & Business of BioPharmaceuticals

IVT
INSTITUTE OF
VALIDATION TECHNOLOGY

**ADVANSTAR
COMMUNICATIONS**

Go Beyond the Fundamentals—

ADVANCED and SPECIAL FOCUS Sessions include:

- FMEA: A Quantitative Tool to Identify and Help Manage Risk
- Quality by Design (Design Space): Balancing Efforts — Development versus Commercial Stage
- Statistics for Process Validation Using Multivariate Analysis and DOE
- Process Validation for Packaging Validation: Hear Step by Step Case Study on what needs to be done during Packaging Validation
- Process Validation for Blend Uniformity- Impact of Product Characteristics: Learn the Powder Blend Guidelines, PAT in Blend Uniformity
- Minimizing/Analyzing Process Validation Risks — Planning, Organization and Execution

REGISTER NOW AT: www.ivthome.com/conferences

Process Validation • December 5-7, 2006

Event At-A-Glance

TUESDAY, DECEMBER 5TH, 2006

7:30 AM – Registration and Continental Breakfast

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

INTERACTIVE WORKSHOP A (FIELDS)

Process Validation Basics: Everything You Ever Wanted to Know, but Were Afraid to Ask

INTERACTIVE WORKSHOP B (ADVANCED) (LINCOLN)

CASE STUDY: FMEA :A Quantitative Tool to Identify and Help Manage Risk 

10:00 AM — Refreshment Break

12:00 PM — Lunch for Pre Conference Participants

Main Conference 90-Minute Sessions 1:00 PM – 2:30 PM

INTERACTIVE SESSION 1 (JENKINS)

Master Planning for Validation

INTERACTIVE SESSION 2 (NEMAK)

Establishing Acceptance Criteria

2:30 PM — Refreshment Break

Main Conference 90-Minute Sessions 3:00 PM – 4:30 PM

INTERACTIVE SESSION 3 (RIGGIN)

Excellence in Protocol Development

INTERACTIVE SESSION 4 (SUMMERS)

Implementing a Risk Management Program

4:30 PM — Close of Day One

4:45PM – 5:45PM — Networking
Cocktail Reception 

WEDNESDAY, DECEMBER 6TH, 2006

7:30 AM – Continental Breakfast

Main Conference 90-Minute Sessions 8:30 AM – 10:00 AM

INTERACTIVE SESSION 5 (RIGGIN)

Process Validation for Biological Products

INTERACTIVE SESSION 6 (LINCOLN)

CASE STUDY: Process Mapping—
A Tool for All Seasons 

10:00 AM — Refreshment Break

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

INTERACTIVE SESSION 7 (JENKINS)

Validation vs. Verification

INTERACTIVE SESSION 8 (SUMMERS)

CASE STUDY: Auditing a Validation Program
for Companies with Domestic and
International Regulatory Requirements 

12:00 PM — Lunch

Main Conference Half-Day Workshops 1:00 PM – 4:30 PM

INTERACTIVE WORKSHOP C (ADVANCED) (VIDAL)

CASE STUDY: Quality by Design Balancing
Efforts — Development versus
Commercial Stage 

INTERACTIVE WORKSHOP D (ADVANCED) (MCCREADY)

Statistics for Process Validation Using Multivariate
Analysis and DOE

2:30 PM — Refreshment Break

4:30 PM — Close of Day Two

THURSDAY, DECEMBER 7TH, 2006

7:30 AM — Continental Breakfast

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

INTERACTIVE SESSION 9 (RODRIGUEZ)

Revalidation for Process Validation

INTERACTIVE SESSION 10 (SPECIALIZED SESSION) (DÜBLIN)

CASE STUDY: PAT— A GMP Tool You can Use 

10:00 AM — Refreshment Break

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

INTERACTIVE SESSION 11 (ADVANCED) (NEMAK)

CASE STUDY: Minimizing/Analyzing Process
Validation Risks- Planning, Organization
and Execution 


INTERACTIVE SESSION 12 (SPECIALIZED SESSION) (VIDAL)

CASE STUDY: Process Validation for Blend
Uniformity – Impact of Product
Characteristics 

12:00 PM — Lunch

Post-Conference 90-Minute Sessions 1:00 PM – 2:30 PM

INTERACTIVE SESSION 13 (ADVANCED) (MCCREADY, KOTECHA)

CASE STUDY: Generation of Process
Understanding for Execution of PAT and
Manufacturing Excellence Initiatives 

INTERACTIVE SESSION 14 (SPECIALIZED SESSION)

(RODRIGUEZ)

CASE STUDY: Process Validation for
Packaging Validation 

2:30 PM — Close of Conference

INTERESTED IN EXHIBITING?

