

## PDA INDIA CHAPTER

# 2025 ANNUAL MEETING

Conference : 30th July - 1st August 2025, Hyderabad, India

### Agenda

Day 1  
30 July 2025

Novotel Convention Center, Hyderabad

Day 1 Theme: Inspection & Responses

7:15 am - 8:30 am

Registration Open

8:30 am - 9:30 am

Plenary Session - Opening Plenary Session and Keynote Presentations

Welcome Address

**Dr. Rustom Mody**, Senior Vice President and Head R&D (Biologics), Sun Pharmaceuticals Industries Ltd.; President, PDA India Chapter

**Dr. Anil Sawant**, Senior Vice President, Global Quality Transformation, Merck Sharpe & Dohme, USA; Chair, Board Of Directors, PDA Inc.,

**Glenn Wright**, President and CEO, PDA Inc.,

**Constance L. Richard-Math**, Sr. Assistant Country Director, US FDA India Office

9:35 am - 10:50 am

Session 1

Regulatory Perspective for Addressing the Inadequacies of Regulatory Responses- Trends and Expectations

**Oisin Daly**, GMP Inspector, EDQM ( Virtual Mode)

**Ian Jackson**, Expert GMP Inspector, MHRA

**Meera Kumari Ram Navas**, Senior Principal Assistant Director, GMP Section, Centre of Compliance and Quality Control, NPRA

10:50 am - 11:20 am

Refreshment Break

11:20 am - 11:50 am

Leading Inspection Preparedness and Enabling Onsite Inspections

**Binh Nguyen**, President, Wynngate Corporation

11:55 am - 12:20 pm

Session 2

Understand the outcomes of Self-Inspection & Internal Audits

**Hemanth Panasa**, Vice President, Centre of Excellence, Sterile Quality Operations, Cipla Ltd.

12:25 pm - 1:15 pm

Session 3

Panel Discussion

**Oisin Daly**, GMP Inspector, EDQM ( Virtual Mode)

**Ian Jackson**, Expert GMP Inspector, MHRA

**Meera Kumari Ram Navas**, Senior Principal Assistant Director, GMP Section, Centre of Compliance and Quality Control, NPRA

**Binh Nguyen**, President, Wynngate Corporation

**Hemanth Panasa**, Vice President, Centre of Excellence, Sterile Quality Operations, Cipla Ltd.

Moderated By **Reem Malki**, Chief Quality Officer, Sun Pharmaceutical Industries Ltd.

1:15 pm - 2:00 pm

Networking Lunch

2:00 pm - 3:30 pm

Session 4

Investigation Approaches and CAPA ( Case study Discussion)

**Ravi Chander Katta**, Site Quality Director, Global Sterile Injectables, Pfizer Healthcare India Pvt. Ltd.

**Raghuram Chandra Rao**, AVP Quality, Gland Pharma Ltd.

**Milind Suryawanshi**, General Manager - Vaccines Quality Audit , GSK

**Dr. Carmelo Rosa**, Director, Division of International Drug Quality, US FDA (Virtual mode)

**Atul Agrawal**, Division Director, Office of Inspections & Investigations, US FDA (Virtual mode)

**Jose Melendez**, Consumer Safety Officer, US FDA (Virtual mode)

**Eileen Liu**, Consumer Safety Officer, US FDA (Virtual mode)

3:30 pm - 3:50 pm

Refreshment Break

3:55 pm - 4:55 pm

Session 5

Regulatory Perspective for Addressing the Inadequacies of Regulatory Responses - Trends and Expectations

**Dr. Carmelo Rosa**, Director, Division of International Drug Quality, US FDA (Virtual mode)

5:00 pm - 5:30 pm

Foreign Inspection

**Atul Agrawal**, Division Director, Office of Inspections & Investigations, US FDA (Virtual mode)

5:35 pm - 6:05 pm

Question & Answer Session

**Dr. Carmelo Rosa**, Director, Division of International Drug Quality, US FDA (Virtual mode)

**Atul Agrawal**, Division Director, Office of Inspections & Investigations, US FDA (Virtual mode)

6:10 pm - 6:15 pm

Closing remark

**Rishikesh Jaiwant**, Executive Vice President, Head of India Supply Chain Operation, GSK; President Elect, PDA India Chapter

## Day 2 Theme: Data Integrity & Quality Culture

**8:15 am - 8:30 am** **Building Blocks of Quality System -Setting the tone for the Day**  
**Moderator for the day - Dr. Antony Gomas**, Chief Quality Officer, Matrix Pharma Corp.

