Agenda

PDA Week 2025

Sunday, 6 April

11:00 – 13:00

PDA Chapter Council Meeting (Invite Only)

Chapter Representative: Betsy Anda-Harris, **MS**, Site Based Compliance Manager, *Johnson & Johnson*

Chapter Representative: Virginia Andreotti-Jones, Consultant, Quality Risk Management, *ValSource, Inc.*

Chapter Representative: Karin Baer, VP Quality, *Neuroderm*

Chapter Representative: Monick Bassi de Paula, **MBA**, QA Manager, *Instituto Butantan*

Chapter Representative: Stephen Beekman, Inspection Readiness Site and Audit Support, *Pfizer*

Chapter Representative: Mirko Gabriele, **PhD**, CEO, *InfiniteVision*

Chapter Representative: Deborah Gessell-Lee, **MS, PhD**, Director of Quality Assurance and Regulatory Compliance, *M2DCON*

Chapter Representative: Aidan J. Harrington, **PhD**, Principal Consultant, *Arcadis*

Chapter Representative: Martin S. Jenkins, **PMP**, Senior Project Manager, Qualification and Validation, *Circle MJ Consulting*

Chapter Representative: Christopher Lewis, Head of Quality, *Umoja Biopharma*

11:30 – 12:45

PDA Advisory Board Member Lunch (Invite Only)

13:00 – 17:00

PDA Biopharmaceutical Advisory Board Meeting (Invite Only)

AB Chair: Maxwell De Long, **MS, MechE**, Director and Senior Principal, Individualized Medicines, *Genentech*

AB Vice-Chair: Peter J. Makowenskyj, **MEng**, Director of Design Consulting, *G-CON*

AB Member: Maria Amaya, **PhD**, Lead External Advocacy North America (Quality Policy), *Genentech*

AB Member: Kurt A. Brorson, **PhD**, Vice President Technical, *PAREXEL*

AB Member: Andrew C. Chang, **PhD**, Vice President, Quality and Regulatory Compliance, Regulatory Policy and Intelligence, *Novo Nordisk*

AB Member: Jennifer Cheung, VP of Global Quality Assurance Operations, *Gilead Sciences*

AB Member: Jesper Davidsen, **PhD**, Principal Scientist, *Novo Nordisk*

AB Member: Christopher Hwang, **PhD**, Chief Technology Officer, *Transcenta*

AB Member: Guido Kremer-van der Kamp, Senior Consultant - Global BioPharm Center of Excellence, *Merck KGaA*

AB Member: Mahesh Krishnan, **PhD**, Director - Global Vaccines and Biologics Commercialization, *Merck & Co., Inc.*

13:00 – 17:00

PDA Regulatory Affairs and Quality Advisory Board Meeting (Invite Only)

AB Chair: Denyse D. Baker, **PE, RAC**, AVP Global Quality Compliance, *Eli Lilly and Company*

AB Vice-Chair: Eva M. Urban, **MSc**, Senior Director, Risk Management, *Bristol Myers Squibb*

AB Member: Masahiro Akimoto, Director, Quality Assurance Department, *Heartseed Inc.*

AB Member: Lisa Bennett, **MSc**, Director, *LB Consulting Australia Pty Ltd*

AB Member: Chuck Bornhoeft, **MS**, Vice President of Quality Operations, *Rion*

AB Member: Vinny Browning, **MS**, Executive Director Quality Assurance, *Amgen*

AB Member: Austin G. Caudle, **MSc**, Vice President, *Project Farma*

AB Member: Karolyn Gale, **RAQC**, VP Regulatory Affairs, *Emergent BioSolutions*

AB Member: Beth J. Haas, **MChE**, Owner/Consultant, *Haas Pharma Consulting*

AB Member: Kir F. Henrici, Chief Executive Officer, *The Henrici Group*

13:00 – 17:00

PDA Science Advisory Board Meeting (Invite Only)

AB Chair: Gabriele Gori, Senior Quality Advisor, *Consultant*

AB Vice-Chair: Ivy Louis, **MPharm, MBA(HRM)**, Founder-Director, *Vienni Training & Consulting LLP*

AB Member: Frederic B. Ayers, Senior Consultant - Microbiology, *ValSource, Inc.*

AB Member: Tiffany A. Baker, **MBA**, Senior Consultant, *ValSource, Inc.*

AB Member: Greg Bassett, **MBA**, VP Cell Therapy Global Drug Product Quality, *Bristol Myers Squibb*

AB Member: Emily Cheah, **PhD**, Senior Managing Director Singapore and APAC Technical Operations Lead, *Charles River Laboratories*

AB Member: Thomas Damratoski, Senior Vice President Biopharmaceutical Products, *Civica Rx*

AB Member: Cheryl E. Essex, **MSc**, Head of Contamination Control, R&D Global Quality, *Sanofi*

AB Member: David L. Exline, **MSFS**, President, *Gateway Analytical*

AB Member: Rhonda Ezell, **MS**, Site Head of Quality, *Alkermes*

14:00 – 19:00

Registration Open

14:00 – 19:00

Speaker Ready Room Open

18:30 – 21:30

PDA Awards Dinner (Ticket Required – Cocktail Attire)

Monday, 7 April

Agenda

PDA Week 2025

07:00 – 19:00

Registration Open

08:00 – 09:30

Roundtable 1: Speeding Innovation Through Global Regulatory Convergence (Ticket Required)

Join your peers to discover, discuss, and dissect ideas and innovations that could move global regulatory convergence forward to accelerate treatments for patients with terminal illnesses and treatments targeted for future epidemics and pandemics.

