Program Agenda

2006 ISPE/PDA Joint Workshop
Challenges of Implementing ICH Q8 and ICH Q9 - Practical Applications

Omni Shoreham Hotel, Washington, DC
December 6-7, 2006

2006 ISPE/PDA Joint Workshop
Challenges of Implementing ICH Q8 and ICH Q9 - Practical Applications
Omni Shoreham Hotel, Washington, DC
December 6-7, 2006

Wednesday, December 6, 2006

7:30 a.m. - 8:30 a.m.
Continental Breakfast — Palladian Foyer

7:30 a.m. - 4:00 p.m.
Registration — Palladian Foyer

8:30 a.m. - 8:45 a.m. — Palladian Ballroom
Welcome and Opening Remarks: Conference Co-Chairs
Joseph Phillips, International Regulatory Affairs Advisor, *ISPE*
Robert L. Dana, Vice President Quality &Regulatory Affairs, *PDA*

8:45 a.m. - 9:15 a.m.
Keynote Presentation
Session Moderator: **Joseph Phillips,** International Regulatory Affairs Advisor, *ISPE*
What Does the Future of Pharmaceutical Manufacturing Look Like?
Dr. Janet Woodcock, Deputy Commissioner for Operations, *FDA*

9:15a.m. - 10:15 a.m.
Session P1: Introduction to Q8 and Q9
Session Moderator: **Joseph Phillips,** International Regulatory Affairs Advisor, *ISPE*

The joint presentation will provide the history and the importance of pharmaceutical development (ICH Q8) and of quality risk management (ICH Q9) on the lifecycle of a drug product. The challenges on implementation and the connectivity of these two topics will be presented.

9:15 a.m. - 10:00 a.m.
Introduction to ICH Q8 Pharmaceutical Development and ICH Q9 Quality Risk Management
Dr. -Ing Stephan Roenninger, Global Quality Manager, *F. Hoffmann-LaRoche Ltd.*
Dr. Jean-Louis Robert, Service du Controle des Medicaments, *Laboratoire National de Sante, Luxembourg*

10:00 a.m. - 10:15 a.m.
Question and Answer

10:15 a.m. - 10:30 a.m.
Refreshment Break — Palladian Foyer

10:30 a.m. - 11:45 a.m.
Session P2: Q8 Implementation Challenges - A Regulatory Perspective
Session Moderator: **Dr. Charles Hoiberg,** Senior Director, Global Regulatory CMC & QA, *Pfizer, Inc.*

A perspective of the regulatory challenges in implementing Q8 in the US and Europe will be presented. These challenges include: how to conduct science-and risk-based assessment of submissions rich in product knowledge and process understanding information and how to balance between expectations for a QbD-based submission and approval of a quality product without raising the bar; how to provide regulatory flexibility while assuring product quality; how to handle legacy products; and how to maintain a dual system that encompasses both QbD-based and traditional submissions.

10:30 a.m. - 11:00 a.m.
Implementation of Q8: An EU Perspective
Dr. Susanne Keitel, Division Head, EU, International Affairs, *Federal Institute for Drugs and Medical Devices, Germany*

11:00 a.m. - 11:30 a.m.
Implementation of Q8 an FDA Perspective
Dr. Moheb Nasr, Director, ONDQA, *FDA*

11:30 a.m. - 11:45 p.m.
Question and Answer

11:45 a.m. - 12:45 p.m. Empire Ballroom
Lunch

1:00 p.m. - 2:15 p.m.
Session P3: Q8 Implementation Challenges - An Industry Perspective
Session Moderator: **Dr. Moheb Nasr,** Director ONDQA, *FDA*

The industry expectations when implementing Q8 will be presented. Potential benefits, e.g., enhanced process capability and robustness, improved product quality, lowered risk for product rejects and recalls, integrated review-inspection system, regulatory flexibility for setting specifications and post-approval change management, will be discussed.