Exhibitor and sponsorship opportunities are available for this and other IVT conferences.

Please contact Michele Leyden, Sales Manager
800-276-4242 (U.S. toll-free) or 954-567-3152 • mleyden@advanstar.com



TRAIN THE ENTIRE TEAM: Buy three Ultimate Passport registrations from the same company, and get the 4th one FREE!

Please call 1-888-524-9922 (US) or 1-218-740-7130 with the registration and payment information for all four attendees to take advantage of this offer.

EARLY BIRD DISCOUNT: REGISTER BEFORE OCTOBER 23 FOR A 10% DISCOUNT

TO REGISTER GO TO: ivthome.com

7:30 AM – Conference Registration and Continental Breakfast

INTERACTIVE WORKSHOP A 8:30 AM – 12:00 PM

Process Validation Basics: Everything You Ever Wanted to Know, but Were Afraid to Ask

Timothy J. Fields, President, Drumbeat Dimensions, Inc

I. Worldwide Regulatory Requirements for Process Validation

- US, EU, Canadian, Japanese, and ICH requirements
- FDA Compliance Policy Guide on process
- Comparison of worldwide requirements
- ICH Q8, pharmaceutical development

II. Process Validation Lifecycle

- Terminology
- Risk management, commissioning, qualification
- Understanding the Process Validation lifecycle steps

III. Documenting Process Validation

- Validation Plans, Validation Reports
- Protocols
- Document Management

IV. Additional Items

- Training
- Suppliers, Change Control/Management
- Validation teams

V. Interactive Exercise

Developing a PV Plan. Attendees will discuss possible critical process parameters, quality attributes for hypothetical product and outline steps to validate the process.

ADVANCED WORKSHOP

INTERACTIVE WORKSHOP B 8:30 AM – 12:00 PM

Case Study Failure Mode Effects Analysis (FMEA): A Quantitative Tool to Identify and Help Manage Risk



John E. Lincoln, Principal, J. E. Lincoln and Associates

I. Introduction to Failure Mode Effects and Criticality Analysis (FMECA)

- Part of the ISO 14971 “Toolkit” (Annex F)
- Concurrent use of Hazard List / FTA
- Types: design, process, software, user
- 5 and 10 level RPNs

II. “Touring” a Typical FMECA

- Column headings; basic and specialized
- Differences in purpose

III. Key Elements in FMECA Preparation

- Hazard Analysis
- Sources: Annexes, Manufacturer and User Device Experience (MAUDE) database, industry, CAPA
- Failure Modes
- Complementary tools
- Traceability and RPN
- Broadly Acceptable Region (BAR), (ISO 14971): As Low As Reasonably Practicable (ALARP), intolerable regions

IV. Major Industry Problems

- Capturing all sources
- Neglected areas
- Obtaining ‘buy in’
- Obtaining value – the business case
- Recent FDA 483 and warning letter violations.
- Continuous improvement

V. Case Study / Interactive Exercise

Attendees will initiate different types of FMECAs. Select some hazard categories, determine failure modes, assign values, calculate RPNs. Determine what the FMECA is “saying”.

Participants will take home the following Bonus Information:

- Typical “blank” FMECA forms for use during the session and off -site

10:00 AM — Refreshment Break

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

INTERACTIVE SESSION 1 1:00 PM – 2:30 PM

Master Planning for Validation

Martin Jenkins, PMP Senior Project Scientist, BD Biosciences

I. Master Validation Plan (MVP) the Process

- Designing and implementing MVPs
- Implementing the protocols of a process validation
- Creating MVPs

II. Understanding the Validation Lifecycle

- Developing a system from concept
- The creation and maintenance of a validation process
- Validation lifecycle inputs and outputs

III. Identifying the “Business Case” for having a Global Validation Strategy

- The application of strategies
- The need for regulatory compliance
- Business benefits of validation
- Assessing the current status of a company’s validation planning

IV. Documenting and Tracking VMP’s and Validation Protocols

- Utilizing metrics to assess, monitor and improve
- Tracking protocols from concept through obsolesce
- Pharmaceutical, biotechnical, R&D, quality and mfg. focus

V. Interactive Activities

Attendees will focus on role responsibility and authority for various levels of participants involved in the process of implementing various levels of validation strategies, from Master Plans to Protocols.

