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Best regards,

Jason E. Brown
Senior Manager, Programs and Meetings

2013 PDA ANNUAL MEETING SESSION RECORDINGS

Modern Sterile Product Manufacture – Exploring Best Practices and Seeking New Approaches

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- Twelve (12) recorded sessions from the 2013 PDA Annual Meeting
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Opening Plenary Session

PDA's membership is based on pharmaceutical and biopharmaceutical drug developers and manufacturers, which comply with global regulations to supply safe and efficacious sterile products. To support these efforts, PDA fosters networking, educational and communication opportunities, which bring peer companies, consultants and regulators together to learn, inform and improve.

Presenters:

David Cutler, PhD, Otto Eckstein Professor, Applied Economics, *Harvard University*
Joyce Bloomfield, Executive Director, Divisional Quality and Compliance Management, *Merck Sharp & Dohme*

B – Modular Systems – Facility Consideration

Future facility requirements asked for flexibility in regard to capacity variations, multi-product production and potential mobility. Furthermore, more robust containment solutions within facilities or as facilities are necessary to fulfill regulatory needs and protection of the environment. The sessions covers both topics in detail.

Flexible modular systems are described in regard to the functionality of either being a unit operation or utilized as assembled product site. Example cases show the benefits of these modular pods for start-up companies, failed product approval, multi-product or varying capacity production sites.

Presenters:

Maik Jornitz, Chief Operating Officer, *G-Con Manufacturing, LLC*
Hank Rahe, Technical Director, *Enguard Systems*

C – Current Trends in Process Validation

This session focuses on two new challenges in process validation, single use systems and Continued Process Verification (CPV). The single use, presentation reviews the advantages of this technology as it applies to manufacturing. Based on these drivers, a strategy for the qualification / validation of a single use system is presented, including the challenges that need to be addressed during execution. The session continues with the challenges of implementing a Continued Process Verification program, aligned with the 2011 FDA guidance on process validation. Applying statistical process control following a standard "text book" approach results in several common real life issues during execution of the CPV program. The presentation offers some practical solutions to overcome these issues during implementation.

Presenters:

Christopher Smalley, PhD, Director, *Merck Sharp & Dohme*
Julia O'Neill, Director, Principal Engineer, *Merck & Company, Inc.*

F – Complementing Your Quality Systems with Technology While Meeting New Regulatory Requirements in a Global Market

This recorded session provides listeners with alternatives to comply with global market requirements for product traceability using serialization and barcoding techniques. In addition it explores microbiological applications that can lower your operation cost of controlled environments. This session is designed to provide the audience with innovative approaches with potentially cost savings opportunities while remaining compliant in a global environment.

Presenters:

Cyndi Poetker, Senior Program Manager of Global Standards and Serialization, *Abbott Laboratories*
Peter Noverini, Field Application Scientist, *Azbil BioVigilant Systems, Inc.*
Miguel Nogueras, PhD, Global Manager, QA, Microbiology, *Abbott Medical Optics (AMO)*

2013 PDA Annual Meeting Session Recordings (continued)

Plenary Session 2 – Major Changes to the Industry

The second plenary session presents updates, current thoughts, and discussion from and with those in the industry directly involved with meeting the increasing complex challenges to public trust posed by drug product shortages and product counterfeiting.

Presenters:

Marty Nealey, Vice President, Operations, Plant Manager, *Hospira Pharmaceuticals, Inc.*
Martin VanTrieste, Senior Vice President, Quality, *Amgen, Inc.*

H – Contemporary Practice in the Manufacture of Sterile Products

This session explores the important considerations in the development of novel sterilization processes and then reviews the application of these in a case study. Additionally, contemporary approaches such as the use of Restricted Access Barrier Systems, Isolators and other advanced aseptic process technologies are highlighted.

Presenters:

Patrick McCormick, PhD, Manager, Research Sterilization, *Bausch & Lomb, Inc.*
James Akers, PhD, President, *Akers Kennedy & Associates*

I – Outsourcing Related

The approval of a Contract Manufacturer is a critical decision and must be taken to the highest level of detail including in-depth audits, agreements, communication strategies, handling of any discrepancies/ conflicts and the documentation to be provided to the process owner. The internal procedure must define internal requirements, the selection, initial audits and approval process and the continued monitoring requirements including frequent audits.

Suppliers of ready-to-use components such as sterilized containers/ closures, stoppers, single-use bags must be treated with the same level as your most critical process even if full GMP are not required at their manufacturing process.

