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

7:00am – Registration Open

8:30am - 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 a regulatory perspective, and how to move the needle towards Quality Management Maturity.

8:30am – 8:45am
Welcome and Opening Remarks
Dr. Rustom Mody, Senior Vice President and Head R&D (Biologics), Sun Pharma Ltd., and PDA President – India Chapter
Vishal Sharma, Immediate Past President, PDA India Chapter and Director, Vienni Training & Consulting LLP and Co-Chair, PDA India Chapter Annual Meeting
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA and Co-Chair, PDA India Chapter Annual Meeting
Glenn Wright, President and CEO, PDA Global

8:45am – 9:10am
Dr. Patrizia Cavazonni, Director, Center for Drug Evaluation and Research (CDER), US FDA

9:10am - 9:20am
Update on FDA Initiatives: Impact in India and the Region
Dr. Sarah McMullen, Country Director, US FDA India Office

9:20am – 9:30am
Update on CDSCO Initiatives and Regulatory Compliance Expected from the Industry
Dr. Rajeev Sing Raghuvanshi, Drug Controller General of India

9:30am - 10:00am
The Cost of Poor Quality
Dr. Anil Sawant, Senior Vice President, Global Quality Compliance, Merck Sharpe & Dohme, USA and Chair, Board of Directors, PDA Inc.

10:00am – 10:30am
Updates from the Office of Pharmaceutical Quality (FDA/CDER/OPQ)

- **OPQ's Pharmaceutical Quality Initiative Updates**
  Mahesh Ramanadham, Pharm.D, Deputy Director, CDER/OPQ/US FDA

- **Office of Pharmaceutical Manufacturing Assessment (OPMA) Initiative Updates**
  Dr. Vidya Pai, Branch Chief, Office of Pharmaceutical Manufacturing Assessment, CDER/OPQ/US FDA

10:30am – 11:00am
Updates from the Office of Pharmaceutical Quality Operations/ORA
Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, ORA/US FDA

11:00am – 11:30am
Refreshment Break

11:30am -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
Quality Culture of API Manufacturers in India – A Time Travel over 16 Years of GMP Inspections by EDQM
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: D*r. C*armelo 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, Vice President of Operations, PQE Group

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 K. Higgins,** Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, 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, Board of Directors, PDA Inc.
- **Stephen Tyrpak,** Vice President of Operations, PQE Group

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, 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**, Director, Division of Foreign Pharmaceutical Quality Inspections, ORA/OMPTO/OPQO/US FDA

6:15 pm – Adjourn Day One

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, 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

9:30am – 10:00am
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,

10:00am – 10:30am
Panel Discussion and Questions and Answers

- **Cathy Burgess,** Partner, Alston & Bird, LLP
- **Alonza Cruse,** Director, Office of Pharmaceutical Quality Operations, ORA/US FDA
- **Jerry Greco,** Chief Quality Officer, Baxter International
- **Brooke K. 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
- **Mahesh Ramanadham, Pharm.D,** Deputy Director, CDER/OPQ/US FDA
- **Reem Malki,** Chief Quality Officer, Sun Pharma
- **Dr. Carmelo Rosa**, Director Division of Drug Quality I, CDER/OMQ/US FDA
- **Jeff Yuen, MPH,** President and CEO, Jeff 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

1:15pm – 2:15pm Lunch and Exhibition

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 (Remote)

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 (Remote)

2:15pm – 3:45pm
B1 | Process Validation
Session Leader: Brooke K. Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, 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
Knowledge Management Role in Process Validation; Guide to Sustainable Compliance
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**

4:30pm – 6:30pm
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
Dr. Mark Mowery, Associate Vice President, Analytical Chemistry in Development and Supply, *Merck & Co., Inc.*

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

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

6:30pm - Adjourn for Day Two

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.