INTERACTIVE SESSION 2 1:00 PM – 2:30 PM

Establishing Acceptance Criteria

Dr. Nemák Katalin, Quality & Compliance GMP auditor, Science & Medical Affairs, CHINOIN Private Co. LTD. – a member of Sanofi-Aventis group

I. Preparing for Process Validation

- Functional analysis of the steps, definition of control points
- Choice of model products for “Worst Case” simulations
- Establishing acceptance criteria based on product characters & safety factors
- Organization, training, human factors

**Tuesday, December 5, 2006
Main Conference 90-Minute Sessions**

**Wednesday, December 6, 2006
Main Conference
90-Minute Sessions**

II. Process Validation Cycles (Risk Evaluation and Risk Controls)

- Interim reports, evaluation of experiences (trend analysis)
- Summary Reports - indicated revalidation and process improvements
- Closing validation period, entering the monitoring phase (PQR based on PV results)

III. Interactive Exercise

Participants will fill up a risk-analyzing table. Examples from the real life will demonstrate how the better knowledge on product characters can help process and product improvements.

Participants will take home the following Bonus Information:

Easy implementation tools-Annexes of the GHTF/Study Group 3 Process Validation Guidance

2:30 PM — Refreshment Break

INTERACTIVE SESSION 3 3:00 PM – 4:30 PM

Excellence in Protocol Development: Practices that Provide a Good Scientific Foundation for, and Effective Execution of, Validation Protocols

Ralph M. Riggan, PhD, Senior Research Fellow, Eli Lilly and Company

I. Best Practices for Validation Study Design

- Scientific/Technical requirements for a successful validation program
- Overview of the components of an appropriate validation program
- Pre-requisites for validation protocol preparation

II. Validation Protocol Content and Format

- Validation protocol content
- Example formats

III. Interactive Exercise

Attendees will participate in a Q and A content of the previous two parts of the presentation. Participants will share their own experiences and best practices and analyze examples provided to determine best practices for particular situations.

INTERACTIVE SESSION 4 3:00 PM – 4:30 PM

Implementing a Risk Management Program

Wendilyn Summers, Technical Specialist, Continuous Improvement- Diosynth Biotechnology

I. Discuss Risk Management Tools and Techniques

- Prioritize actions based on risk of product and process failures
- Provide an overview of quality risk management
- Evaluate process risk and possible failure causes

II. Evaluate Process Risk

- Identify corrective actions based on risk level
- Learn how using the risk management approach can result in preventive actions rather than reactions

III. Interactive Exercise

Attendees will discuss the guidance needed in the implementation of the appropriate risk based approach using ICH (Q9) "Quality Risk Management".

4:30 PM — Close of Day One

**4:45 PM – 5:45 PM
Networking Cocktail Reception**



7:30 AM — Continental Breakfast

INTERACTIVE SESSION 5 8:30 AM – 10:00 AM

Process Validation for Biological Products

Ralph M. Riggan, PhD, Senior Research Fellow, Eli Lilly and Company

I. Overview of Process Validation Requirements

- Fundamental basis for process validation
- Linkage between product development and validation activities
- Technical considerations for "common" biologicals (recombinant proteins, monoclonal antibodies, etc.)
- Critical role of analytical chemistry in PV and example

II. Additional Challenges for Complex Biologicals

- Example product types (e.g. cell therapies, gene therapies, certain vaccine types, etc.)
- Special PV considerations for complex biologicals

III. Interactive Exercise

Attendees will participate in a Q and A regarding content of previous two parts of the presentation. Participants will also share their own experiences and discuss best practices.

INTERACTIVE SESSION 6 8:30 AM – 10:00 AM

Case Study: Process Mapping— A Tool for All Seasons

John E. Lincoln, Principal, J. E. Lincoln and Associates



I. Introduction to Process Mapping

- Enhanced applications from an old friend
- Types; advantages / disadvantages

II. The Process Map / Flow Chart

- Depicting inputs
- Lines and nodes of activity
- Design to allow detailed workflow analysis
- Optimization of workflow.

