Sunday, December 8

3:00 p.m. – 6:00 p.m.
Registration Open

Monday, December 9

7:00 a.m. – 5:45 p.m.
Registration Open
7:00 a.m. – 8:00 a.m.
Continental Breakfast

8:00 a.m. – 10:15 a.m.
P1: Realizing the Power and Potential of Risk Management: A Regulatory Perspective
Moderator: Tina S. Morris, PhD, Vice President, Scientific & Regulatory Affairs, Parenteral Drug Association

The opening plenary brings together two compelling perspectives on the power and potential of risk management – across the international pharmaceutical space, as codified by ICH Q9, but also domestically as a tool employed by Federal Agencies. Dr. Janet Woodcock will discuss how the FDA currently views the application and future potential of risk management approaches – has the potential of QRM been fully realized, yet, and where are we on the journey to fully leverage the paradigms laid out in ICH Q9 and Q10? Thomas Stanton, Author of Public Sector Enterprise Risk Management, will provide a perspective on the journey of introducing and successfully establishing acceptance of ERM concepts in the federal government context.

8:00 a.m. – 9:45 a.m.
Welcome and Opening Remarks
2019 PDA Quality Week Program Planning Committee Co-Chairs
Ghada N. Haddad, PhD, Executive Director, Global cGMP & Compliance Auditing Organization, Merck & Co., Inc., and
Susan J. Schniepp, BS, Distinguished Fellow, Regulatory Compliance Associates Inc.

8:15 a.m. – 9:00 a.m.
Enterprise Risk Management: A Powerful Management Tool
Thomas H. Stanton, MA, JD, Fellow, Johns Hopkins University

9:00 a.m. – 9:45 a.m.
FDA Perspective
Janet Woodcock, MD, Center Director, CDER, U.S. FDA

9:45 a.m. – 10:15 a.m.
Questions and Answers/Discussion

10:15 a.m. – 10:45 a.m.
Refreshment Break and Poster Presentations

Poster Presentations
The following posters will be presented during refreshment breaks and the networking reception

1. Benefits of Using Quality Risk Management Proactively During Facility Design
   Adam M. Caruso, MBA, Associate Director, Quality Risk Management Center of Excellence, Merck & Co., Inc.

10:45 a.m. – 12:15 p.m.
P2: The Global Perspective on QRM
Moderator: Harold S. Baseaman, MBA, Chief Operations Officer, ValSource, LLC

There are good reasons and strong expectations for our industry to use QRM principles to make sound, informed, and better decisions related to the control of manufacturing processes, the prioritization of resources, and the supply of quality products.
This session will explore current and on-going expectations, opportunities, challenges, and solutions for the use of QRM principles from the perspective and practical experience of health authority and industry experts.

### 10:45 a.m. – 11:15 a.m.

**Risk Identification and Management Led to the Creation of Civica**

**A Transformative – Disruptive Company Serving Patients by Delivering Quality Medicines that are Available and Affordable**

**Martin G. VanTrieste, BS Pharmacy**, President & CEO, **Civica Inc.**

11:15 a.m. – 11:45 a.m.

**Risk Management in the Assessment of Quality Submissions for Biologics: Reviewer’s Perspective**

**Martin Nemec, PhD**, Senior Biologist/Evaluator, **Health Canada**

11:45 a.m. – 12:15 p.m.

**Questions and Answers/Discussion**

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12:15 p.m. – 1:15 p.m.

**Lunch**

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### 1:15 p.m. – 2:45 p.m.

**P3: Quality Risk Management for Combination Products**

**Moderator: Denyse D. Baker, PE, RAC**, Senior Director of Regulatory Policy, **AstraZeneca**

As biopharma companies work to deliver optimal solutions for patients, more drug and biologic products are coming to market in combination with delivery devices, wearable electronics, or mobile apps. The complexities of drug or biologic-to-device and patient-to-device interfaces create new risks that must be appropriately managed by manufacturers. This session will feature FDA and industry experts discussing current regulatory expectations, including the new U.S. FDA guidance on Post-market Safety Reporting, and practical examples of using risk information in the manufacturing and quality systems for combination products.

1:15 p.m. – 1:45 p.m.

**FDA Perspective: Combination Product Postmarket Requirements and Risk Management**

**Melissa B. Burns, MS**, Senior Program Manager, **U.S. FDA**

1:45 p.m. – 2:15 p.m.

**Doug Hamann**, Compliance Lead – Device & Complaints, **AstraZeneca**

2:15 p.m. – 2:45 p.m.

**Questions and Answers/Discussion**

2:30 p.m. – 5:45 p.m.

**Exhibit Area Open**

2:45 p.m. – 3:15 p.m.

**Refreshment Break and Poster Presentation**

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### 3:15 p.m. – 4:45 p.m.

**P4: Risk Models used by Regulators**

**Moderator: Steve R. Mendivil, BS**, Independent Consultant

The FDA is using risk principles in several different programs including: Inspectional Risk Models, and Drug Shortage Program. Explore the risk principles being utilized and how those might be developed to focus FDA’s resources and efforts to assess and addressing quality and compliance issues at global manufacturing sites that impact patient safety and drug availability. The pharmaceutical manufacturing industry utilities metrics, assessments and other risk principles in preventing quality and drug shortage issues. This session explores how those can help prevent quality and drug shortage issues and how those might be shared with regulators to be considered a “low risk manufacturing site” and its potential benefits.

