PDA India Chapter Annual Meeting

Maintaining QUALITY & COMPLIANCE in Pharmaceutical Drug Manufacturing and Regulatory Expectations

11 – 15 March 2024
Hyderabad, India

Day One – Monday, 11 March 2024

8:00am – Registration Open

9:00am - 12:30pm
Plenary Session One (P1) - Opening Plenary Session and Keynote Presentations

Session Leaders: Rishikesh Jaiwant, Senior Director Manufacturing & Operations and Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA and Co-Chair, PDA India Chapter Annual Meeting

Session Overview: Strategic planning, concurrent monitoring, and critical evaluation of FDA initiatives will enable us to stay complaint with cGMP as well. It is important to understand regulators’ expectations. Their candid feedback and directive for new initiatives should be taken in the right spirit as their unending support for the betterment of the industry per se. Simultaneously, equal importance should be levied to comply with the basic GMP, which when violated, restricts our capacity to serve our end users – the patients. This session will bring an overarching perspective on how to maintain a state of supreme quality from regulatory perspective, and how to move the needle towards Quality Management Maturity.

9:00am – 9:30am
Welcome and Opening Remarks

9:30am - 9:50am
Update on FDA Initiatives and Strategic Plans for the Region
Dr. Sarah McMullen, Country Director, US FDA India Office (Invited)
Dr. Rajeev Sing Raghuvanshi, Drug Controller General, India (Invited)

9:50am - 10:20am
The Cost of Poor Quality
Dr. Anil Sawant, Senior Vice President, Global Quality Compliance, Merck Sharpe & Dohme, USA and Chair-Elect Board of Directors, PDA Inc.

10:20am – 10:50am
Updates from the Office of Pharmaceutical Quality Operations/ORA
Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, ORA/US FDA

10:50am -11:20am
Regulatory Update: State of Quality from a Regulatory Perspective
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA and Co-Chair, PDA India Chapter Annual Meeting

11:20am -11:50am
API Inspections in India and Update on Current Issues
Dr. Thomas Hecker, Inspector, EDQM  EDQM is correct
11:50am – 12:30pm
Questions and Answers

12:30pm – 1:30pm Lunch and Exhibition

1:30pm - 3:30pm
Plenary Session Two (P2) - Quality Culture to Quality Maturity - What Does it Mean?
Session Leader: Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA
Session Overview: Global regulators continue to focus on the importance of quality culture and its impact on the entire life cycle of pharmaceuticals. This session will illustrate how to elevate the concept of quality culture to quality maturity. The discussion will include the importance of building a reliable quality culture throughout the entire organization from technician to C-suite, how to maintain and nurture it, and how to gather and analyze metrics to understand if an organization's quality culture initiatives are working.

1:30pm - 2:00pm
Importance of having a Strong Quality Culture from C Suite to Technicians
Dr. G.K. Raju, Chairman and CEO, Light Pharma Inc.

2:00pm - 2:30pm
Quality Culture; is it Working?
Stephen Tyrpak, Associate Vice President of Operations, PQE

2:30pm - 3:00pm
What does True Quality Sustainability Mean?
Dr. Deva Puranam, Head-Global Quality Investigations, Surveillance & Regulatory Communications, Viatris

3:00pm – 3:30pm
Panel Discussion & Questions/Answers
- Peter Baker, President, Live Oak Quality Assurance
- Dr. Thomas Hecker, Inspector, EDQM
- Brooke Higgins, Senior Policy Advisor, Global Compliance Branch, CDER/OMQ/US FDA
- Mahesh Ramanadham, Pharm.D, Deputy Director, CDER/OPQ/US FDA
- Dr. Deva Puranam, Head-Global Quality Investigations, Surveillance & Regulatory Communications, Viatris
- Dr. G.K. Raju, Chairman and CEO, Light Pharma Inc.
- Dr. Anil Sawant, Senior Vice President, Global Quality Compliance, Merck Sharpe & Dohme, USA and Chair-Elect Board of Directors, PDA Inc.
- Stephen Tyrpak, Associate Vice President of Operations, PQE
- Delete Carmelo Rosa

3:30pm – 4:15pm Refreshment Break and Exhibition

4:15pm – 6:15pm
Plenary Session Three (P3) - Data Integrity: Back to the Future, An Open and Transparent DI-SIX System Approach
Session Leader: Dr. Anil Sawant, Senior Vice President, Global Quality Compliance, Merck Sharpe & Dohme, USA; Chair-Elect Board of Directors, PDA Inc
Session Overview: Data Integrity continues to be a major focus for regulatory agencies and regulated companies. This session will focus on identifying and implementing strategic controls for maintaining the integrity of the data. Get a better understanding of Data Integrity fundamentals and how they impact the Pharma industry; how to maintain your data integrity program as current through annual review; the most efficient and effective DI approaches to use as part of your DI implementation strategy; and the impact to
the integrity of the data with increases in volume, sources, and complexity.