III. Development

- High or low level
- 'New' questions
- Inputs, pathways and circuits
- Rooting out "Hidden Factories" and true yield
- Completion and verification



Thank You!

Special Thank You to our Technical Advisor **John E. Lincoln**, principal of J. E. Lincoln and Associates,

a consulting company with over 24 years experience serving FDA-regulated industries. John specializes in client culture/systems change in product-to-market, defect and cycle time reduction, software documentation/validation, quality/regulatory management, product clearance, and issue resolution in the US FDA-regulated environment. Additional experience has been in government (civil and military), aerospace, and the electronics industries. He has published numerous peer-reviewed articles on culture change, training, biohazards, quality, risk management, CAPA, regulatory submissions / responses, as well as a monthly newsletter, *Medical Device News*.

Wednesday, December 6, 2006
Main Conference 90-Minute Sessions and Half-Day Workshops

IV. Use

- Process definition / selection
- Facilitating detailed analysis
- Neglected primary step in SOP / WI development
- Simplification / optimization of workflow
- HACCP “overlay”; critical-to-quality analysis
- Critical action, monitoring and decision points
- Team analysis and management review
- A regulatory AND business tool

V. Major Industry Problems

- Underutilized
- Obtaining ‘buy in’
- FDA 483 and Warning Letter issues
- CAPA input

VI. Interactive Exercise

Participants will review case studies.

10:00 AM — Refreshment Break

INTERACTIVE SESSION 7 10:30 AM – 12:00 PM

Validation vs. Verification

Martin Jenkins, PMP Senior Project Scientist, BD Biosciences

I. Understanding the Different Forms of Qualification

- Understanding the need for process qualification
- Defining verification and the elements of verification

II. Determining Why, What, and When to Validate

- Recognizing the benefits of verification, and of validation
- Industry perspectives - pharmaceutical, biotech, and life sciences
- R&D, quality and manufacturing focus

III. Creating Comprehensive Qualification Protocols

- Determining different types of systems, and process qualifications
- Creating the proper protocols; IQ, OQ, PQ
- Implementation of system monitoring and measurement tools

IV. Identifying the Risks Associated with Validation, and Verification

- Understanding the impact of acceptance criteria
- Designing systems to identify and control change
- Using statistical tools and risk analysis
- Identifying indicators; predictive, real time, and latent

V. Interactive Exercise

Attendees will focus on identifying the proper course of qualification for various elements of systems and processes.

INTERACTIVE SESSION 8 10:30 AM – 12:00 PM

Case Study: Auditing a Validation Program for Companies with Domestic and International Regulatory Requirements

Wendilyn Summers, Technical Specialist, Continuous Improvement - Diosynth Biotechnology



I. Structure of an Effective Internal Auditing Program

- Developing an audit schedule based regulatory requirements
- Audit training, plan and report templates
- Defining the audit process and responsibilities

II. Execution of Successful Internal Audits

- Defining scope and methodology in audit plans
- Reviewing general GMP principles and training records
- Document positive findings and gaps with compliance in an objective audit report
- Monitoring corrective actions to ensure timely completion

III. Appropriate Internal Auditing Documentation

- Audit reporting
- Documenting the completion of observation closure and corrective action implementation

IV. Interactive Exercise

Participants will review case studies of internal audit findings, write and classify audit observations.

12:00 PM — Lunch

ADVANCED WORKSHOP

INTERACTIVE WORKSHOP C 1:00 PM – 4:30 PM

Quality by Design: Balancing Efforts — The Development versus Commercial Stage



Jose E. Vidal PhD, Technology Operations Director, Biovail Corporation

I. Process Development and Product Characterization

- Conceptualizing a product
- Product specifications: initial formulations
- Human testing: Phases I, II and III; regulatory and post-marketing

II. Process Development and Process Capability

- ICH Q8: pharmaceutical development
- Process characterization – process tolerance and extremes
- Pilot plant – manufacturability potential
- PAT – product/process X-Ray

III. Scale Up and Points to Consider in Process Validation

- Manufacturing process design and scale up
- In Process testing / control –check points
- Process optimization / manufacturability – robust, reproducible, rentable (3 R's)