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

8:30am – 8:45pm
Question and Answers

8:45am – 9:15am
Current Cases on Applications
Brooke K. 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 K. 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, 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 – 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 & Compliance during Technology Transfer
Dr. Rajesh Kumar Singh, Associate Director, Genova Biopharmaceuticals

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 K. 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, Vice President of Operations, PQE Group

11:15am – 11:45am
Case Study on the Mishandling and Managing Combination Products Resulting in Regulatory Actions
Jose Melendez, Consumer Safety Officer, ORA/OMPTO/US FDA (Recorded)

11:45am 12:15pm
Panel Discussion and Questions and Answers
Jose Melendez, Consumer Safety Officer, ORA/OMPTO/US FDA
Stephen Tyrpak, Vice President of Operations, PQE Group

12:30pm – 1:30pm Lunch and Exhibition

1:30pm - 4:00pm
Plenary Session Eight (P8) - 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, 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 – 2:30pm
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, Director, Division of Foreign Pharmaceutical Quality Inspections, ORA/OMPTO/OPQO/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 K. Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Global Compliance Branch, CDER/OMQ/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

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

Day Four – Thursday, 14 March 2024

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 – 8:45am **Welcome**
Dr. Rustom Mody, Senior Vice President and Head R&D (Biologics), Sun Pharma Ltd., and PDA President – India Chapter

8:45am- 9:00am **Workshop Introduction Day One**
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

9:00am – 10:00am **Why Quality Matters: Patient Perspective**
Moderator: Dr. Anil Sawant, Senior Vice President, Global Quality Compliance, Merck Sharpe & Dohme, USA and Chair Board of Directors, PDA Inc.

Patient Perspective
Ms. Harita Vasireddi, Managing Director, Vimta Labs

10:00am – 10:15am **Refreshment Break**

10:15am – 11:15am **Introduction to Quality: FDA Guidance Quality Systems and ICH Q10 & General Overview of OOS Specification Guidance**
Examples of Inspectional Trends
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

11:15am - 12:15pm **OOS Specification Guidance – Case Studies on Commercial and Drug Applications**
Moderator Dr. Rebecca Frey Cooper, Associate Director, CDER/OMQ/US FDA

Case 1
Peter Baker, President, Live Oak Quality Assurance
Atul Agrawal, Director, Division of Foreign Pharmaceutical Quality Inspections, ORA/OMPTO/OPQO/US FDA

Case 2
Brooke K. Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Office of Compliance, CDER/OMQ/US FDA
Dr. Rebecca Frey Cooper, Associate Director, CDER/OMQ/US FDA
Ileana Barreto-Pettit, Vice President, Technical Strategic Compliance, Parexel

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

12:15pm – 1:15pm **Luncheon**

1:15pm – 2:00pm **Introduction to Pre-Approval Inspections**

Mahesh Ramanadham, Pharm.D, Deputy Director, CDER/OPQ/US FDA

Pre-reading FDA Guidance Documents:

- Compliance Program Guide to Pre-Approval Inspections
- Preapproval Inspections Compliance Program
- INTEGRATION OF FDA FACILITY EVALUATION AND INSPECTION PROGRAM FOR HUMAN DRUGS: A CONCEPT OF OPERATIONS
- Questions and Answers: Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations

2:00pm - 2:30pm **PAI Case Study**

Dr. Vidya Pai, Branch Chief, Office of Pharmaceutical Manufacturing Assessment, CDER/OPQ/FDA

2:30pm - 3:00pm **Refreshment Break**

3:00pm – 5:00pm **Introduction to Sterile Aseptic Processing | Case Studies**

Brooke K. Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Office of Compliance, CDER/OMQ/US FDA
Thomas J. Arista, Pharmaceutical Consultant, Ventana Novo, LLC

Question & Answer Session
Moderator: **Jeff Yuen, MPH,** President and CEO, Jeff Yuen & Associates, Inc.