4:15pm – 4:45pm
Digitisation & Data Integrity – Lessons Learned
Alicja Wolska, Executive Director, Data and Digital Quality, Merck Sharpe Dohme

4:45pm - 5:15pm
Current Trends on Data Integrity
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

5:15pm - 5:45pm
Data Integrity in 2024 – How Far Have We Gone?
Peter Baker, President, Live Oak Quality Assurance

5:45pm – 6:15pm
Panel Discussion/Question and Answers
- Peter Baker, President, Live Oak Quality Assurance
- Dr. Carmelo Rosa, Director Division of Drug Quality, CDER/OMQ/US FDA
- Alicja Wolska, Executive Director, Data and Digital Quality, Merck Sharpe Dohme
- Atul Agrawal, Supervisory Consumer Safety, ORA/OMPTO/US FDA
- Dr. Ruth Moore, Consumer Safety Officer and Senior Reviewer for Manufacturing Process and Facilities, CDER/OPQ/OPMA/US FDA (Invited)

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Day Two – Tuesday, 12 March 2024

7:00am - Registration Open

8:00am – 10:30am
Plenary Session Four (P4) - How we Rise After a Regulatory Action
Session Leader: Rishikesh Jaiwant, Senior Director Manufacturing & Operations
Session Overview: No company would want a regulatory action, which indicates non-compliance, and breach of regulators’ trust. Such regulatory action hurts – it impacts the capacity to serve patients, the morale of employees, and the brand image. Having said that, regulatory action is about continuous improvement and hence, instead of justifying the risks, the focus should be on accepting the challenge, being resilient to overcome the gaps, and staying committed to building a quality culture. The remediation plan should be confirmed with the agency. Considering the legalities involved, regulators should be timely updated about the progress of CAPA commitments with utmost honesty and transparency. It is all about doing what we say, and saying what we do. This session will focus on how to rebuild the trust and confidence with the agency through dedicated and committed efforts towards quality culture.

8:00am – 8:30am
Rebuilding Trust and Confidence with the Agency - Lessons Learned
Jeff Yuen, MPH, MBA, President and CEO, Jeff Yuen & Associates, Inc.

8:30am – 9:00am
Building Capabilities & Establishing GMP Compliance Sustainability
Jerry Greco, Chief Quality Officer, Baxter International

9:00am – 9:30am
How the Pharmaceutical Quality System (PQS) Enables Pharmaceutical Lifecycle Management
Mahesh Ramanadham, Pharm.D, Deputy Director, CDER/OPQ/US FDA
DELETE 9:30-9:50 Lessons Learned

9:30am – 10:10am
An Examination of CAPAs Commitments and Remediation Plans
Brooke K. Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Office of Compliance, CDER/OMQ/US FDA
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA,

10:10am – 10:40am
Panel Discussion and Questions and Answers
- Cathy Burgess, Partner, Alston & Bird, LLP
- Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, ORA/US FDA
- Brooke Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Office of Compliance, CDER/OMQ/US FDA
- Dr. Thomas Hecker, Inspector, EDQM
- Reem Malki, Chief Quality Officer, Sun Pharma
- Jose Melendez, Consumer Safety Officer, ORA/OMPTO/US FDA
- Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA
- Jeffrey Yuen, President and CEO, Jeffrey Yuen and Associates, Inc.

10:40am - 11:00am Refreshment Break and Exhibition

11:00am - 1:15pm
Executive Leadership Forum (P5) | The Role of Executive Leadership and Bringing the Two Worlds Together | Deep Dive into the Meaning of Quality
Session Leader: Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA
Session Overview: Organizational culture influences quality outcomes and requires continuous reinforcement through senior leadership behavior and creating an 'enabling environment'. Hear from senior leaders as they take an even deeper dive into the meaning of Quality and Culture and the overlap of Quality with Culture.