1:00 p.m. - 1:30 p.m.
European Perspective on Q8 Implementation Challenges
Dr. John Berridge, Vice President, Pharmaceutical Sciences, *Pfizer*

1:30 p.m. - 2:00 p.m.
US Perspective on Q8 Implementation Challenges
Dr. Karen Main, Associate Director, US/UK Investigational Products, *AstraZeneca*

2:00 p.m. - 2:15 p.m.
Question and Answer

2:15 p.m. - 3:30 p.m.
Session P4: Q9 - Regulatory Perspective
Session Moderator: **Betsy Fritschel,** Director, Quality & Compliance, *Johnson & Johnson*

Regulatory perspectives from both the US FDA and EU on the implementation of Q9 Quality Risk Management will be presented. This will include the challenges and opportunities that arise during the product assessment (review) process and the inspection process.

2:15 p.m. - 2:45 p.m.
US Regulatory Perspective on Q9
Joe Famulare, Acting Deputy Director, Office of Compliance, CDER, *FDA*

2:45 p.m. - 3:15 p.m.
European Regulatory Perspective on Q9
Dr. Jean-Louis Robert, Service du Controle des Medicaments, *Laboratoire National de Sante, Luxembourg*

3:15 p.m. - 3:30 p.m.
Question and Answer

3:30 p.m. - 3:45 p.m.
Refreshment Break Palladian Foyer

3:45 p.m. - 5:00 p.m.
Session P5: Q9 - Industry Perspective
Session Moderator: **Joe Famulare,** Acting Deputy Director, Office of Compliance, CDER, *FDA*

ICH Q9, Quality Risk Management, forms and integral part of the ICH Quality Guidance process. Risk management concepts and principles have been used of some time within the pharmaceutical industry. This session will focus on how the US and European industry is further integrating the risk management principles contained in Q9 into their systems and processes, as well as looking at some of the challenges associated with its implementation. Industry expectations with respect to regulatory oversight will also be discussed.

3:45 p.m. - 4:15 p.m.
US Industry Perspective on Q9
Zena Kaufman, Director, Quality Center of Excellence, *Abbott Laboratories*

4:15 p.m. - 4:45 p.m.
European Industry Perspective on Q9
Malcolm Holmes, Director, Global Quality Assurance, *GlaxoSmithKline*

4:45 p.m. - 5:00 p.m.
Question and Answer

5:00 p.m. - 6:00 p.m.
Networking Reception Hampton Ballroom

Thursday, December 7, 2006

7:30 a.m. - 8:30 a.m.
Continental Breakfast — Palladian Foyer

7:30 a.m. - 4:00 p.m.
Registration — Palladian Foyer

8:30 a.m. - 9:45 a.m.
P6: Japanese Perspective of Q8 and Q9
Session Moderator: **Gail Sherman,** Vice President of Education, *PDA*

The Japanese regulatory authority and pharmaceutical industry has participated as partners in the global development of ICH Q8 and Q9 guidances. This session will describe the Japanese industry and regulatory perspectives on these documents.

8:30 a.m. - 9:00 a.m.
Regulatory Perspectives on Q8/Q9
Dr. Yukio Hiyama, Chief, Third Section Division of Drugs, *National Institute of Health Sciences*

9:00 a.m. - 9:30 a.m.
Industry Perspectives on Q8/Q9
Dr. Shigeki Tamura, Research Fellow, Oral Formulation, *Astellas Pharma Inc.*

9:30 a.m. - 9:45 a.m.
Question and Answer

9:45a.m. - 10:15a.m.
Refreshment Break — Palladian Foyer

10:15 a.m. - 11:45 a.m.
P7: Q8 Case Studies and Potential Applications - Industry/Regulatory
Session Moderator: **Dr. Chi-Wan Chen,** Deputy Director, ONDQA, *FDA*

