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

10:00am - 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.

10:00am - 10:30am
**Welcome and Opening Remarks**

10:30am - 10:50am
**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)

10:50am -11:20am
**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.

11:20am -12:00pm
**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

12:00pm -12:30pm
**Current Trends in API Inspections and an Update on Current Issues**

- Dr. Thomas Hecker, Inspector, EDQM

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. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA
• 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

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.
Digitisation & Data Integrity – Lessons Learned
Alicja Wolska, Executive Director, Data and Digital Quality, Merck Sharpe Dohme

Current Trends on Data Integrity
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

Data Integrity in 2024 – How Far Have We Gone?
Peter Baker, President, Live Oak Quality Assurance

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 (invited)
- Dr. Ruth Moore, Consumer Safety Officer and Senior Reviewer for Manufacturing Process and Facilities, CDER/OPQ/OPMA/US FDA (Invited)

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
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 (Invited)
9:30am – 9:50am
Lessons Learned
Reem Malki, Chief Quality Officer, Sun Pharma

9:50am – 10:20am
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,

10:20am – 10:30am
Panel Discussion and Questions and Answers
- Cathy Burgess, Partner, Alston & Bird, LLP (Invited)
- 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
- 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.

10:30am - 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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Day Three – Wednesday, 13 March 2024

7:00am - Registration Open

Concurrent Sessions
8:00am – 10:15am
A2 | Aseptic Operations

Session Leader: Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

Session Overview: Globally, one of the fundamental issues with aseptic processing of pharmaceuticals involves a local misinterpretation of standards and guidance documents which can impact the initial approval, ongoing regulatory status and efficiency of aseptic processing operations. This session will continue earlier discussions on aseptic process controls and expectations as well as provide a summary of experiences with the global interpretation of regulatory documents and misinterpretations.
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

3:00pm – 3:45pm  Refreshment Break

1:30pm - 3:30pm
**Plenary Session Eight (P9) - Open Mic with the Current and Former Investigators**

**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 – 2:00pm
**Update on FDA’s Remote Assessment Program**
Dr. Rebecca Frey Cooper, Associate Director, CDER/OMQ/US FDA

2:00pm – 3:30pm
**Panel Discussion: Open Mic**
Atul Agrawal, Supervisory Consumer Safety, ORA/US FDA (Invited)
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
Dr. Ruth Moore, Consumer Safety Officer and Senior Reviewer for Manufacturing Process and Facilities, CDER/OPQ/OPMA/US FDA (Invited)

Ileana Barreto-Pettit, Vice President, Technical Strategic Compliance, Parexel
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA
FDA India Office Investigator (Invited)
Mahesh Ramanadham, Pharm.D, Deputy Director, CDER/OPQ/US FDA

3:30pm – 3:40pm
Closing Remarks
Dr. Rustom Mody, Senior Vice President and Head R&D (Biologics), Sun Pharma Ltd., and PDA President Elect – India Chapter