Presenters:

Ian Elvins, Vice President, Quality, *Lonza Biologics*
Edwin Rivera-Martinez, Vice President, U.S. Quality Liaison, Global Quality, *Sanofi-Aventis*

K – Fundamentals

This session covers two important elements impacting the quality of finished pharmaceutical products. First it addresses the technology associated with steaming of process equipment, including the design and validation of steam in place cycles. A second presentation discusses the important concepts associated with visually inspecting each container of finished drug product to ensure the absence of visible particulates and cosmetic defects.

Presenters:

John G. Shabushnig, PhD, President, *Insight Pharma Consulting, LLC*
Kevin Trupp, Principal Consultant, *Sterilization Technology and Compliance*

L – Fundamentals

During this recorded session a comparison of the traditional and continuous process verification approaches to process validation are described. The similarities and differences of the various international guidance documents and practices, both regulatory and non-regulatory are addressed.

Presenters:

Scott Bozzone, PhD, Senior Manager, Validation, Quality Systems Technical Services (QSTS-V), *Pfizer, Inc.*
Greg Flexman, Process and Risk Analysis, *Grifols, Inc.*

N – Advances in Single-use Technology Applications

This session discusses medium to large scale precision filling using single-use systems, which avoid the need of cleaning and assembly. Sensor technology advances are critical to determine the process stability and support PAT. The described advances are platforms to build on further innovations.

Presenters:

Lukas Munzinger, Sales Manager, *Bosch Packaging Technology*
Govind Rao, PhD, Professor/ Director, Center for Advanced Sensor Technology, *University of Maryland Baltimore County*

O – Conducting an Effective Investigation

Properly investigating unwanted events and process failures, identifying process failure causes, and determining corrective and preventive actions are an essential element of an effective Quality System program. This session presents discussions on recent and important case studies, updates, and effective tools for conducting and closing investigations.

Presenters:

Joseph Chen, PhD, Associate Director, *Genentech, Inc.*
Johnnie Williams, Director, Quality Engineering/Quality Systems, *DSM Pharmaceuticals, Inc.*

Closing Plenary Session: Focus on the Future

We are witnessing a far-reaching change in therapeutic approaches: personalized healthcare, cell therapies and gene therapies are increasingly making the headlines owing to their potential to provide more effective treatments to patients. These new therapies will entail a complete change in the pharmaceutical industry's traditional manufacturing paradigm. What will the future of our industry look like? Our speakers and panelists provide you with the opportunity to hear about a pioneering technology with the potential of transforming the future of cancer treatments, and get a glance into the future of personalized medicines.

Presenters:

Carl June, MD, Program Director, Translation Research, Professor, Department of Pathology & Laboratory Medicine, *University of Pennsylvania Abramson Cancer Center*
John Yu, MD, Vice Chair, Dept. of Neurosurgery, *Cedars-Sinai Medical Center*

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2013 PDA/FDA Glass Packaging Conference Session Recordings

New Opportunities for the Future

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- All six (6) recorded sessions from 2013 Glass Packaging Conference
- Access to 13 downloadable presentation handouts
- Unlimited access to the recordings for 90 days from receipt of login information

Introduction – Overview

This recorded session provides listeners with a summary of data collected from the 2013 glass survey. In addition, it addresses the challenges of factors that increase or decrease glass breakage during transport in the supply chain – an area of increasing interest for maintaining glass quality.

Presenters:

Steven Wolfgang, PhD, *FDA*
Richard Johnson, *PDA*

Glass Raw Materials

This session provides detailed insight for the selection criteria and specifications for glass containers, and how they change in response to adverse drug product interaction, higher defect detection capabilities, and manufacturing improvements.

Presenter:

Folker Steden, PhD, *Schott AG*

Panelists:

Juan Cerdan-Diaz, PhD, *Nipro Glass Americas*
Mads Reedtz Espersen, *Novo Nordisk A/S*
Mihaela Simianu, *Eli Lilly and Company*
Folker Steden, PhD, *Schott AG*
Steven Wolfgang, PhD, *FDA*

Raw Material to Tubular Vial

This recording provides an insight into the entire manufacturing process for a tubular glass vial which will include control of raw materials, batching, testing, glass tube forming and fabrication of a tubular glass vial. Each presenter provides a description of the process which includes steps that are followed and the controls that are in place to assure the quality of the product through each phase of the process.

Presenters:

Mark Fitzgerald, *Nipro Glass Americas*
John McDermott, *Gerresheimer Glass Inc.*
Boris Schmid, *Ompi*

Material Science Considerations for Glass Containers

This session includes a case study on the design of experiments work that Alfred University and a glass manufacturer performed on delamination. In addition, listeners receive an update from USP on its Evaluation of the Inner Surface Durability of Glass Containers Chapter, which provides methods to assess the possibility of a drug product to form glass particles and delamination and to detect their occurrence.