Moderator: Julian Petersen, Head of Business Development, *Groninger*

Discussion Leader: Cristiana Campa, **PhD**, Technical R&D Advisor, *GSK*

Discussion Leader: Stephan K. Roenninger, **Dr.-Ing.**, Director Compliance, External Affairs, *Amgen*

08:00 – 09:30

Roundtable 2: Strategies for Modern Knowledge Management Implementation (Ticket Required)

Management of product and product knowledge plays a critical role across the product lifecycle. However, knowledge management (KM) has not been fully realized in practice. This roundtable will explore the objectives of ICH Q10 and how to best implement KM to the benefit of the industry at large beyond the regulatory expectations.

Moderator: Malav Parikh, **ME**, Director, Quality Risk Management, Global Quality Compliance and Systems, *Takeda*

Discussion Leader: Martin J. Lipa, **PhD**, Senior Research Fellow, *Technological University Dublin Pharmaceutical Regulatory Science Team*

Discussion Leader: James L. Vesper, **PhD, MPH**, Director, Learning Solutions, *ValSource, Inc.*

08:00 – 09:30

Roundtable 3: Developing the Next Generation of Pharmaceutical Professionals (Ticket Required)

This roundtable will explore strategies for early and mid-career professionals in the biopharmaceutical industry, focusing on skill development, career advancement, mentorship, and navigating industry challenges. Participants will share insights on fostering growth, building networks, and preparing for leadership roles in a dynamic and evolving sector.

Moderator: Kate Malachowski, **PhD**, Director, MS&T, *Novavax*

Discussion Leader: Stephanie P. Kurtz, **MS**, Strategic Account Executive, *SQA Services*

Discussion Leader: Robin Usselman, Sr. Business Development Manager, USA & Canada, *PBL (Performing Beyond Limits)*

08:00 – 09:30

Roundtable 4: Effective AI Deployment in Drug Manufacturing (Ticket Required)

The integration of Artificial Intelligence (AI) into drug manufacturing is in its early stages, offering both immense opportunities and unique challenges. This roundtable is designed to explore strategies and identify potential barriers such as data quality, system complexity, and workforce readiness. Discussion will also delve into the regulatory landscape and the practical burdens of adopting this transformative technology.

Moderator: Ryan Murray, **MS**, Senior Consultant, *ValSource, Inc.*

Discussion Leader: Peter J. Makowenskyj, **MEng**, Director of Design Consulting, *G-CON*

Discussion Leader: Toni Manzano, Co-Founder and CSO, *Aizon*

09:45 – 12:15

Mini-Workshop 1: Driving Global Vaccine Access and Acceleration: Exploring Enablers and Overcoming Challenges (Ticket Required)

With more emphasis on enhancing worldwide access to vaccines while simultaneously accelerating their development and launch, manufacturers and regulators are focusing efforts on developing best practices and shared understanding of the opportunities and challenges. This mini-workshop will explore innovations in vaccine production and delivery strategies and attendees will grapple with hands-on case studies to discover paths for success.

Workshop Leader: Cristiana Campa, **PhD**, Technical R&D Advisor, *GSK*

Workshop Leader: Sabrina Restrepo, **PhD**, Executive Director - Quality Assurance, *Merck & Co., Inc.*

09:45 – 12:15

Mini-Workshop 2: CDMO Selection and Tech Transfer Fundamentals (Ticket Required)

Outsourcing a pharmaceutical project is a strategic decision that has a huge influence on the long-term success of any project. This mini-workshop will focus on the critical steps following the decision to outsource – selecting the right partner for the project and determining technology transfer (TT) requirements. A hands-on exercise on selecting a CDMO (from RFP to scoring criteria) will guide attendees in the thought processes and pathways to select the best partner for the job.

Workshop Leader: Maria Amaya, **PhD**, Lead External Advocacy North America (Quality Policy), *Genentech*

Workshop Leader: Maxwell De Long, **MS, MechE**, Director and Senior Principal, Individualized Medicines, *Genentech*

Workshop Leader: Morten Munk, Director, Global Alliance Management, *FUJIFILM Diosynth Biotechnologies*

11:00 – 17:00

Speaker Ready Room Open

13:00 – 15:00

P1: From Manufacturing Excellence to Patient Impact: The Future of GLP-1 Therapies

Moderator: Vanessa Vasadi Figueroa, **MA**, Chief Microbiologist, *VVF Science*

13:00 – 13:25

Welcome from PDA Leadership and PDA Week Co-Chairs

Chairperson: Anil A. Sawant, **PhD**, Senior Vice President, Global Quality Compliance, *Merck & Co., Inc.*

President: Glenn E. Wright, **MA**, President and CEO, *PDA*

Co-Chair: Kate Malachowski, **PhD**, Director, MS&T, *Novavax*

Co-Chair: Susan J. Schniepp, Distinguished Fellow, *Regulatory Compliance Associates Inc.*

13:25 – 13:50

The Future of GMP Manufacturing: Disruptive Technologies in Peptide Synthesis and Continuous Processing

Presenter: Lorraine O'Shea, **MS**, Small Molecule and Peptide Plant Manager, *Eli Lilly and Company*

13:50 – 14:15

Provider Perspective on Technology and Market Disruption

Presenter: Lucia M. Novak, **MSN, ANP-BC, BC-ADM**, President, *Diabesity, LLC*

14:15 – 14:40

Pharma Perspective on Manufacturing Excellence to Patient Impact

Presenter: Melissa S. Seymour, **MBA**, EVP and Chief Quality Officer, *Eli Lilly and Company*

14:40 – 15:00

Q&A

15:00 – 15:30

Networking Break

15:30 – 17:00

A1: Disruptive Therapies

This session will explore cutting-edge developments and new modalities in the ATMP or biopharmaceutical space. Experts will share insights into these emerging technologies, highlighting challenges, risks, opportunities, and best practices for bringing next-generation therapies to market.