**8:30 am - 8:40 am** **Peek review of scripting rewards for poster**

**8:30 am - 9:20 am** **Passport to Prosperity; Poster Evaluation**

**9:20 am - 10:20 am** **Session 6**  
**Process: Data and it's integrity**  
**Scott Deckebach**, Executive Director, Lachman Consultant Services  
**Vikram Shukla**, President Operations, Zydus Lifesciences Ltd.

**10:25 am - 10:45 am** **Refreshment Break**

**10:45 pm - 11:55 pm** **Session 7**  
**People: Human errors: Why do they occur( Role Play & Discussion)**  
**Abhay Kumar Shrivastava**, President Operations, Mankind Pharma  
**Vishal Sharma**, Co-founder, Director - Vienni Training & Consulting LLP; PDA India Chapter Board Member  
**Andrew Hopkins**, Sr. Director of Compliance, Lachman Consultant Services  
**Binh Nguyen**, President, Wynngate Corporation

**12:00 pm - 1:00 pm** **Session 8**  
**Teaching modes and methods- Change foreseen to implementation at the shopfloor**  
**David Talmage**, Vice President PDA Inc.,  
**Dr.Marla Phillips**, CEO& President , Pathway for Patient Health

**1:00 pm - 2:00 pm** **Lunch**

**2:00 pm - 3:00 pm** **Session 9**  
**Interpretation of Guidances (With specific reference to Cleaning)**  
**Andrew Hopkins**, Sr. Director of Compliance, Lachman Consultant Services  
**Ian Jackson**, Expert GMP Inspector, MHRA

**3:05 pm - 3:45 pm** **Inspection Trends on Cleaning Validation**  
**Jose Melendez**, Consumer Safety Officer ,US FDA (Virtual Mode)

**3:50 pm - 4:20 pm** **Case Study: Cleaning Practices**  
**Lisa Flores**, Consumer Safety Officer, US FDA India  
**Guerlain Ulysse**, Consumer Safety Officer, US FDA India

**4:25 pm - 5:15 pm** **Creating Strategies of cleaning & disinfection that work effectively at all levels ( Discussion)**  
**Andrew Hopkins**, Sr. Director of Compliance, Lachman Consultant Services  
**Ian Jackson**, Expert GMP Inspector, MHRA  
**Jose Melendez** (Virtual mode)  
**Lisa Flores**, Consumer Safety Officer, US FDA India  
**Guerlain Ulysse**, Consumer Safety Officer, US FDA India

**5:20 pm - 6:05 pm** **Panel discussions & Question & Answer**  
**Scott Deckebach**, Executive Director,Lachman Consultant Services  
**Vikram Shukla**, President Operations, Zydus Lifesciences  
**Abhay Kumar Shrivastava**, President Operations, Mankind Pharma  
**Vishal Sharma**, Co-founder, Director, Vienni Training & Consulting LLP & PDA India Chapter Board Member  
**Andrew Hopkins**, Sr. Director of Compliance, Lachman Consultant Services  
**Binh Nguyen**, President, Wynngate Corporation  
**Avinash Joshi**, President - Quality, Intas Pharmaceuticals Ltd.  
**Abhijeet Kulkarni**, Vice President, Corporate Quality, Lupin Ltd.  
**Jose Melendez**, Consumer Safety Officer,USFDA (Virtual Mode)  
**David Talmage**, Vice President PDA TRI  
**Marla Phillips**, CEO& President, Pathway for Patient Health  
**Ian Jackson**, Expert GMP Inspector, MHRA  
**Lisa Flores**, Consumer Safety Officer, US FDA India  
**Guerlain Ulysse**, Consumer Safety Officer, US FDA India  
Moderated By **Reem Malki**, Chief Quality Officer, Sun Pharmaceutical Industries Ltd.