FDA CMC Pilot Program - FDA and industry representatives will discuss their experiences with the FDA CMC Pilot Program that is intended to explore how to apply the QbD principles and implement Q8. Case studies and lessons learned will be presented

10:15 a.m. - 10:30 a.m.
Introduction
Dr. Chi-Wan Chen, Deputy Director, ONDQA, *FDA*

10:30 a.m. - 11:00 a.m.
Rational Design of a Drug Substance Crystallization Process - A QbD Approach
Dr. John Lepore, Senior Director, API Technology, *Merck Manufacturing Division*

11:00 a.m. - 11:30 a.m.
Rational Design of HPMC and Roller Compaction for an Extended Release Drug Product - A QbD Approach
Dr. Nirdosh Jagota, Assistant Vice President, WWRA Pharma, *Wyeth Research*

11:30 a.m. - 11:45 a.m.
Questions and Answer

11:45 a.m. - 12:45 p.m.
Lunch Empire Ballroom

1:00 p.m. - 3:00 p.m.
P8: Q9 Case Studies and Potential Applications - Industry/Regulatory
Session Moderator: **Dr. H. Gregg Claycamp,** Risk Assessment Manager, ONADE, *FDA*

Beyond the theories contained within the ICH Q9 document, "Quality Risk Management" a discussion of implementation strategies will be performed by case studies from industry and Competent Authorities. Potential applications for Quality Risk Management will be presented and discussed of how others have successfully used Quality Risk Management in industry and by regulators.

1:00 p.m. - 1:15 p.m.
Introduction
Dr. H. Gregg Claycamp, Risk Assessment Manager, ONADE, *FDA*

1:15 p.m. - 1:45 p.m.
Risk Management in Quality Systems
Dr. Ulrich Becht, Director Quality Assurance, *Abbott GmbH & Co.KG*

1:45 p.m. - 2:15 p.m.
Risk Management in Production Systems
Betsy Fritschel, Director, Quality & Compliance Worldwide, *Johnson & Johnson*
Diane Hagerty, Senior Director, QA Compliance & Validation, *Global Biologics Supply Chain, LLC*

2:15 p.m. - 2:45 p.m.
A Risk Based Audit Planning Tool
Dr. -Ing Stephan Roenninger, Global Quality Manager, *F. Hoffmann-LaRoche Ltd*

2:45 p.m. - 3:00 p.m.
Question and Answer

3:00 p.m. - 3:15 p.m.
Refreshment Break Palladian Foyer

3:15 p.m. - 4:15 p.m.
P9: Regulator Panel: Vision of the Future - What Does This Look Like 10 Years Out?
Session Moderator: **Dr. Robert Baum,** Executive Director, Global Regulatory CMC Policy, Pfizer, Inc

Panelists will address questions from the audience as well as provide thoughts as to how the evolution of these guidelines will influence pharmaceutical development and manufacturing practices in the future.

(All US and European Regulatory Presenters)

4:15 p.m. - 4:45 p.m.
P10: ISPE/PDA Perspective and Activities Related to Q8 and Q9
Session Moderator: **Robert L. Dana,** Vice President Quality and Regulatory Affairs, *PDA*

This session will provide an update on the plans and programs underway in ISPE and PDA regarding the implementation of Q8 and Q9 and the impact these Guidances will have on the industry.

4:15 p.m. - 4:30 p.m.
ISPE Perspectives and Activities Related to Q8 and Q9
Dr. Charles Hoiberg, Executive Director, Global Regulatory CMC & QA, *Pfizer, Inc.*

4:30 p.m. - 4:45 p.m.
PDA Perspectives and Activities Related to Q8 and Q9
Harold Baseman, COO, *Valsource LLP*

4:45 p.m. - 5:00 p.m.
Conference Wrap Up and Adjourn
Joseph Phillips, International Regulatory Affairs Advisor, *ISPE*
Robert L. Dana, Vice President Quality and Regulatory Affairs, *PDA*