Moderator: Peter J. Makowenskyj, **MEng**, Director of Design Consulting, *G-CON*

15:30 – 15:50

Overview of Drug Modalities

Presenter: Wendy Haines, **PhD**, Director of Toxicology & Quality Services, *PharmEng Technology*

15:50 – 16:10

It’s Just Dilute Liquid (Or Is It?): Why Understanding the Risks Matters in ADC Processes

Presenter: Ashley Harp, **PE**, Process Engineer, *CRB*

16:10 – 16:30

Microbial Marvels: LBPs Leading the Charge Against Gut Diseases

Presenter: Ankur K. Shah, **PE**, Lead Process Engineer, *Arcadis*

16:30 – 17:00

Q&A

15:30 – 17:00

B1: Innovative Pharmaceutical Manufacturing Solutions

This session will focus on innovative approaches addressing modern pharmaceutical manufacturing challenges. Discussions will cover the justification and execution of simulated leachables testing when drug products are unavailable, the development of sustainable modular platforms for small batch production, and strategies for designing automation to meet stringent regulatory and quality standards. Through case studies and actionable guidance, attendees will learn how to align manufacturing innovations with compliance and quality objectives.

Moderator: Julian Petersen, Head of Business Development, *Groninger*

15:30 – 15:50

How to Handle Leachable Testing When a Drug Product is Not Available or Analytically Feasible: Guidance for Performing Simulated Leachables

Presenter: Sam Albeke, Chromatography Manager, *Element Materials Technology*

15:50 – 16:10

Transforming Small Batch Drug Product Production with Modular Solutions: Flexibility and Sustainability in Pharma Manufacturing

Presenter: Erik Anderson, Principal Engineer, *Novavax*

16:10 – 16:30

Specifying, Designing, and Developing Automation for Novel Products and Aseptic Processes

Presenter: David Phasey, Projects Director, *3P innovation*

16:30 – 17:00

Q&A

15:30 – 17:00

C1: Enhancing Quality Maturity

This session will explore strategies and tools to elevate quality maturity in pharmaceutical manufacturing. Topics will include selecting impactful key performance indicators (KPIs) to drive positive organizational outcomes, leveraging collaborative technologies to enhance root cause analysis effectiveness, and using innovative inspection intelligence tools to prepare for regulatory inspections of sterile products. Through case studies and expert insights, attendees will gain practical approaches to integrating quality principles with manufacturing excellence.

Moderator: Ken Paddock, Quality Director, Sterility Assurance, *Baxter*

15:30 – 15:50

Metrics Simplified! Avoiding the KPI Doldrums

Presenter: Ivailo Neov, Director, Internal Manufacturing, *Novavax*

15:50 – 16:10

Improving Effectiveness of Root Cause Analysis Through Collaborative Technologies

Presenter: Jeff Lewis, Director Global Manufacturing Sciences, Head of RAPID, *Takeda*

16:10 – 16:30

A Roadmap with Innovative Tools for Quality Leaders to Successfully Navigate Inspections for Sterile Products

Presenter: Raj Gulati, **MPharm, MBA, MS**, Founder & CEO, *Regunalys*

16:30 – 17:00

Q&A

15:30 – 17:00

D1: Ready, Set, Prep: Practical Tools for Audits and QRM in Contamination Control

This session will explore effective preparation strategies for GxP audits and inspections, including mock inspections and past audit reviews, while shedding light on integrated CMC strategy and quality risk management (QRM) for contamination control. Participants will gain practical insights for getting audit-ready and learn new models for effective risk-based approaches, ensuring robust compliance and patient safety.

Moderator: Stephanie N. Lee, **MBS, PMP**, Strategic Planning & Operations Manager, *Amgen*

15:30 – 15:50

GXP Auditing and Inspections Preparation and Understanding

Presenter: Neal Siegel, **PhD**, Consultant, *The FDA Group*

15:50 – 16:10

From Compliance to Confidence: Redefining Risk Management in Contamination Control

Presenter: Patrick Mains, Senior Consultant, *ValSource, Inc.*

16:10 – 16:30

Integrated CMC Strategy: Ensuring Patient Safety Through Contamination Control

Presenter: Grace Lee, **PhD, MBA, CQA**, Founder and Principal Consultant, *Elevalue Consulting LLC*

16:30 – 17:00

Q&A

17:00 – 18:30

Happy Hour in the Exhibit Hall

18:30 – 21:00

Opening Reception

The Opening Reception is included for all full meeting registrants and exhibitors. Guest tickets are available for purchase for $75.