11:00am – 11:25am
How to Go Global and Meet Expectations
Sanat Chattopadhyay, Executive Vice President and President, Merck Manufacturing Division

11:25am – 11:50am
Executive Perspective on Quality
Rajiv Malik, President, Viatris

11:50am – 12:15pm
The Constructive Role that Executive Leadership Plays
Dilip Shanghvi, Managing Director, Sun Pharma

12:15pm – 12:40pm
Quality Operational Perspective
M. Madan Mohan Reddy, Whole Time Director, Aurobindo

12:40pm – 1:15pm
Leadership Forum Discussion & Questions and Answers
Sanat Chattopadhyay, Executive Vice President and President, Merck Manufacturing Division
Rajiv Malik, President, Viatris
Dilip Shanghvi, Managing Director, Sun Pharma
M. Madan Mohan Reddy, Whole Time Director, Aurobindo
Concurrent Sessions
2:15pm – 3:45pm
A1 | Cleaning Validation
Session Leader: Ivy Louis, PDA Board of Directors and Director, Vienni Training & Consulting LLP
Session Overview: Chemistry plays a significant role in cleaning processes and could involve reactions such as saponification, oxidation-reduction, acid-base neutralization, hydrolysis or precipitation, based on the type of soil or dirt. Cleaning processes also involve a combination of physical actions (e.g., scrubbing, wiping rinsing). The confirmation of the removal depends on the agents used, the target surface or substance, the specific contaminants being addressed, and the methods of cleaning adopted. When soil or dirt is being cleaned, it either gets dislodged/breaks apart, gets dissolved, emulsified or suspended, or gets removed depending on the cleaning method and the nature of the dirt itself. There is the need to quantify this process of elimination, removal which necessitates qualification backed by validation of the cleaning process. Verification of cleaning for consistency of removal is the final aspect that provides assurance regarding the lifecycle management of cleaning. This session will discuss the regulatory expectations of the cleaning process lifecycle design to execution against the background of cases of contamination and cross contamination.

2:15pm – 2:45pm
Understanding the Compliance Risks with Cleaning Validation
Andrew D. Hopkins, Director, Operation Quality QA Audit and Compliance, AbbVie Inc

2:45pm – 3:15pm
Inspection Trends on Cleaning Validation/Cross-Contamination Issues
Jose Melendez, Consumer Safety Officer, ORA/OMPTO/US FDA

3:15pm – 3:45pm
Questions and Answers
Andrew D. Hopkins, Director, Operation Quality QA Audit and Compliance, AbbVie Inc
Jose Melendez, Consumer Safety Officer, ORA/OMPTO/US FDA

2:15pm – 3:45pm
B1 | Process Validation
Session Leader: Brooke Higgins, Senior Policy Advisor, Global Compliance Branch, CDER/OMQ/US FDA
Session Overview: This session will focus on the quality and compliance requirements for an effective validation program.

2:15pm – 2:55pm
Evaluating Processes
Dr. G.K. Raju, Chairman and CEO, Light Pharma Inc.

2:55pm – 3:35pm
Understanding the Compliance Risks
Tracy Moore, Founder and CEO, TM Pharma Group Ltd

3:35pm – 4:00pm
Questions and Answers
Dr. Thomas Hecker, Inspector, EDQM
Tracy Moore, Founder and CEO, TM Pharma Group Ltd
Dr. G.K. Raju, Chairman and CEO, Light Pharma Inc.

4:00pm – 4:30pm | Refreshment Break and Exhibition
Plenary Session Six (P6) - ICH Impurities

Session Leader: Dr. Sumitra Pillai, Vice President, Head of R&D, Slayback Pharma

Session Overview: Many things in life can be designed or chosen and so can be the case with impurities. Hear from industry and regulator experts who will address the important role of CGMP compliance, and the impact of drug components, supply chains, manufacturing facility competencies, ongoing testing, and other quality risk management strategies to detect, prevent, and mitigate nitrosamine impurities in drug products based on sound science for delivery of consistent quality drugs for patients. As a result of unexpected and recent findings of nitrosamine impurities in human drugs which has resulted in batch recalls or delayed marketing for some drugs, this session will discuss the current understanding of the potential root causes of nitrosamine impurities.

4:30pm – 5:00pm
Practical Application of Nitrosamine – Aurobindo Experience
Dr. Vishnubhotla Nagaprasad, President, Aurobindo

5:00pm – 5:30pm
Nitrosamines Challenges and Mitigation
Mark Mowery, PhD, Associate Vice President, Analytical Chemistry in Development and Supply, Merck & Co., Inc. (Invited)

5:30pm – 6:15pm
FDA Guidance on Nitrosamine
Dr. Andre Raw, Associate Director, CDER/OPQ/OLDP/US FDA (Invited)

6:15pm – 6:30pm
Question and Answers
Dr. Vishnubhotla Nagaprasad, President, Aurobindo
Mark Mowery, PhD, Associate Vice President, Analytical Chemistry in Development and Supply, Merck & Co., Inc. (Invited)
Dr. Andre Raw, Associate Director, CDER/OPQ/OLDP/US FDA (Invited)