IV. Technology Transfer

- Receiving vs. sending site – structure and systems
- Experimental / troubleshooting - co-development or process transfer
- Process Validation / post approval changes – challenging process design quality

V. Interactive Exercise (Case Study)

Participants will take home the following Bonus Information:

- Case Study: Analysis of an underdeveloped manufacturing process
- Real life applications of Quality by Design

HOTEL INFORMATION | Marriott San Diego Mission Valley

8757 Rio San Diego Drive • San Diego, California 92108 USA.
 Phone: 1-619-692-3800 • Fax: 1-619-692-0769 • www.marriott.com/sanmv



\$\$\$ SUPER SAVINGS \$\$\$

Make hotel reservations early for the discounted rate; hotel rates can increase as the event date approaches. You must call the hotel directly at the above number and mention IVT to receive the reduced room rate.

Wednesday, December 6, 2006
Main Conference Half-Day Workshops

ADVANCED WORKSHOP

INTERACTIVE WORKSHOP **D** 1:00 PM – 4:30 PM

**Statistics for Process Validation
Using Multivariate Analysis and
DOE**

Chris McCready, Director Global PAT, Umetrics Inc.
Seongkyu Yoon, PhD, Manager, Manufacturing
Sciences, BiogenIdec Biopharmaceuticals

**I. Benchmarking Pharma and
Biotech Quality Systems to Other
Industries**

- Purpose of manufacturing quality systems
- Six sigma basics and role in pharma
- Process evolution and continuous improvement
- Use of data generated from the process

**II. Process Models and Design of
Experiments**

- Experimental design a tool for troubleshooting, product design
- Mapping the process: connecting variations in the raw materials and process to variability in the final product
- Multivariate modeling of batch processes including assessment of mammalian cell culture bioreactors
- Challenges and path forward

III. Risk Analysis

- Specifying the required model resolution
- Defining the adequacy of the measurement system
- Categorize the background influences and variability

IV. Validation of Process Models

- Understanding the precision and repeatability of a reference method
- Performance of the model relative to specifications
- Designing models robust to manufacturing disturbances
- Standards and best practice for pharma and biotech such as ASTM E55

**V. Activities in Development and
Manufacturing**

- New products versus existing
- Quality by Design, Design Space and operating space
- Automation and monitoring in manufacturing

VI. Interactive Exercise

Participants will perform a risk analysis of a process monitoring and automation system to define required specifications for the measurement system, process models and associated process controls. A predicted quality measurement will be used to replace a laboratory measurement for parametric release.

2:30 PM — Refreshment Break

4:30 PM — Close of Day Two

Thursday, December 7, 2006
Post-Conference
90-Minute Sessions

7:30 AM — Continental Breakfast

INTERACTIVE SESSION **9** 8:30 AM –10:00 AM

Revalidation for Process Validation
Jackelyn Rodriguez, President, Monarch Quality
Systems Solutions

**I. The Fundamentals of
Revalidation Requirements**

- Definitions of Re-validation
- How does CAPA fit in?
- Types of change control systems
- Levels of change

**II. Actions to Build a Formal
Change Control System**

- Best approaches to manage and track revalidations
- Where does CAPA and change control apply?
- Identify the different types of changes
- Planning an effective Change control process

III. The Classification System

- Evaluating recommended changes as a result of CAPA
- Monitoring change to confirm effectiveness of validated processes
- Classifying what needs to be changed while confirming a validated state

IV. Interactive Exercise

Participants will review and critique an example of a proposed change for a validated process.

Thursday, December 7, 2006
Post-Conference
90-Minute Sessions

SPECIALIZED SESSION

INTERACTIVE SESSION **10** 8:30 AM –10:00 AM

Case Study:

PAT— A GMP Tool You can Use

Martin Dublin, CEO, Y-Tec GmbH

CASE
STUDY

I. Introduction

- Understanding what the inspectors see
- Learning how to make improvements using the GMP tools
- Exploring whether PAT is the only way to deliver quality
- Discovering a practical approach on how to use PAT

II. Essentials for a Lifecycle Concept

- Focusing on the specific needs
- PAT and GMP
- Alternatives to a traditional approach
- Learning the five steps for the implementation of PAT
- Understanding the trends

III. Interactive Exercise

Case studies will be presented and verified. Participants will discover together in an open discussion the advantages and disadvantages of using PAT.