Tuesday, 8 April

07:00 – 08:00

Continental Breakfast

07:00 – 18:30

Registration Open

07:30 – 10:30

Speaker Ready Room Open

08:00 – 09:30

P2: Sustainability

Moderator: Sebastian B. Teitz, **PhD**, Senior Development Scientist, *Novo Nordisk*

08:00 – 08:25

Sourcing and Supply Change Perspective on Sustainability

Presenter: Jane Zhang, Co-Founder & Co-CEO, *ETCH Sourcing*

08:25 – 08:50

Pharmaceutical Perspective on Sustainability

Presenter: Phil Duncanson, **PhD**, Senior Director, Global Quality Control, *AstraZeneca*

08:50 – 09:30

Q&A

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09:00 – 16:15

Exhibit Hall Open

09:30 – 10:30

Networking Break in the Exhibit Hall

09:30 – 10:30

Poster Presentations in the Exhibit Hall

10:30 – 12:00

A2: Data Management and Lifecycle Strategies for Advanced Therapies

This session will examine cutting-edge approaches to data management and lifecycle strategies in ATMP and biopharmaceutical manufacturing. Topics will include optimizing digital ecosystems for patient traceability, transitioning from batch to campaign filling modes, and leveraging pharmaceutical continuous manufacturing (PCM) for lifecycle management. Attendees will gain insights into integrating data-driven strategies with regulatory frameworks to enhance efficiency, compliance, and scalability.

Moderator: Divyang Patel, Senior Specialist, Commissioning, Qualification & Validation (CQV), *AtkinsRéalis*

10:30 – 10:50

A Concept for Optimized Digital Data Management: What is Required to Make the ATMP Industry Ready for the Future

Presenter: Judith Koliwer, **PhD**, Senior Industry Advisor & Principal Consultant Advanced Therapies, *Körber Pharma Software*

10:50 – 11:10

Transitioning from Batch to Campaign Filling Mode – Walking Before Running, APS Qualifications, and Other Considerations

Presenter: Aidan J. Harrington, **PhD**, Principal Consultant, *Arcadis*

11:10 – 11:30

PCM – An Agile Risk and Data-Driven Lifecycle Management Approach

Presenter: Margarida Ventura, **MS**, Quality Risk Management Senior Consultant, *ValGenesis*

11:30 – 12:00

Q&A

10:30 – 12:00

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B2: Advancing Quality Control: Automated Visual Inspection in Parenterals

This session will explore cutting-edge advancements in automated visual inspection (AVI) for parenterals. Topics will include lifecycle and risk management for visible particles, reducing false rejects using data analytics and machine learning (ML), and a novel human-inspired inspection approach. Attendees will leave this session with enhanced knowledge of improving accuracy, efficiency, and compliance in AVI systems.

Moderator: Ryan Murray, **MS**, Senior Consultant, *ValSource, Inc.*

10:30 – 10:50

Lifecycle and Risk Management for Visible Particles in Parenterals - Industry Best Practices

Presenter: Antonio Burazer, Global Head Visual Inspection & Particle LCM, *Takeda*

10:50 – 11:10

Enhancing AVI Accuracy: Reducing False Reject by Distinguishing Air Bubbles from Defects Using Data Analysis and ML

Presenter: Berwald Gomes, **MSc**, Vision Engineer/Engineer Optical Control, *Roche*

11:10 – 11:30

Human-Inspired AVI: The Next Level of Parenteral Packaging Quality Control

Presenter: Chiara Sinito, **PhD**, Head of AVI, *WILCO AG*

11:30 – 12:00

Q&A

10:30 – 12:00

C2: Digital Transformation

This session will delve into the impact of digital transformation on biopharmaceutical processes, highlighting innovations in contamination control, risk management in fill-finish, and streamlining technology transfers. Experts will discuss how digital tools are driving efficiency, reducing risk, and ensuring compliance across the manufacturing lifecycle.

Moderator: Malav Parikh, **ME**, Director, Quality Risk Management, Global Quality Compliance and Systems, *Takeda*

10:30 – 10:50

Digitalization Strategies for Contamination Control Under Annex 1

Presenter: Sheba S Zaman, Head of Product Specialists and Training Services, *Novatek*

10:50 – 11:10

QRM & QbD in Fill-Finish: Measure Risk Reduction Scientifically

Presenter: Sebastian Scheler, **MSc**, Managing Director, *Innerspace*

11:10 – 11:30

A Digital Transformation Path for Better Technology Transfers

Presenter: Yowvanaraj Gopal, Director Professional Services, *ValGenesis*

11:30 – 12:00

Q&A

10:30 – 12:00

D2: Regulatory Insights and Challenges: Annex 1, PUPSIT, and Drug Compounding

This session will address key regulatory challenges impacting the pharmaceutical industry. Topics will include insights from the Kilmer Community PUPSIT survey post-Annex 1 implementation, the evolving regulatory framework for compounded drugs, and findings from the PDA Annex 1 survey. Attendees will gain a deeper understanding of regulatory trends, compliance strategies, and their implications for patient safety.

Moderator: Susan J. Schniepp, Distinguished Fellow, *Regulatory Compliance Associates Inc.*

10:30 – 10:50

PDA Annex 1 Survey

Presenter: Marcia C. Baroni, **MBA**, VP Quality, Enterprise GxP Compliance & Systems, *Emergent BioSolutions*

10:50 – 11:10

Does the Current Regulatory Framework Ensure the Safety of Compounded Drugs?