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8:00am – 8:30am
Aseptic Process Trends and Issues
Rick Friedman, Deputy Director for Manufacturing Quality, CDER/OMQ/US FDA

8:30am – 8:45pm
Question and Answers

8:45am – 9:15am
Current Cases on Applications
Brooke Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Office of Compliance, CDER/OMQ/US FDA

9:15am – 9:45am
How to Evaluate an Aseptic Process Operation
Thomas J. Arista, Pharmaceutical Consultant, Ventana Novo, LLC

9:45am – 10:15am
Question and Answers
Thomas J. Arista, Pharmaceutical Consultant, Ventana Novo, LLC
Brooke Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Office of Compliance, CDER/OMQ/US FDA
Tracy Moore, Founder and CEO, TM Pharma Group Ltd
Jeff Yuen, MPH, MBA, President and CEO, Jeff Yuen & Associates, Inc.

B2 | Unlocking Commercial Success: The Vital Role of R&D, Knowledge, and Process Transfer in Drug Manufacturing
Session Leader: Dr. Rustom Mody, Senior Vice President and Head R&D (Biologics), Sun Pharma Ltd., and PDA President Elect – India Chapter
Session Overview: During this session, hear why technology transfer is difficult and how to streamline transfers and shorten timelines, including vaccine case study transfer in India. Additionally, discover hidden and unexplored aspects of a successful technology transfer and regulatory considerations during tech transfer.

8:00am – 8:30am
Maintaining Quality and Compliance during Technology Transfer
Chandrakant Kathote, Site Head & Vice President- Operations, Lupin Limited

8:30am – 9:00am
Lessons Learned from Vaccine Tech-Transfer
Dr. Priyabrata Pattnaik, Deputy Managing Director, Indian Immunological Limited

9:00am – 9:30am
CMO perspectives on Technology Transfer for Clinical and Commercial Stage Products
Dr. Dhananjay Patankar, Pharmaceutical Consultant

9:30am – 10:15am
Question and Answers

10:15am – 10:45am Refreshment Break and Exhibition
**10:45am – 12:15pm**

**Plenary Session Seven (P7) - Combination Products**

**Session Leader:** Brooke Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Office of Compliance, CDER/OMQ/US FDA

**Session Overview:** As India’s life science community continues to grow, a strong focus is on combination products and their impact on traditional pharmaceutical manufacturers, especially since the court case *Genus Medical Technologies vs. FDA*. This session will include the regulatory and quality aspects that pharmaceutical companies need to consider when working with combination products and the importance of supplier management when developing or distributing a combination product. This session will also include case studies that illustrate how mishandling and managing combination products resulted in regulatory actions being taken.

10:45am – 11:15am

*Understanding and Managing the Quality and Risk Across the Entire Combination Product Lifecycle*

**Stephen Tyrpak,** Associate Vice President of Operations, PQE

11:15am – 11:45am

*Regulatory Update on Combination Products*

**Jose Melendez,** Consumer Safety Officer, ORA/OMPTO/US FDA

11:45am 12:15pm

*Panel Discussion and Questions and Answers*

**Jose Melendez,** Consumer Safety Officer, ORA/OMPTO/US FDA

**Stephen Tyrpak,** Associate Vice President of Operations, PQE

**12:30pm – 1:30pm**  
Lunch and Exhibition

**1:30pm - 4:00pm**

**Plenary Session Eight (P9) - Open Mic with the Current and Former Investigators and Legal Counsel**

**Session Leader:** Dr. Anil Sawant, Senior Vice President, Global Quality Compliance, Merck Sharpe & Dohme, USA and Chair-Elect Board of Directors, PDA Inc.

**Session Overview:** This last session is designed to focus on key messages from current and former regulators to bring strategic and collaborative opportunities to the forefront in the discussion. Prepare your questions in advance and use this Open Mic opportunity to ask your questions and get answers.

