

PDA INDIA CHAPTER 2025 QUALITY MANAGEMENT MATURITY

in continuation to 2024 QMM & Supply Chain Resilience

Conference : 4th December - 5th December 2025, Hyderabad, India

Agenda

Day 1
4th December 2025

Novotel Convention Center, Hyderabad

8:00 - 8:55	Registration Open
9:00 - 9:15	Welcome - Address by Member of 2 Chairs, PDA Inc. Ivy Louis, Chair of Science Advisory Board (SAB), PDA Inc. Eva Urban, Chair of Regulatory Affairs and Quality Advisory Board (RAQAB) PDA Inc.
9:15 - 9:30	Setting the frame - Introduction to the Conference Theme PDA India Chapter Officer
9:30 - 10:00	Current activities & Overview of the Expectations Introduction to the U.S. FDA Office of Global Policy and Strategy Leadership Mark Abdoo, Associate Commissioner for Global Policy and Strategy, U.S.FDA Introduction to the activities of the US FDA India Office Greg Smith, Country Director, U.S.FDA India Office
10:00 - 10:30	Over view of the FDA QMM Program Dr. Jennifer Maguire, Director of the Office of Quality Surveillance/OPQ/CDER U.S. FDA
10:30 - 11:00	Refreshment Break
11:00 - 11:20	Lessons Learned from the 2024 QMM Prototype Assessment Protocol Evaluation Program Alex Viehmann, Division Director, OPQ, CDER, U.S. FDA
11:20 - 11:50	Value of quality: Why QMM makes a difference Eva Urban, Senior Director, Risk Management, Bristol Myers Squibb
11:50 - 12:35	Leadership & Management Commitment to Quality: A Case Study Discussion Nandini Rakala, Visiting Associate, OQS, CDER U.S. FDA
12:35 - 13:20	Advanced Pharmaceutical Quality System: Introduction + Case Study Eric Twum, Regulatory Specialist, OQS, CDER, U.S. FDA
13:20 - 14:20	Networking Lunch
14:20 - 15:25	Practice Area: QMM and Business Continuity (Workshop) Ivy Louis, Chair of Science Advisory Board (SAB), PDA Inc. Eva Urban, Chair of Regulatory Affairs and Quality Advisory Board (RAQAB) PDA Inc.
15:25 - 15:55	Technical Excellence: Visual Inspection: Investment in unit operation; incremental improvements major gains Avinash Joshi, President Quality, Intas Pharmaceuticals Ltd.
15:55 - 16:15	Refreshment Break
16:15 - 16:45	Advanced Pharmaceutical Quality System: ICHQ6; Specifications: Test Procedures And Acceptance Criteria For New Drug Substances And New Drug Products: Chemical Substances Dr. Cristiana Campa, CMC External Intelligence Lead, GSK (Virtual)
16:45 - 17:15	QMM Assessment: The journey for preparation of the assessment Dr. Damodharan Muniyandi, Chief Quality Officer, Sai Life Sciences Ltd
17:15 - 17:30	Wrap up and Closing of the day

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Day 2
5th August 2025

9:00 - 9:15	Recap of previous day Ivy Louis, Chairs of Science Advisory Board (SAB), PDA Inc. Eva Urban, Chair of Regulatory Affairs and Quality Advisory Board (RAQAB) of PDA Inc.
9:15 - 9:45	Employee Engagement & Empowerment: How to build culture ground up Vikram Shukla, President - Parenteral Operations, Zydus Lifesciences Ltd.
9:45 - 10:15	Business Continuity: Importance of manufacturing and quality coming together Dr. G K Raju, Founder, Chairman, Light Pharma Inc.
10:15 - 10:35	Refreshment Break
10:35 - 11:05	Management Commitment to Quality: The Who, The What and The How? Ivy Louis, Board of Director, PDA Inc., Founder- Director, Vienni Training & Consulting LLP
11:05 - 11:35	QMM Assessment: The experience and the Lessons Learnt Sumant Pilgaonkar, Senior Vice President, Rubicon Research Limited Sanjay Renapurkar, Vice President Quality, Rubicon Research Limited
11:35 - 12:05	Employee Engagement & Empowerment: Quality Culture Journey - A case study Mona Hakeem, HR Head - Global Manufacturing & Quality, Sun Pharmaceutical Industries Ltd. Pravin Kulkarni, Global Head, Quality Sustainability, Training & Quality Culture, Sun Pharmaceutical Industries Ltd
12:05 - 13:05	QMM Protocol and Process (Panel Discussion) Dr. Jennifer Maguire, Director of the Office of Quality Surveillance/OPQ/CDER U.S. FDA Alex Viehmann, Division Director, OPQ, CDER, U.S. FDA Nandini Rakala, Data Scientist, CDER U.S. FDA Eric Twum, CDER, U.S. FDA Vishal Sharma, Co Founder- Director, Vienni Training & Consulting LLP - Moderator
13:05 - 14:00	Lunch
14:00 - 14:30	Technical Excellence: Journey from grounds up to Digital Light house Madhu Sundar M.S., SVP & Head Global Manufacturing, Dr. Reddy's Laboratories Ltd.
14:30 - 16:00	Practice Area: QMM and Advanced PQS (Workshop) Ivy Louis, Chair of Science Advisory Board (SAB), PDA Inc. Eva Urban, Chair of Regulatory Affairs and Quality Advisory Board (RAQAB) PDA Inc.
16:00 - 16:30	Refreshment Break
16:20 - 17:20	Management Commitment to Quality (Panel Discussion) Vikram Shukla, President - Parenteral Operations, Zydus Lifesciences Ltd. Mona Hakeem, HR Head - Global Manufacturing & Quality, Sunpharmaceuticals Industries Ltd. Pravin Kulkarni, Global Head, Quality Sustainability, Training & Quality Culture, Sunpharmaceutical Industries Ltd. Ivy Louis, Board of Director, PDA Inc., Founder- Director, Vienni Training & Consulting LLP Sumant Pilgaonkar, Senior Vice President, Rubicon Research Limited Sanjay Renapurkar, Vice President Quality, Rubicon Research Limited Dr. G K Raju, Founder, Chairman, Light Pharma Inc. Madhu Sundar M.S., SVP & Head Global Manufacturing, Dr. Reddy's Laboratories Ltd. Ranjit Menon, Cipla Ltd - Moderator
17:20 - 17:30	Felicitatation & wrap up