Presenters:

Carol Rea Flynn, *Gerresheimer Glass Inc.*
Desmond Hunt, PhD, *United States Pharmacopeia (USP)*

Analytical Techniques and Testing Protocols

This recording addresses the increasing interest in industry and regulatory about state of the art inspection technologies capable to visualize stress and tension in glass and sub-visble particles in drug formulations. The first presentation focuses on an imaging measurement system that helps determine the magnitude and orientation of stress by measuring birefringence. The second topic addresses measuring glass sub-visible particles in protein drug formulations by analytical techniques.

Presenters:

Henning Katte, *ilis GmbH*
John Shabushnig, PhD, *Insight Pharma Consulting, LLC*

Integrated Measures to Control Glass Quality during Manufacturing Processes

These presentations illustrate how pharmaceutical firms ensure quality in their manufacturing process as well as how they work to mitigate glass particulates throughout their manufacturing process. The final presentation provides information on the latest activities and plans for the Glass Handling Task Force.

Presenters:

Gregory Pitt, *Eli Lilly and Company*
Mads Reedtz Espersen, *Novo Nordisk A/S*
Patrick Begley, *Becton Dickinson*

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2013 PDA/FDA Process Validation Workshop Session Recordings

Practical Implementation of the Life Cycle Approach

Member/ Nonmember: $280

Price of recordings includes:

- Seven (7) recorded sessions from the 2013 Process Validation Workshop
- Access to 6 downloadable presentation handouts
- Unlimited playback of the recordings for 90 days from receipt of login information

Introduction – Regulatory Perspectives

During this recorded session, speakers introduce and present views on the U.S. and European process validation guidance, as well as respective life cycle approaches, expectations, and recommendations.

Presenters:

Jeffrey Baker, PhD, Deputy Director, Office of Biotechnology, CDER, *FDA*
Vijay Chiruvolu, PhD, Director, Corporate Quality, *Amgen, Inc.*

Process Design – Where to Begin

This recording explores how companies are and can be developing and implementing plans for determining, identifying, and interpreting information from process design functions in an effort to develop process control strategies and process validation approaches.

Presenters:

Patrick Swann, PhD, Deputy Director, Division of Monoclonal Antibodies, CDER, *FDA*
Michael Blackton, Senior Director, Manufacturing Validation, *ImClone Systems*

Process Qualification Part I – How to Test

This recorded session presents methods which can be used to design Stage 2 test functions and acceptance criteria to assure that control strategies are effective. Presentations are given on best practices for equipment and facility assessment/qualification and for the development of pragmatic and effective, statistically sound Process Qualification sampling plans.

Presenters:

Greg Sears, Manager, Process and Computer Systems Validation, *Lonza*
Wayne A. Taylor, PhD, Chairman, *Taylor Enterprises, Inc.*

Process Qualification Part II – Case Studies

This session presents case studies for drug substances and drug products utilizing the life cycle and guidance principles. The case studies include discussions on the challenges faced by the participants and actions taken to address those challenges.

Presenters:

David Paolella, PhD, Director, Manufacturing Science and Technology, *Glaxo Smith Kline*
Timothy J.N. Watson, PhD, Research Fellow, *Pfizer; Pharma Therapeutics Pharmaceutical Sciences*
Chris Ames, Director Quality Assurance Validation, *Genzyme*

Continued Process Verification Part I – Confirmation and Vigilance

This session focuses on developing strategies for deciding on the sources of information, presentation of data, and interpretation of results – to help companies better use this knowledge.

Presenters:

Cliff Campbell, Principal Consultant, *Cliff Campbell Consulting Ltd.*
Steven Hertz, Consumer Safety Officer, CDER, *FDA*
John McShane, Head of Global Quality System Biologics, *Roche Pharmaceuticals/Genentech*

Continued Process Verification Part II – Case Studies

This session presents case studies illustrating how the principles discussed in previous recorded sessions from this workshop are used to during the validation of large molecule and small molecule products.

Presenters:

David Reifsnyder, PhD, Head, Process Validation, *Genentech*
Raj Jani, Senior Research Scientist, *Baxter Healthcare*
Stephen Galvin, Regulatory Scientist, *Eli Lilly S.A. Irish Branch*

Report of Breakout Sessions and Panel Discussion

The recording of the final session of the workshop discusses feedback from the breakout sessions given by facilitators followed by an interactive discussion with a panel comprised of workshop presenters.

