PDA Parenteral Drug Association India Chapter

PDA INDIA CHAPTER ANNUAL MEETING
Regulatory Expectations : The Quality Advantage
Agenda

Four Seasons Hotel
Bangalore

Day 1
21 February 2023

7:00 am - 7:45 am	**Registration Open**
8:00 am - 10:50 am	**Session 1** **Opening Plenary Session and Keynote Presentations** **Session Leaders:** **Vishal Sharma,** President-PDA India Chapter, Director, Vienni Training & Consulting LLP **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ FDA
8:00am - 8:15am	**Welcome and Opening Remarks** **Vishal Sharma,** President-PDA India Chapter, Director, Vienni Training & Consulting LLP **Dr. Rustom Mody,** PDA President Elect, SVP and Head R&D (Biologics), Sun Pharma Ltd.
8:15am - 8:45am	**Welcome, FDA Initiatives and Strategic Plans for the Region** **Dr. Sarah McMullen,** Country Director, US FDA India Office **Mark Abdoo,** Associate Commissioner, Global Policy and Strategy, US FDA
8:45am – 9:15am	**Regulatory and Inspectional Trends, a General Overview** **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ US FDA
9:15am – 10:05am	**Inspection Trends during API Inspections; Current Approach for Remote Assessments by EDQM and EDQM's Approach on sharing of GMP Information, Assessment of CAPA and lifecycle Management of Sites involved in the CEP Scheme** **Dr. Thomas Hecker,** Inspector, EDQM

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10:05am – 10:35am	**Regulatory Trends in Aseptic Operations** **Brooke Higgins,** Senior Policy Advisor, Global Compliance Branch, CDER/OMQ/US FDA
10:35am – 10:50am	**Question and Answers**
10:50am – 11:15am	**Refreshment Break**
11:15am – 12:10pm	**Session 2** **Inspections, Record Requests, and other Agency Communications** **Session Leader:** **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ/ US FDA
11:15am - 11:50am	**704 Record Requests and Other Agency Communications** **Atul Agrawal,** Supervisory Consumer Safety, ORA/OMPTO/US FDA - Virtual **Aditi Thakur,** Senior Pharmaceutical Assessor, CDER/OPQ/OPMA US FDA **Dr. Rebecca Frey-Cooper**, Associate Director, CDER/OMQ/US FDA - Virtual
11:50am -12:10pm	**Panel Discussion** • **Atul Agrawal,** Supervisory Consumer Safety, ORA/OMPTO/FDA (Virtual) • **Dr. Rebecca Frey-Cooper,** Associate Director, CDER/OMQ/FDA (Virtual) • **Dr. Thomas Hecker,** Inspector, EDQM • **Aditi Thakur,** Senior Pharmaceutical Assessor, CDER/OPQ/OPMA/FDA • **Saleem Akhtar,** Consumer Safety Officer, ORA/OMPTO/US FDA
12:10pm – 1:00pm	**Networking Lunch**
1:00pm – 2:40pm	**Session 3** **Internal Audits and Having a Robust and Sustainable Quality System** **Session Leader:** **Deva Puranam,** Head-Global Quality Investigations, Surveillance & Regulatory Communications, Viatris

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1:00pm – 1:20pm	**Ensuring a Strong Corporate Oversight over a Multiple Site Organization (Identifying gaps from site to site)** **Dr. Anil Sawant,** Senior Vice President, Global Quality Compliance, Merck Sharpe & Dohme, USA; Chair-Elect Board of Directors, PDA Inc.
1:20pm – 2:10pm	**Assuring Data Integrity in Commercial Drug Manufacturing and Drug Application Submissions: Regulatory Expectations and Challenges** **Aditi Thakur,** Senior Pharmaceutical Assessor, CDER/OPQ/OPMA/FDA **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ FDA
2:10pm – 2:40pm	**Panel Discussion** • **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ FDA • **Dr. Anil Sawant,** Senior Vice President, Global Quality Compliance, Merck Sharpe & Dohme, USA; Chair-Elect Board of Directors, PDA Inc. • **Aditi Thakur,** Senior Pharmaceutical Assessor, CDER/OPQ/OPMA/FDA
2:40pm – 2:55pm	**Transitioning for next session and Short Break**
2:55pm – 4:30pm	**Session 4** **Communicating with the Investigator, Auditor and Consultants** **Session Leader:** **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ FDA
2:55pm – 3:15pm	**The Role of an Investigator** **Saleem Akhtar,** Consumer Safety Officer, ORA/OMPTO/US FDA **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ/US FDA
3:15pm – 3:35pm	**The Role of an Auditor** **Dr. Mary Farbman,** Global Executive Director, QC, Merck Sharpe & Dohme, USA