Panelist:
Atul Agrawal, Director, Division of Foreign Pharmaceutical Quality Inspections, ORA/OMPTO/OPQO/US FDA
Thomas J. Arista, Pharmaceutical Consultant, Ventana Novo, LLC
Peter Baker, President, Live Oak Quality Assurance
Dr. Rebecca Frey Cooper, Associate Director, CDER/OMQ/US FDA
Brooke K. 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
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

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
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/inspection-injectable-products-visible-particulates
- Q4B Annex 3: Test for Particulate Contamination: Subvisible Particles General Chapter | FDA

5:00pm **Adjourn for the Day**

Day Five – Friday, 15 March 2024

8:30am – 10:30am **Workshop Introduction Day Two**
Moderator: Ivy Louis, Member, Board of Directors and Director, Vienni Training & Consulting LLP

8:35am – 9:20am **Introduction to Data Integrity Remediation | Case Studies**
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

9:20am – 10:30am **The Heart of Data Integrity**
Peter Baker, President, Live Oak Quality Assurance
Atul Agrawal, Director, Division of Foreign Pharmaceutical Quality Inspections, ORA/OMPTO/OPQO/US FDA

Pre-reading FDA Guidance Documents:

- Data Integrity and Compliance with Drug CGMP: Questions and Answers: Guidance for Industry
- Guidance on Data Integrity (picscheme.org)
- Guidance on GxP data integrity - GOV.UK (www.gov.uk)
- PDA Technical Report No. 84 (TR 84) Integrating Data Integrity Requirements into Manufacturing & Packaging Operations (single user digital version) | PDA
- PDA Technical Report No. 80 (TR 80) Data Integrity Management System for Pharmaceutical Laboratories (single user digital version) | PDA
- trs1033-annex4-guideline-on-data-integrity.pdf (who.int)

10:30am – 11:00am **Refreshment Break**

11:00am – 4:00pm **Session Introduction: Visual Inspections**
Moderator: Vikram Shukla, Vice President, PGS - Sterile Injectables & Biotech Operations, APAC Cluster, Pfizer

11:00am – 11:30am **Visual Inspections: The Foundation with Case Studies**
Stephen Tyrpak, Vice President of Operations, PQE Group

11:30am – 12:45pm **FDA Case Studies of Visual Inspection Issues**
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

Pre-reading FDA Documents:

- Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice: Guidance for Industry
- Annex 1: Manufacture of Sterile Products
- Inspection of Injectable Products for Visible Particulates | FDA

12:45pm – 1:45pm **Luncheon**

2:00pm – 3:00pm **Visual Inspection (Hands on Demonstration)**
Stephen Tyrpak, Vice President of Operations, PQE Group

3:00pm – 3:30pm **Inspection, Re-inspection, Bubble and Squeak**
Tracy Moore, Founder and CEO, TM Pharma Group Ltd
Andrew D. Hopkins, Director, Operation Quality QA Audit and Compliance, AbbVie Inc

3:30pm – 3:45pm **Refreshment Break**

3:45pm – 4:45pm **Training and It's Effectiveness**
Ivy Louis, Member, PDA Board of Directors and Director, Vienni Training & Consulting LLP
Vishal Sharma, Immediate Past President, PDA India Chapter and Director, Vienni Training & Consulting LLP

4:45pm – 5:15pm **Question & Answer Session for Day 2**
Moderator: Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA

Panelist:
Atul Agrawal, Director, Division of Foreign Pharmaceutical Quality Inspections, ORA/OMPTO/OPQO/US FDA
Peter Baker, President, Live Oak Quality Assurance
Brooke K. Higgins, Acting Branch Chief and Senior Policy Advisor, Division of Drug Quality I, Office of Compliance, CDER/OMQ/US FDA
Andrew D. Hopkins, Director, Operation Quality QA Audit and Compliance, AbbVie Inc
Ivy Louis, Member, PDA Board of Directors and Director, Vienni Training & Consulting LLP
Tracy Moore, Founder and CEO, TM Pharma Group Ltd
Vishal Sharma, Immediate Past President, PDA India Chapter and Director, Vienni Training & Consulting LLP
Stephen Tyrpak, Vice President of Operations, PQE Group
Jeff Yuen, MPH, President and CEO, Jeff Yuen & Associates, Inc.

5:15pm – 5:20pm **Closing Remarks**
Vishal Sharma, Immediate Past President, PDA India Chapter and Director, Vienni Training & Consulting LLP
Dr. Carmelo Rosa, Director Division of Drug Quality I, CDER/OMQ/US FDA