**6:10 pm - 6:30 pm** **Wrap up of Day-2 and Award announcement**  
**Dr. Carmelo Rosa**,Director, Division of International Drug Quality, US FDA (Virtual mode)  
**Dr. Rustom Mody**, Senior Vice President and Head R&D (Biologics), Sun Pharmaceutical Industries Ltd. ; President PDA India Chapter

**6:30 pm - 6:45 pm** **Refreshment Break**

**Day 3 Theme: Life cycle approach to risk assessment in sterile product manufacturing; Comparison of legacy installations/practices against newer ones**

9:00 am - 10:00 am	<b>Session 10</b> <b>History and aspects of Journey from open filling lines to using Isolators</b> <b>Marcel Menhorn</b> , Area Sales Manager, Bausch+Ströbel <b>Frank Homberger</b> , Regional Sales Director Asia, SKAN AG <b>Dirk Schuster</b> , Vice President Sales, Groninger & Co. <b>Gabriele Cassanelli</b> , Area Sales Manager, IMA Group
10:05 am - 10:50 am	<b>Session 11</b> <b>Legacy of Facilities: Engineering excellence in motion: Designing of smoke studies to identify risks in legacy systems and ringfence the infrastructure (Live Demonstration)</b> <b>Thomas J. Arista</b> , Pharmaceutical Consultant, Ventana Novo LLC <b>Andrew Hopkins</b> , Sr. Director of Compliance, Lachman Consultant Services <b>Raghuram Chandra Rao</b> , AVP, Gland Pharma Ltd
10:50 am - 11:20 am	<b>Refreshment Break</b>
11:25 am - 11:55 am	<b>Session 12</b> <b>Identifying traps for daily operations and ways to overcome them in a traditional/non-traditional manner - review of smoke study (Good vs area of improvement)</b> <b>Thomas J. Arista</b> , Pharmaceutical Consultant, Ventana Novo LLC
12:00 pm - 12:30 pm	<b>Regulatory Expectations for air flow visualization studies</b> <b>Lisa Flores</b> , Consumer Safety Officer, US FDA India Office <b>Guerlain Ulysse</b> , Consumer Safety Officer, US FDA India Office
12:35 pm - 1:05 pm	<b>Open Restricted Access Barrier Systems (RABS)</b> <b>Eileen Liu</b> , Consumer Safety Officer, US FDA (Virtual mode)
1:10 pm - 2:10 pm	<b>Lunch</b>
2:15 pm - 3:15 pm	<b>Session 13</b> <b>Legacy of Architectural framework : Facility, Equipment, People &amp; Procedure</b> <b>Krishna Venkatesh</b> , Global Head Quality & Pharmacovigilance, Dr. Reddy's Laboratories <b>Ranjit Menon</b> , Site Director, Al-Shifa Pharma, Kuwait
3:20 pm - 4:20 pm	<b>Quality Culture: How to begin the journey of transformation + Course on Decision making from PDA</b> <b>Dr. Anil Sawant</b> , Senior Vice President, Global Quality Transformation, Merck Sharpe & Dohme, USA; Chair, Board Of Directors PDA Inc.,
4:25 pm - 5:05 pm	<b>Panel Discussion</b> <b>Thomas Arista</b> , Pharmaceutical Consultant, Ventana Novo LLC <b>Lisa Flores</b> , Consumer Safety Officer, US FDA India Office <b>Guerlain Ulysse</b> , Consumer Safety Officer, US FDA India Office <b>Krishna Venkatesh</b> , Global Head Quality & Pharmacovigilance, Dr. Reddy's Laboratories <b>Ranjit Menon</b> , Site Director, AL-Shifa Pharma, Kuwait <b>Dr. Anil Sawant</b> , Senior Vice President, Global Quality Transformation, Merck Sharpe & Dohme, USA; Chair, Board Of Directors, PDA Inc., <b>Eileen Liu</b> , Consumer Safety Officer, US FDA (Virtual mode) Moderated By <b>Mona Hakeem</b> , VP-HR head Manufacturing & Quality, Sun Pharmaceutical Industries Ltd.
5:10 pm - 5:30 pm	<b>Wrap up &amp; Gratitude</b> <b>Dr. Karthik Ramani</b> , Vice President & Head, MSAT/ASAT, Biocon Biologics Limited; Board Member, PDA India Chapter <b>Dr. Sumitra Pillai</b> , Vice President, Product Development/R&D Head, Azurity Pharmaceuticals; Treasurer, PDA India Chapter