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3:35pm – 3:55pm	**The Role of a Consultant** • **Gilda D'Incerti,** CEO & Founder, PQE Group • **James (Jim)** Johnson, Partner, Sidley Austin LLP • **Ivy Louis, Member,** Board of Directors, PDA Inc; Director-Vienni Training & Consulting LLP
3:55pm – 4:35pm	**Panel Discussion** • **Gilda D'Incerti,** CEO & Founder, PQE Group • **Dr. Mary Farbman,** Global Executive Director, QC, Merck Sharpe & Dohme, USA • **Brooke Higgins,** Senior Policy Advisor, Global Compliance Branch, CDER/OMQ/FDA • **James Johnson,** Partner, Sidley Austin, LLP • **Ivy Louis, Member,** Board of Directors, PDA Inc; Director-VIENNI Training & Consulting LLP • **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ FDA • **Aditi Thakur,** Senior Pharmaceutical Assessor, CDER/OPQ/OPMA/FDA • **Anil Arora,** President, Formulation Operations, Granules india
4:35pm – 4:45pm	**Transitioning for next session and Short Break**
4:45pm – 6:15pm	**Session 5** **Understanding Regulatory Expectations and a Deep Dive into the FDA OOS Guidance** **Session Leader:** **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ/US FDA
4:45pm – 5:15pm	**Laboratory Controls** **Saleem Akhtar,** Consumer Safety Officer, ORA/OMPTO/US FDA
5:15pm -5:30pm	**Update OOS Guidance** **Rebecca Parrilla,** Consumer Safety Officer, CDER/OMQ/US FDA (Virtual)

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5:30pm – 6:15pm	**How to Respond to a 483 Warning Letter/Import Alert Administrative Proceeding & Q&A** **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ/US FDA
6:30pm – 7:30pm	**PDA India Chapter 10th Anniversary Recognition and Reception**

Day 2
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8:00am – 9:30am	**Session 6** **CGMPs** **Session Leader** : **Brooke Higgins,** Senior Policy Advisor, Global Compliance Branch, CDER/OMQ/US FDA
8:00am – 8:30am	**Aseptic Process Controls and Expectations (Virtual)** **Rick Friedman,** Deputy Director for Manufacturing Quality,CDER/OMQ/US FDA
8:30am – 8:45am	**Question and Answers**
8:45am – 9:15am	**Cleaning Validation Trends and Regulatory Expectations – What does Clean Mean?** **Brooke Higgins,** Senior Policy Advisor, Global Compliance Branch, CDER/OMQ/US FDA
9:15am – 9:30am	**Question and Answers**
9:30am – 9:45am	**Refreshment Break**
9:45am – 11:00am	**Session 7** **OOS Investigations** **Session Leader:** **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ FDA

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OOS Investigations

- **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ FDA
- **Aditi Thakur,** Senior Pharmaceutical Assessor, CDER/OPQ/OPMA/FDA

Panel discussion/Question & Answers

- **Brooke Higgins,** Senior Policy Advisor, Global Compliance Branch, CDER/OMQ/FDA
- **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ FDA
- **Aditi Thakur,** Senior Pharmaceutical Assessor, CDER/OPQ/OPMA/FDA
- **Saleem Akhtar,** Consumer Safety Officer, ORA/OMPTO/US FDA

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

11:30pm - 1:00pm

Session 8:

Closing Session: Questions to the Regulators

Session Leader:

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

Presenters and Panelist:

- **Brooke Higgins,** Senior Policy Advisor, Global Compliance Branch, CDER/OMQ/FDA
- **Dr. Thomas Hecker,** Inspector, EDQM
- **Dr. Carmelo Rosa,** Director Division of Drug Quality, CDER/OMQ FDA
- **Aditi Thakur,** Senior Pharmaceutical Assessor, CDER/OPQ/OPMA/FDA
- **Saleem Akhtar,** Consumer Safety Officer, ORA/OMPTO/US FDA

1:00pm – 1:15pm

Closing Remarks and Adjourn

Vishal Sharma, President-PDA India Chapter, Director, Vienni Training & Consulting LLP ; Conference Chair

Rishikesh Jaiwant, Secretary - PDA India Chapter, Sr. Director, Manufacturing and Operations, Baxter India

Dr. Sumitra Pillai, Board Member -PDA India Chapter, VP, Head of R&D, Slayback Pharma

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BONUS PRESENTATION – On-Demand

Data Integrity: Regulatory Expectations and Challenges

Peter Baker, Live Oak Quality Assurance