Panelists:

Jeffrey Baker, PhD, Deputy Director, Office of Biotechnology, CDER, *FDA*
Vijay Chiruvolu, PhD, Director, Corporate Quality, *Amgen*
Steven Hertz, Consumer Safety Officer, CDER, *FDA*
Patrick Swann, PhD, Deputy Director, Division of Monoclonal Antibodies, CDER, *FDA*

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2013 PDA Aseptic Processing-Sterilization Conference Session Recordings

Member/ Nonmember: $300

Price of recordings includes:

- All eight (8) recorded sessions from the 2013 Aseptic Processing-Sterilization Conference
- Access to 16 downloadable presentation handouts
- Unlimited playback of the recordings for 90 days from receipt of login information

Lessons Learned

This session begins by summarizing the tragic situations and resulting lessons learned from recent aseptic compounding issues that can be used to strengthen Sterility Assurance programs. This recording also explores the benefits of a "re-evolving" role for the microbiologist which includes dedication to applied microbiology to improve microbial control practices in the manufacture of pharmaceuticals.

Presenters:

Hal Baseman, Chief Operating Officer, *ValSource LLC*
Robert D. Seltzer, Senior Manager, Quality GMP, *Acorda Therapeutics, Inc.*

Regulatory Perspectives

This session highlights the recent experiences from the complementary perspectives of an inspector and reviewer to provide valuable insight into the regulatory expectations for the development, validation and ongoing control of sterile product manufacturing processes.

Presenters:

Thomas J. Arista, National Expert Investigator, ORA, *FDA (Via teleconference)*
Jessica Cole, PhD, Product Quality Microbiology Reviewer, CDER, *FDA*

Novel Sterilization Technologies

The use of new technologies for sterilization continues to evolve as product and packaging characteristics change. This recording addresses several new approaches to sterilization and how they can be applied to commercial manufacturing.

Presenters:

Barry Ressler, Chairman & CEO, *Triton Thalassic Technologies, Inc.*
Myron Civils, Validation Consultant, *Eli Lilly & Company*

PDA Technical Report Showcase

This session highlights several recent technical reports which address areas important to sterile products, such as manual aseptic processing, and biofilm/bioburden.

Presenters:

Hal Baseman, Chief Operating Officer, *ValSource LLC*
Mark Pasmore, PhD, Senior Principal Engineer, *Baxter Healthcare Corporation*

Best Demonstrated Practices

Parametric release, Restricted Access Barrier Systems (RABS) and Isolators are key components of a sterile manufacturing process. This session explores some of the latest practices involving these two methods.

Presenters:

Michael Sadowski, Director, Sterile Manufacture Support, *Baxter Healthcare Corporation*
Gerry Morris, PhD, Global Quality Systems, *Eli Lilly and Company*
Marcia Baroni, Director of Quality, *Eli Lilly Italia S.p.A.*

Quality Risk Management

Practical and novel approaches for applying Quality Risk Management are presented in case studies that explore the integration of ICH Q8, Q9, and Q10 to develop, implement and sustain a sterile drug product manufacturing control strategy and utilization of quantitative risk modeling to rapidly assess risk of bioburden ingress during aseptic filling.

Presenters:

Jason S. Collins, Director of Process Architecture, *Integrated Project Services (IPS)*
Ghada Haddad, Associate Director, Engineering, BioSterile Validation, *Merck Sharpe & Dohme*

Update on Global Regulations

This session provides points of view from US and EU delegates on the latest procedures and guidelines regarding Aseptic Processing and Sterilization, as well as an update on biological indicators in the preparation of sterile products.

Presenters:

Radhakrishna Tirumalai, PhD, Staff Liaison, Microbiology and Sterility Assurance, *USP*
David Opie, PhD, Senior Vice President, Research and Development, *Noxilizer*

Ask the Experts Panel Discussion

The recording of the last session provides further discussion regarding the trends, issues, solutions and best demonstrated practices in the manufacture of sterile products.