Presenter: Brad Jordan, **PhD**, Associate Vice President, Global Regulatory Policy & Strategy, *Eli Lilly and Company*

11:10 – 11:30

Results of the Kilmer Community PUPSIT Survey

Presenter: Maik W. Jornitz, Principal Consultant, *BioProcess Resources*

11:30 – 12:00

Q&A

12:00 – 13:30

Networking Lunch in the Exhibit Hall

12:00 – 13:30

Agenda

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Poster Presentations in the Exhibit Hall

13:30 – 14:15

IG01: Combination Products

Interest Group Leader: Maggie Bandel, **MBA**, Global Head Lifecycle Management ATSC MSAT, *Johnson & Johnson*

13:30 – 14:15

IG02: Drug Compounding

Interest Group Leader: Arie Anahory, **MS**, Senior Director, Strategy and Customer Excellence, *Regulatory Compliance Associates Inc.*

Interest Group Leader: David Short, Chief Quality Officer, *QuVa Pharma*

13:30 – 14:15

IG03: Management of Outsourced Operations and Technology Transfer

Interest Group Leader: Maria Amaya, **PhD**, Lead External Advocacy North America (Quality Policy), *Genentech*

Interest Group Leader: Morten Munk, Director, Global Alliance Management, *FUJIFILM Diosynth Biotechnologies*

Interest Group Leader: Mirko Gabriele, **PhD**, CEO, *InfiniteVision*

Interest Group Leader: Elizabeth Kramer, **PhD**, Senior Director, *Eli Lilly and Company*

13:30 – 14:15

IG04: Quality Risk Management and Supply Chain Management

Interest Group Leader: Malav Parikh, **ME**, Director, Quality Risk Management, Global Quality Compliance and Systems, *Takeda*

Interest Group Leader: Henry Ames, **MBA**, General Manager, Logistics Orchestration, *TraceLink*

13:30 – 15:30

Mini-Training Course 1: Lyophilization (Ticket Required)

This mini-training course will help participants gain an understanding of the basic principles and practical aspects of lyophilization technology. Attendees will learn about the process and equipment, vacuum technology use for freeze drying, solidification during freezing, sublimation in primary drying, desorption during secondary drying, application of principles to product and process development, analysis of product characteristics, and process scale-up to production.

Instructor: Nathaniel Milton, **PhD, RPh**, Professor of Practice - Industrial and Physical Pharmacy, *Purdue University*

14:15 – 14:30

Transition to Next IG

Agenda

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14:30 – 15:15

IG05: Data Governance, Management, Integrity, and Digitalization

Interest Group Leader: Kir F. Henrici, Chief Executive Officer, *The Henrici Group*

Interest Group Leader: Ulrich Koellisch, **PhD**, Partner, *GxP-CC*

14:30 – 15:15

IG06: Microbiology/Environmental Monitoring

Interest Group Leader: Kurt Jaecques, **MA**, Global Quality Technical Senior Lead, *GSK*

Interest Group Leader: Kim Sobien, **MBA**, Senior Consultant - Microbiology, *ValSource, Inc.*

14:30 – 15:15

IG07: Process Validation

Interest Group Leader: Robert Dream, Managing Director, *HDR Company*

Interest Group Leader: Mauro Giusti, **MSc**, Senior Director, Parenteral Technical Knowledge, *Eli Lilly and Company*

14:30 – 15:15

IG08: Sterile Processing/Parenteral Drug Manufacturing

Interest Group Leader: Julian Petersen, Head of Business Development, *Groninger*

14:30 – 15:15

Lightning Session 1

PDA's Lightning Presentations will use the Pecha Kucha presentation method, which calls for telling a story using images rather than reading text from slides during a PowerPoint presentation. Each presentation will have 20 slides set to automatically advance after only 20 seconds of commentary per slide for a total talk time of 6 minutes and 40 seconds.

Moderator: Ken Paddock, Quality Director, Sterility Assurance, *Baxter*

14:30 – 14:35

Session Introduction

14:35 – 14:42

A Risk Based Approach for Pre-Use/Post-Sterilization Integrity Test Simulation During Bacterial Retention Testing as Part of the Process Specific Filter Validation of Sterilizing Grade Filters.

Presenter: Yvonne Groß, **Dipl.-Ing**, Senior Scientist, *Sartorius Stedim Biotech*

14:42 – 14:49

Successful In Situ Disinfectant Field Trials

Presenter: Dan A. Klein, **MA**, Senior Technical Service Manager, *STERIS*

14:49 – 14:56

Smart Manufacturing with Intelligent Sensors

Presenter: Bethany Silva, Industry Manager - Life Sciences, *Endress+Hauser*

14:56 – 15:15

Q&A

15:15 – 16:15

Networking Break in the Exhibit Hall

15:15 – 16:15

Poster Presentations in the Exhibit Hall

16:15 – 17:45

A3: CMC Insights for Biosimilars and Container Closure Integrity Testing Advancements

This session will explore key aspects of CMC for biosimilars, including clone selection, manufacturing processes, and comparative assessments. It will address upcoming challenges in container closure integrity testing (CCIT) for low-temperature containers, biopharmaceutical compatibility, and delivery systems. Attendees will also learn about future innovations in CCIT and automated visual inspection (AVI) integration for automated, high-throughput inspection of low-volume solutions.

Moderator: Sebastian B. Teitz, **PhD**, Senior Development Scientist, *Novo Nordisk*

16:15 – 16:35

Key CMC considerations for Biosimilar Success

Presenter: Kurt A. Brorson, **PhD**, Vice President Technical, *PAREXEL*

16:35 – 16:55

Vial Containment and Syringe Systems for Low Temperature Applications

Presenter: Page McAndrew, **PhD**, Director, Scientific Communications, *West Pharmaceutical Services, Inc.*

16:55 – 17:15

A Novel Approach for CCIT and AVI of Fusion-Sealed Pre-Filled Syringes (PFS) with Opaque Suspensions

Presenter: Matthias Kahl, Head of R&D and Lab Services, *WILCO AG*

17:15 – 17:45

Q&A

16:15 – 17:45

B3: Transforming Contamination Control: Innovative Strategies, Technologies, and Risk Management

Contamination control remains critical to pharmaceutical manufacturing, with innovations and methodologies aimed at addressing regulatory compliance challenges and enhancing operational efficiency. This session will delve into real-time microbial monitoring using biofluorescence particle counters, environmental control and monitoring driven by quality risk management (QRM), and approaches to modernizing legacy systems through process modeling and AI-enabled automation. Each presenter will provide actionable insights and practical strategies for contamination control optimization.