3:15 p.m. – 3:45 p.m.

**Guy Villax, CEO, Hovione**

3:45 p.m. – 4:15 p.m.

**Risk-Based Quality Surveillance Program**

**Lucinda Buhse, PhD**, Director, OPQ/Office of Surveillance, **CDER, U.S. FDA**

4:15 p.m. – 4:45 p.m.

**Questions and Answers/Discussion**

4:45 p.m. – 5:45 p.m.

**Networking Reception**
Tuesday, December 10

7:00 a.m. – 5:15 p.m.
Registration Open

7:00 a.m. – 8:00 a.m.
Continental Breakfast

8:00 a.m. – 9:30 a.m.

**P5: Integration of QRM into Quality Systems**
**Moderator:** Marcello Colao, MS, Director, Regulatory & Technical Lifecycle, GSK Vaccines

Quality Risk Management (QRM) is a key enabler of the Pharmaceutical Quality System. This session explores how QRM principles can be integrated into two critical Quality systems such as Change Control and Deviation Management; more specifically this session will explore how QRM can facilitate the management of Post-Approval Changes during lifecycle in order to foster continual improvement and innovation, and how it can be used as a strong foundation to build an effective Deviation Management system.

8:00 a.m. – 8:30 a.m.

**Solving the Global Continual Improvement and Innovation Challenge: A Risk-Based Approach to Management of Post-Approval Changes**
**Anders Vinther,** Head of Quality, *Intarcia*

8:30 a.m. – 9:00 a.m.

**QRM as Key Foundation for an Effective Deviation Management System**
**Katie Link,** Director Quality Systems Site Support, *Pfizer Inc*

9:00 a.m. – 9:30 a.m.

Questions and Answers/ Discussion

9:15 a.m. – 3:30 p.m.

Exhibit Area Open

9:30 a.m. – 10:15 a.m.

Refreshment Break and Poster Presentations in Exhibit Area

10:15 a.m. – 11:45 a.m.

**P6: ICH Q9 Journey: Where are We?**
**Moderator:** Magaly E. Aham, MSc, Head Knowledge Management, *Takeda*

This session will explore ICHQ9 from both the industry and regulatory perspective since its initial implementation on 2005. The session will discuss the maturity level of QRM and tools application in the industry, common pitfalls and potential improvements that can be made to further enhance its benefits. Practical examples on how ICHQ9 can be effectively implemented and most importantly sustained linking quality to protection of the patient will be shared.

10:15 a.m. – 10:45 a.m.

**Quality Risk Management at 15: Are QRM Resilience and Process Maturity on the Horizon?**
**H. Gregg Claycamp,** PhD, Biologist, CVM, *U.S. FDA*

10:45 a.m. – 11:15 a.m.

**15 Years of ICH Q9 Practical implementation & Pitfalls**
**Stephan K. Roenninger,** PhD, Quality External Affairs, *Amgen GmbH*

11:15 a.m. – 11:45 p.m.

Questions and Answers/ Discussion

11:45 a.m. – 1:15 p.m.

Facilitated Roundtable Lunch

1:15 p.m. – 2:45 p.m.

**P7: Facilitated Roundtable Lunch Recap**
**Moderator:** Magaly E. Aham, MSc, Head Knowledge Management, *Takeda*

1:15 p.m. – 1:45 p.m.

**Driving Stakerholders to Consensus: Unraveling the ICH Process**
**Janeen A. Skutnik-Wilkinson,** Associate Director for Quality Intelligence, *Biogen*

1:45 p.m. – 2:45 p.m.

Panel Discussion
H. Gregg Claycamp, PhD, Biologist, CVM, U.S. FDA  
Stephan K. Roenninger, PhD, Quality External Affairs, Amgen GmbH

2:45 p.m. – 3:30 p.m.  
Refreshment Break and Poster Presentations in Exhibit Area

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<th>Time</th>
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| 3:30 p.m. – 5:15 p.m. | P8: Quality Risk Management in Aseptic Processing  
Moderator: Jaap Venema, PhD, Chief Science Officer, U.S. Pharmacopeia (USP)  
Aseptic processes can be some of the most difficult processes to conduct in the pharmaceutical industry. If not properly controlled, aseptic processes present a significantly higher risk than terminally sterilization processes. An effective risk-management program is critical in the careful control of the process, reducing the risk of loss of sterility as well as ensuring a commensurate approach to risk management based on the potential risk to the patient. This session provides industry perspectives on the regulatory expectations, challenges and opportunities for improvement in controlling aseptic processing. |
| 3:30 p.m. – 4:00 p.m. | Regulatory Requirements for QRM and the Link to the Contamination Control Strategy  
Andrew D. Hopkins, BSc, Hon PGDip, Director, Operation Quality QA Audit and Compliance, AbbVie, Inc. |
| 4:00 p.m. – 4:30 p.m. | Why is QRM of Aseptic Processing so Difficult and How to Make it Better?  
Harold S. Baseman, MBA, Chief Operating Officer, ValSource LLC |
| 4:30 p.m. – 5:00 p.m. | Questions and Answers/ Discussion |
| 5:00 p.m. – 5:15 p.m. | Closing Remarks and Adjournment  
Ghada N. Haddad, PhD, Executive Director, Global cGMP & Compliance Auditing Organization, Merck & Co., Inc. |

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