Presenter:

Richard V. Levy, PhD, Senior Vice President, Science and Regulatory Affairs, *PDA*

Panelists:

Thomas J. Arista, National Expert Investigator, ORA, *FDA*
Jessica Cole, PhD, Product Quality Microbiology Reviewer, CDER, *FDA*

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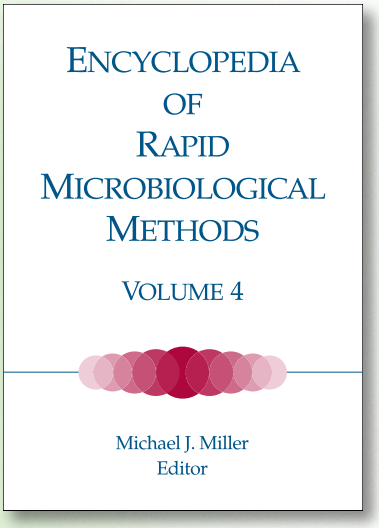

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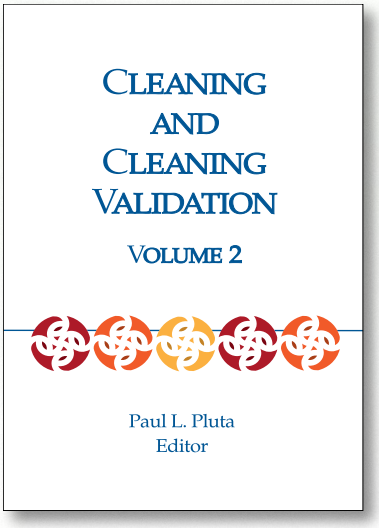

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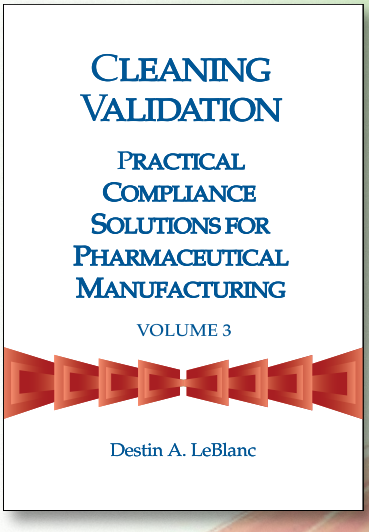

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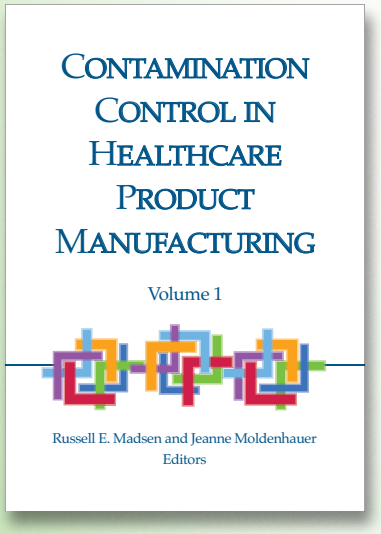

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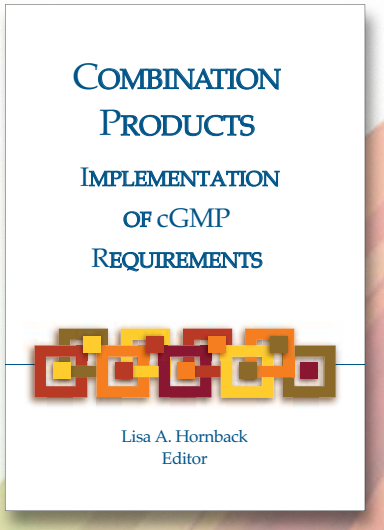

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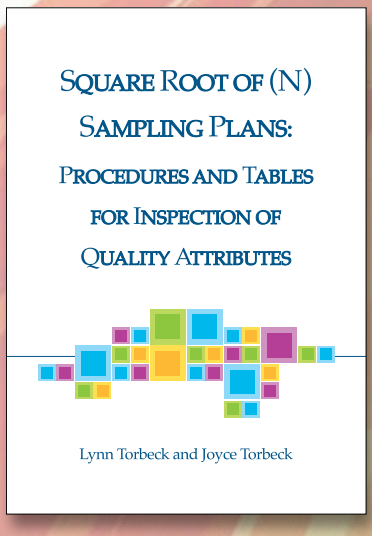

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2014 PDA Quality Risk Management/Knowledge Management Conference	Bethesda, MD	19-20 May
2014 PDA FDA Supply Chain Conference – Supported by RX-360	Washington, DC	3-4 June
2014 PDA/FDA Viral and TSE Safety Conference	Bethesda, MD	9-11 June
2014 PDA Aseptic Sterilization Conference	Chicago, IL	17-18 June
2014 PDA/FDA Joint Regulatory Conference	Washington, DC	8-10 Sept
2014 PDA/FDA Drug Shortage Workshop	Washington, DC	10-11 Sept
2014 PDA Universe of Prefilled Syringes and Injection Devices	Huntington, CA	7 Oct
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