Moderator: Vanessa Vasadi Figueroa, **MA**, Chief Microbiologist, *VVF Science*

16:15 – 16:35

Real-World Challenges – and Solutions – for the Use of Biofluorescence Particle Counters in Grade A Aseptic Filling Applications

Presenter: Manny Khera, Head of Engineering - Aseptic Filling, *Cytiva*

16:35 – 16:55

Innovative Approaches to Environmental Risk Assessment and Sample Site Selection: Leveraging QRM for Effective Contamination Control

Presenter: Virginia Andreotti-Jones, Consultant, Quality Risk Management, *ValSource, Inc.*

16:55 – 17:15

Improving Legacy Processes: A Case Study on Reducing Risks and Ensuring Regulatory Compliance

Presenter: Jeffrey Gensler, VP Quality, *Kindeva Drug Delivery*

17:15 – 17:45

Q&A

16:15 – 17:45

C3: Applied Artificial Intelligence

Over the past decade, artificial intelligence (AI) has seen exponential growth throughout various industries. While we have seen a slower adoption rate in the biopharmaceutical industry, we are coming to an inflection point. In this session, participants will look at the different ways AI is being implemented in our industry within our current regulations.

Moderator: Peter J. Makowenskyj, **MEng**, Director of Design Consulting, *G-CON*

16:15 – 16:35

Large Language Models in GMP - Risk Management and Validation

Presenter: Ulrich Koellisch, **PhD**, Partner, *GxP-CC*

16:35 – 16:55

Quality Inspection Methods for DIP Products According to Pharmacopoeia Annex I and the Benefits of Implementing AI Technology within Traditional Algorithms

Presenter: Gianmarco Pincelli, Technical Sales Manager, *Bonfiglioli Engineering*

16:55 – 07:15

AI-Driven Holistic Risk Management: Transforming Pharma Supply Chains

Presenter: Fabrizio Maniglio, Industry and Business Development Director, *Honeywell*

17:15 – 17:45

Q&A

16:15 – 17:45

D3: Proactive Data, Quality, and Risk Management for Business Sustainability

This session will explore the power of proactive data, quality, and risk management to achieve business sustainability in the pharmaceutical industry. Topics will include developing data and risk management driven strategies for supply chain resilience, leveraging quality risk management to achieve operational excellence and business growth, and utilizing advanced graph-based intelligence for quality assurance to increase business competitiveness. Attendees will gain actionable insights into aligning quality processes with business success and sustainability.

Moderator: Jennifer Cheung, VP of Global Quality Assurance Operations, *Gilead Sciences*

16:15 – 16:35

Data and Risk Management Challenges in the Evolving Drug Supply Chain

Presenter: Kellen Giroux, **CQA, CQE**, Director, Quality Solutions, *Network Partners Group*

16:35 – 16:55

Quality Risks are Business Risks: Integrating QRM for Strategic Success

Presenter: Lori Richter, **PhD**, Sr. Director, GxP Quality Management Systems, *ALX Oncology*

16:55 – 17:15

From Compliance to Competitiveness: The Power of Graph-Based Intelligence in Quality Assurance

Presenter: Mike Salem, MA, Associate Director of Data Science - Quality Assurance, *Gilead Sciences*

17:15 – 17:45

Q&A

18:00 – 20:30

Architecture and Celebrity Homes Bicycle Tour (Ticket Required)

Riders will get a unique glimpse into Palm Springs' Hollywood history, architectural masterpieces, and destination highlights. The biking route includes the historic Palm Springs neighborhoods where riders will see examples of key architects important to the development of Palm Springs in the 1950s and 1960s as well as several celebrity homes. Bike helmets are required and provided.

18:15 – 20:00

Local Beer Tasting and Dinner (Ticket Required)

La Quinta Brewing Co. opened their doors in the fall of 2013 and has become a destination spot with continued growth in popularity. Participants will enjoy a delicious taco/nacho bar with chicken, beef, and vegetarian options with their choice of four (4) different 5 oz beers to taste from La Quinta Brewing Co.'s rotating selection of IPAs, porters, lagers, ales, wheat, and special seasonal beers. Don't miss your opportunity to enjoy the laid-back desert lifestyle of Palm Springs while sipping craft beer with friends!

18:15 – 20:30

Palm Springs Aerial Tram and Dinner (Ticket Required)

The Palm Springs Aerial Tramway has the world's largest rotating tram car and travels over 2.5 mi/4 km along the cliffs of Chino Canyon and it transports visitors to the pristine wilderness of the Mt. San Jacinto State Park and Wilderness Area. During the 10-min journey on the tram itself, tram cars rotate slowly, offering spectacular views of the valley below. At the tram's Mountain Station (elevation 8,516 ft/2,596 m and 30 degrees cooler than the desert floor) guests will enjoy 180 degrees of spectacular views of the valley from the observation decks, watch two documentary films, visit the natural history museum, and enjoy dinner at Pines Café. This trek to the top of this famous mountain is truly a singular experience!