10:00 AM — Refreshment Break

SPEAKING OPPORTUNITIES:
**Are you interested in
speaking at one of our
upcoming conferences?**

We are continuously searching for industry experts to speak at conferences in the U.S. and Europe. In addition to sharing your expertise with the audience, you will receive complimentary access to the entire event.



PLEASE CONTACT:

Maria A. Cephas
IVT Conference Producer
954.567.3162
mcephas@advanstar.com

ADVANCED SESSION

INTERACTIVE SESSION 11 10:30 AM – 12:00 PM

Case Study: Minimizing/Analyzing Process Validation Risks- Planning, Organization and Execution



Dr. Katalin Nemák, Quality & Compliance GMP Auditor, Science & Medical Affairs, CHINOIN Private Co. LTD. – a member of Sanofi-Aventis Group

I. General Road Maps to Process Validations (ICH Q8,Q9.Q10.)

- Prospective, retrospective and concurrent validations
- Technology Transfers into a new facility
- New product intro to a controlled, monitored facility and working environment

II. Preparing for Process Validation in a New Facility

- Use FMEA for investigation the effect of potential machinery failures
- Define operability ranges and “worst case” simulations for risky operations

III. Process Validation for a New Product

- Get familiar with the product, consistency lots and demo batches
- Biopharmaceutical points in formulation relating mainly to physical parameters
- BCS classification for oral dosage form – what about parenterals?

IV. Interactive Exercise

Attendees will discuss a case study, presented based on examples issued in ICH Q9 briefing pack. Examples from the FDA science forum and some new Warning Letters will also be discussed.

Participants will take home the following Bonus Information

- Examples from ICH Q9 briefing pack.

SPECIALIZED SESSION

INTERACTIVE SESSION 12 10:30 AM – 12:00 PM

Case Study: Process Validation for Blend Uniformity – Impact of Product Characteristics



Jose E. Vidal, PhD, Technology Operations Director, Biovail Corporation

I. Formulation Development

- Equipment operating principles
- Particle size and shape contribution
- Excipients influence

II. Powder Blend Guideline

- Sampling methodology
- Pharmaceutical data statistical analysis
- Product Quality Research Institute (PQRI) blend uniformity

III. PAT in Blend Uniformity

- Spectroscopic real time analysis – reducing development time

IV. Interactive Exercise- Case Study

Participants will analyze real life situations and define actions based on Powder Blends and Finished Dosage Units Guidelines.

Participants will take home the following Bonus Information

- Handout that discusses multiple approaches for addressing a failing blend uniformity case- Development, Sampling Technique and PQRI

12:00 PM — Lunch

ADVANCED SESSION

INTERACTIVE SESSION 13 1:00 PM – 2:30 PM

Case Study: Generation of Process Understanding for Execution of PAT and Manufacturing Excellence Initiatives



Chris McCready, Director Global PAT, Umetrics Inc. Seongkyu Yoon, PhD, Manager Manufacturing Sciences, Biogen/Dec Biopharmaceuticals

I. What Does the FDA Consider a PAT Process?

- Understanding your process
- Handling variability in the process adequately
- Determining PAT standards /best practice and where to find them
- Generation of benefits outside of FDA PAT approval

II. Implementing a PAT System

- Defining specifications for a PAT system through risk analysis
- Characterizing the information content of the process measurement system
- Mapping the process through process modeling and DoE

III. Case Studies

- Raw material assessment on product properties using principal component analysis
- Protein purification column assessment using multivariate data analysis
- Mammalian cell-culture bioreactor modeling using multivariate batch modeling

IV. Interactive Exercise

Participants will review one of case studies listed above for detailed investigation of process variations, cycle time, measurement system and associated process signatures. These issues will be analyzed to benchmark process performance and identify operational areas of improvement. Recommendations will be generated.