1:30pm – 2:30pm

*Update on FDA’s Remote Assessment Program*

**Dr. Rebecca Frey Cooper,** Associate Director, CDER/OMQ/US FDA

*Understanding the Legal Aspects of Information Provided to Regulators as Part of a Remediation Process | If You Said You Did it – Show It!*

**Cathy Burgess,** Partner, Alston & Bird, LLP

2:30pm – 4:00pm

*Panel Discussion: Open Mic*

**Atul Agrawal,** Supervisory Consumer Safety, ORA/US FDA

**Thomas J. Arista,** Pharmaceutical Consultant, Ventana Novo, LLC

**Dr. Rebecca Frey Cooper,** Associate Director, CDER/OMQ/US FDA

**Dr. Thomas Hecker,** Inspector, EDQM
Brooke Higgins, Senior Policy Advisor, Global Compliance Branch, CDER/OMQ/US FDA
Jose Melendez, Consumer Safety Officer, ORA/OMPTO/US FDA
Alicia Mozzachio, Consultant, Global GMP Compliance, LLC (Invited)
Ileana Barreto-Pettit, Vice President, Technical Strategic Compliance, Parexel
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA
Mahesh Ramanadham, Pharm.D, Deputy Director, CDER/OPQ/US FDA
FDA India Office Investigator (Invited)

Delete Dr. Ruth Moore

4:00pm – 4:10pm
Closing Remarks
Dr. Rustom Mody, Senior Vice President and Head R&D (Biologics), Sun Pharma Ltd., and PDA President Elect – India Chapter
Day Four – Thursday, 14 March 2024

THURSDAY WORKSHOP: BACK TO BASICS

Understand Key Regulatory Guidance Documents, Pharmaceutical Regulations and Published Guides, Led by Regulators and Industry Experts

The workshop is intended to have opened discussions on important guidance documents and regulations with the purpose of closing gaps and sharing the regulatory expectations that will allow industry to understand how to operate and remain in a sustainable state of control. The workshop will include practical and real case studies and encourage interaction between the participants and the regulatory and industry experts and answers to your questions.

7:00am - Registration Open

8:30am – 9:00am  Welcome
Dr. Rustom Mody, Senior Vice President and Head R&D (Biologics), Sun Pharma Ltd., and PDA President Elect – India Chapter

Workshop Introductions
Dr. Ruth Moore, Consumer Safety Officer, Senior Reviewer for Manufacturing Process and Facilities, Office of Pharmaceutical Assessment, OPQ/US FDA (Invited)
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

9:00am – 10:30am  Introduction to Quality: FDA Guidance on ICH Q10 | OOS Specification Guidance | Case Studies on Commercial and Drug Applications
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA
Alicia Mozzachio, Consultant, Global GMP Compliance, LLC (Invited)
Ileana Barreto-Pettit, Vice President, Technical Strategic Compliance, Parexel
Panelist:
Jose Melendez, Consumer Safety Officer, ORA/OMPTO/US FDA plus other speakers
Dr. Rebecca Frey Cooper, Associate Director, CDER/OMQ/US FDA

Pre-reading FDA Guidance Documents:
- Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production - Level 2 revision: Guidance for Industry
- Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations

10:30am – 10:45am  Refreshment Break

10:45am – 11:30am  Introduction to Pre-Approval Inspections | Case Studies
Mahesh Ramanadhram, Pharm.D, Deputy Director, CDER/OPQ/US FDA
Dr. Ruth Moore, Consumer Safety Officer, Senior Reviewer for Manufacturing Process and Facilities, Office of Pharmaceutical Assessment, OPQ/US FDA (Invited)

Pre-reading FDA Guidance Documents:
- Compliance Program Guide to Pre-Approval Inspections
12:00pm – 1:00pm  Luncheon

1:00pm – 3:00pm  Introduction to Sterile Aseptic Processing | Case Studies
Thomas J. Arista, Pharmaceutical Consultant, Ventana Novo, LLC
Brooke Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Office of Compliance, CDER/OMQ/US FDA
Panelist: Jeff Yuen, MPH, MBA, President and CEO, Jeff Yuen & Associates, Inc.

Pre-reading FDA Guidance Documents and EU GMP Annex 1 Revision
- Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice: Guidance for Industry
- Annex 1: Manufacture of Sterile Products

3:00pm – 3:15pm  Refreshment Break

3:15pm – 5:15pm  Introduction to Data Integrity Remediation | Case Studies
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

The Heart of Data Integrity
Peter Baker, President, Live Oak Quality Assurance
Atul Agrawal, Supervisory Consumer Safety, ORA/OMPTO/US FDA

Data Integrity: Pre-approval Case Study
Dr. Ruth Moore, Consumer Safety Officer, Senior Reviewer for Manufacturing Process and Facilities, Office of Pharmaceutical Assessment, OPQ/US FDA (Invited)

Pre-reading FDA Guidance Documents:
- Data Integrity and Compliance with Drug CGMP: Questions and Answers: Guidance for Industry

5:15pm – 6:00pm  Closing Remarks
Adjournment for Back to Basic Workshop with FDA and Industry