Dinner includes a green salad, your choice of entrée with two sides, and a soft drink or water. Alcohol is available for purchase.
• Entrée choices: baked herb chicken, creamy vegetarian lasagna with toasted parmesan cheese breadcrumbs, BBQ pork ribs braised and glazed in a smokey sauce, or beef burgundy braised in a cabernet wine
• Side choices (up to 2): corn on the cob, fingerling potatoes, mashed potatoes, or roasted seasonal vegetables

18:30 – 20:30

Wine and Watercolors (Ticket Required)

Calling all artists for this fun and unique experience! Participants will craft beautiful greeting cards with watercolor paints while enjoying their choice of two (2) drinks (wine or beer) and a charcuterie board to snack on. Professional instruction and all supplies to make four (4) greeting cards per person will be provided (cards, pens, paints, brushes, and aprons).

Wednesday, 9 April

07:00 – 08:00

Continental Breakfast

Agenda

PDA Week 2025

07:00 – 15:30

Registration Open

07:30 – 10:30

Speaker Ready Room Open

08:00 – 09:30

A4: Ensuring Quality and Potency in ATMP Manufacturing

This session will explore strategies for maintaining quality and potency in advanced therapy medicinal products (ATMPs). Topics will include developing science-based potency assays, implementing end-to-end product stewardship with modular technologies, and designing robust disinfectant validation programs for cleanrooms. Attendees will gain a deeper understanding of the unique challenges of ATMP production and compliance.

Moderator: Ryan Murray, **MS**, Senior Consultant, *ValSource, Inc.*

08:00 – 08:20

Potency Assurance for ATMPs

Presenter: Andrew C. Chang, **PhD**, Vice President, Quality and Regulatory Compliance, Regulatory Policy and Intelligence, *Novo Nordisk*

08:20 – 08:40

A New Paradigm of Quality: ATMPs and Product Stewardship

Presenter: Josh Russell, Vice President of Sales & Marketing, *AST*

08:40 – 09:00

Designing a Disinfectant Validation Program for ATMP Cleanrooms

Presenter: Jim N. Polarine, **MA**, Principal Consultant, *STERIS*

09:00 – 09:30

Q&A

08:00 – 09:30

B4: Primary Packaging

Moderator: Robin Usselman, Sr. Business Development Manager, USA & Canada, *PBL (Performing Beyond Limits)*

08:00 – 08:20

Vial to Pre-Filled Syringe: Navigating Drug Product Development and Manufacturing - A Comprehensive Case Study

Presenter: Adithya Balasubramanian, **MS**, Director, *ten23 health*

08:20 – 08:40

Primary Packaging Compliance: Regulatory Updates and Annex 1 Implementation Case Study

Presenter: Colleen O'Brien, **MS**, Strategy and Technical Affairs, *Gerresheimer*

08:40 – 09:00

Case Study: Saturated Steam as an Alternative Sterilization Process to EtO for RTF Primary Containers

Presenter: Darren Beckett, Sr. Training and Technology Center Manager, *Fedegari Technologies, Inc.*

09:00 – 09:30

Q&A

08:00 – 09:30

C4: Quality Risk Management

This session will provide a blueprint for advancing quality risk management (QRM) practices in the biopharmaceutical industry, including strategies for developing skilled risk assessment facilitators and optimized portfolios. It will also explore the evolving regulatory landscape for AI applications and associated risks. Participants will gain insights into improving risk management processes and navigating emerging industry challenges.

Moderator: Kate Malachowski, **PhD**, Director, MS&T, *Novavax*

08:00 – 08:20

Regulations for AI Application: Do We Need More?

Presenter: Stephan K. Roenninger, **Dr.-Ing.**, Director Compliance, External Affairs, *Amgen*

08:20 – 08:40

Developing Qualified Risk Assessment Facilitators at Takeda

Presenter: Joseph Horvath, **PhD**, Head, Global Quality Risk Management, *Takeda*

08:40 – 09:00

Developing an Optimized Risk Assessment Portfolio—The QRM Master Plan

Presenter: Kelly Waldron, **PhD**, Business Unit Manager, Quality and Manufacturing Science Consulting, *ValSource, Inc.*

09:00 – 09:30

Q&A

08:00 – 09:30

D4: Innovative Technologies for Sterility Assurance and Aseptic Processing

This session will explore cutting-edge technologies and methodologies for achieving sterility assurance in pharmaceutical manufacturing. Topics will include new guidelines for RABS system design and operation, risk evaluation for transitioning to X-ray sterilization of single-use systems, and the benefits of low-energy electron beam technology for pharmaceutical packaging sterilization. Attendees will gain insights into advancing sterility assurance while addressing regulatory and sustainability challenges.

Moderator: Yeissa M. Chabrier-Rosello, **PhD**, Senior Pharmaceutical Quality Assessor, OPQ, CDER, *U.S. FDA*

08:00 – 08:20

Sterility Assurance – Meeting an Unmet Industry Technical Need on Design and Operation of RABS Systems

Presenter: Bruce A. Loxley, Regulatory Inspection Compliance Director, *GSK*

08:20 – 08:40

Evaluating Risks in Implementing X-Ray Sterilization for Single-Use Systems

Presenter: Samuel Dorey, **PhD**, Principal Scientist Materials & Irradiation, *Sartorius Stedim Biotech*

08:40 – 09:00

Low Energy Electron Beams for the Sterilisation of Pharmaceutical Packaging

Presenter: Thomas Kroc, **PhD**, US Representative, *International Irradiation Association*

09:00 – 09:30

Q&A

09:00 – 13:45

Exhibit Hall Open

09:30 – 10:30

Networking Break in the Exhibit Hall

09:30 – 10:30

Poster Presentations in the Exhibit Hall

Agenda

PDA Week 2025

10:30 – 11:15

IG09: Advanced Manufacturing and Applied Process Digitalization

Interest Group Leader: Peter J. Makowenskyj, MEng, Director of Design Consulting, *G-CON*

Interest Group Leader: Toni Manzano, Co-Founder and CSO, *Aizon*

10:30 – 11:15

IG10: ATMP

Interest Group Leader: Rebecca D. Jordan, Director, Global Cell Therapy Sterility Assurance Lead, *Bristol Myers Squibb*

10:30 – 11:15

IG11: Facilities and Engineering

Interest Group Leader: Shelley M. Preslar, MBA, CEO/Principal SME, *Panacea Group*

10:30 – 11:15

IG12: Quality Systems

Interest Group Leader: Ghada N. Haddad, PhD, Executive Director, Global Quality Transformation, *Merck & Co., Inc.*

Interest Group Leader: Michele Simone, Director, Corporate Quality Compliance, Risk Management, and Continual Improvement, *Bracco*

Interest Group Leader: Eva M. Urban, MSc, Senior Director, Risk Management, *Bristol Myers Squibb*

10:30 – 12:30

Mini-Training Course 2: Parametric Release of Pharmaceuticals Terminally Sterilized by Moist Heat (Ticket Required)

This mini-training course will benefit organizations that are pursuing development of a parametric release moist heat sterilization program as well as organizations seeking to improve conventional moist heat sterilization programs. This lecture and discussion mini-training course will provide an introduction and overview of parametric release.

Instructor: Michael J. Sadowski, Owner, *Sterilexcellence*

11:15 – 11:30

Transition to Next IG

11:30 – 12:15

IG13: Annex 1 Implementation

Interest Group Leader: Marcia C. Baroni, MBA, VP Quality, Enterprise GxP Compliance & Systems, *Emergent BioSolutions*

Interest Group Leader: Stephen E. Langille, **PhD**, Senior Microbiology Consultant, *ValSource, Inc.*

11:30 – 12:15

IG14: Filtration

Interest Group Leader: Maik W. Jornitz, Principal Consultant, *BioProcess Resources*

Interest Group Leader: William Peterson, Director, Global QA, *Merck & Co., Inc.*

11:30 – 12:15

IG15: Vaccines

Interest Group Leader: Cristiana Campa, **PhD**, Technical R&D Advisor, *GSK*

Interest Group Leader: Sabrina Restrepo, **PhD**, Executive Director - Quality Assurance, *Merck & Co., Inc.*

11:30 – 12:15

Lightning Session 2

PDA's Lightning Presentations will use the Pecha Kucha presentation method, which calls for telling a story using images rather than reading text from slides during a PowerPoint presentation. Each presentation will have 20 slides set to automatically advance after only 20 seconds of commentary per slide for a total talk time of 6 minutes and 40 seconds.

Moderator: Susan J. Schniepp, Distinguished Fellow, *Regulatory Compliance Associates Inc.*

11:30 – 11:35

Session Introduction

11:35 – 11:42

The Generated Pre-Trained Transformer Parallels Project: A Practical Method for Generative AI Integration into Workforce Development and Biomanufacturing Research and Manufacturing

Presenter: Richard Jaenisch, **MPH**, Director of Education and Outreach, *Open Biopharma Research and Training Institute*

11:42 – 11:49

Particle Loss in Tubing During Airborne Particle Counting

Presenter: Michael J. Dingle, Senior Product Specialist, *TSI*

11:49 – 11:56

Lean Approach to Analytical Panels to Support Cleaning Validation

Presenter: Brian Bosso, Technical Service Manager, *STERIS*

11:56 – 12:15

Q&A

12:15 – 13:45

Networking Lunch in the Exhibit Hall

12:15 – 13:45

Poster Presentations in the Exhibit Hall

13:45 – 15:15

P3: Culture Disruption

Moderator: Kate Malachowski, **PhD**, Director, MS&T, *Novavax*

13:45 – 14:30

Empower Yourself — Empower Your People

Presenter: Allison Massari, **MFA**, Keynote Speaker, Entrepreneur, and Interdisciplinary Artist, *allisonmassari.com*

14:30 – 15:00

Q&A

15:00 – 15:15

Closing Remarks from Co-Chairs

15:45 – 17:45

Mini-Training Course 3: Introduction to RABS and Isolators (Ticket Required)

This mini-training course will provide practical insights into the design, installation, and operation of barrier technology, specifically isolators. Participants will learn some basics about isolator design, operational requirements, cleaning and decontamination methods, and validation of isolators.

Instructor: Anne Weeks, Senior Commercial Applications Expert, *MilliporeSigma*

18:00 – 21:30

Taste of the Desert Epicurean Tour (Ticket Required)

Your "foodie" guides will introduce you to the Palm Springs Valley as you venture on foot (approx. 1.5 m/2.4 km) to locally owned restaurants to taste varied culinary delights. Between tastings, you will learn about the art, history, and culture of the area and some unique facts about each of the restaurants. With so much happening in Downtown Palm Springs, this tour offers an insiders' take on the diverse culinary and cultural offerings of this famous destination. SAMPLE TOUR

Agenda

PDA Week 2025

MENU – Restaurants and menus to be confirmed in early March 2025 • Tommy Bahama: Coconut Shrimp, Chicken Mango Salad, Mai Tai • Maracas: Variety of Street Tacos, Chips, Salsa, Margarita • Tutti Frutti: Date Shake and Fresh Fruit Frozen Yogurt Samples • Bill's Pizza: Award-Winning 4 cheese Pizza on Sourdough Crust • Brandini Toffee: Toffee and Popcorn Tastings, Take Home Sample • Lulu California Bistro: Signature Triple Chocolate Cake