SPECIALIZED SESSION

INTERACTIVE SESSION 14 1:00 PM – 2:30 PM

Case Study: Process Validation for Packaging Validation



Jackelyn Rodriguez, President, Monarch Quality Systems Solutions

I. Step by Step Case Study — What Needs to be Done During Packaging Validation

- Equipment IQ, OQ
- Optimum conditions
- Process PQ

II. Effective Methodology Intended to Accomplish Effective Packaging Validation

- “Worst case” and nominal conditions selected from the OQ results
- Samples preparation
- Number of lots required, types of testing

III. When Should Burst Testing and Dye Penetration be Performed?

- According to which standard?
- What about accelerated aging?
- Define acceptance criteria

IV. Interactive Exercise

Participants will review and critique an example of a packaging test protocol.

2:30 PM — Close of Conference

Process Validation

December 5-7, 2006 • San Diego, California

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 218.740.7028 (U.S. or International)
 Fax: 218.740.6308 • E-mail: Registration@ivthome.com • www.ivthome.com



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

For hotel information, please see page 5

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

IF FAXING OR MAILING REGISTRATION, PLEASE DO NOT DETACH MAILING LABEL FROM THE BOTTOM OF THIS PAGE.

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: _____

Federal Tax ID # 592757389

#862006

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.

PLEASE CHOOSE ONE BREAKOUT SESSION IN EACH TIMEFRAME.

Tuesday, December 5, 2006

Pre-Conference Workshops • 8:30 AM – 12:00 PM \$795.00
 A B* (Choose one)

Tuesday - Wednesday, December 5-6, 2006

MAIN CONFERENCE: Inclusive Interactive Workshops C-D & Sessions 1-8 \$1,495.00

Tuesday, December 5, 2006 • 90-Minute Interactive Sessions

1:00 PM – 2:30 PM 1 2 (Choose one)
 3:00 PM – 5:00 PM 3 4 (Choose one)

Wednesday, December 6, 2006 • 90-Minute Interactive Sessions

8:30 AM – 10:00 AM 5 6 (Choose one)
 10:30 AM – 12:00 PM 7 8 (Choose one)

3-Hour Main Conference Half-Day Workshops

1:00 PM – 4:30 PM C* D* (Choose one)

* = (ADVANCED)

Thursday, December 7, 2006

Post Conference 90-Minute Sessions

8:30 AM – 10:00 AM 9 10 (Specialized Session) (Choose one) \$495.00
 10:30 AM – 12:00 PM 11* 12 (Specialized Session) (Choose one) \$495.00
 1:00 PM – 2:30 PM 13* 14 (Specialized Session) (Choose one) \$495.00

THE ULTIMATE PASSPORT \$1995 USD

ATTEND THE ENTIRE EVENT AT THIS BEST VALUE PRICE. THE PASSPORT INCLUDES:

- One Pre-Conference Workshop- Tuesday • Main Conference Tuesday through Wednesday
- Three Post-Conference Specialized Sessions • Networking and Cocktail Reception - Tuesday
- Conference CD with All Available Presentations



MULTIPLE REGISTRATIONS: Send three Ultimate Passport registrations from the same company and receive a 4th Ultimate Passport FREE!

Please call 1-888-524-9922 (US) or 1-218-740-7028 with the registration and payment information for all four attendees to take advantage of this offer.

Please check here if you are interested in attending sessions from

EQUIPMENT QUALIFICATION & SYSTEM VALIDATION - SAN DIEGO, CA

TO VIEW THE EQSV BROCHURE, PLEASE VISIT: www.ivthome.com/pdf/1206_eqsv_sandiego.pdf

COST TOTALS: Process Validation

Tuesday, December 5, 2006

Pre-Conference Interactive Workshops A-B \$795 USD \$ _____

Tuesday - Wednesday, December 5-6, 2006

Main Conference including Workshops C-D and Sessions 1-8 \$1495 USD \$ _____

Thursday, December 7, 2006

Post-Conference 90-Minute Sessions 9-14 _____ X \$495 USD \$ _____

OR The Ultimate Passport \$1995 USD \$ _____

(You must check each Session and Workshop above)

SUB TOTAL \$ _____

* **Early Bird Discount - 10% (Register by October 23)** \$ _____

TOTAL Enclosed \$ _____

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 November 21, 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.



Duluth, MN 55806-6296 USA

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

- Manufacturing Engineers ■ Quality Assurance
- Tech Transfer ■ Quality Assurance
- Regulatory Affairs ■ Compliance
- Inspectorates ■ Product Development Engineers
- Process Development
- Clinical Research Organizations



Customer ID: