Agenda

PDA Week 2026

Sunday, 6 April

09:00 – 12:00

PDA Chapter Council Meeting (Invite Only)

11:30 – 13:00

PDA Advisory Board and Chapter Council Joint Luncheon (Invite Only)

13:00 – 17:00

PDA Technical Advisory Board (AB) Meetings (Invite Only)

The four PDA Technical AB meetings taking place during PDA Week 2025 are by invitation only.

ABs are composed of a diverse group of experts drawn from industry, regulatory agencies, and academia. They provide scientific and technical expertise to the PDA Board of Directors and provide support and guidance for PDA's scientific, regulatory, and technical initiatives.

- Advanced Therapy Medicinal Products Advisory Board (ATMP AB)
- Biopharmaceutical Advisory Board (BioAB)
- Regulatory Affairs and Quality Advisory Board (RAQAB)
- Science Advisory Board (SAB)

14:00 – 19:00

Presenter Ready Pavilion Open

Oasis Hall 2

14:00 – 19:00

Registration Open

Oasis Hall 2

18:30 – 21:45

PDA Industry and Honor Awards Ceremony and Dinner (Ticket Required – Cocktail Attire)

Grand Ballroom (Renaissance)

Monday, 7 April

06:00 – 06:30

Morning Wellness Walk

Departs from Renaissance Lobby

Rise and refresh!

Start your day with a refreshing Morning Wellness Walk from 06:00-06:30 in beautiful Palm Springs. Enjoy the crisp desert air, take in the stunning sunrise, and connect with fellow attendees on a light, invigorating outing. It's the perfect way to energize your mind and body before a full day of learning and networking. All fitness levels welcome, and participation is free!

Agenda

PDA Week 2026

Meet in the Renaissance Lobby—walkers will depart promptly at 6:00 AM. After your morning stroll, stop by the PDA Member Lounge for a well-earned cup of coffee!

06:30 – 08:00

PDA Member Lounge Open

Santa Rosa (Renaissance)

The member lounge is a spacious and inviting area designed for relaxation and socializing among PDA members. Members can enjoy coffee and refreshments while engaging in conversations. The lounge is a vibrant hub for networking, community-building and member recognition. With free Wi-Fi and charging stations available, it's the perfect spot to unwind or collaborate with fellow members.

07:00 – 19:00

Registration Open

Oasis Hall 2

08:00 – 09:30

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

Mesquite D

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)

Mesquite E

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: 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)

Mesquite F

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**, Technical Cleanroom Sales Account Executive, *Modular Devices Cleanrooms*

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)

Mesquite G

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*

09:00 – 17:00

Presenter Ready Pavilion Open

Oasis Hall 2

09:45 – 12:15

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

Mesquite B

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 Agenda

- 09:45 | Workshop Welcome
- 09:50 | Phase Appropriate GMP
- 10:15 | CDMO Site Selection Hands-On Activity
- 11:45 | Tech Transfer
- 12:10 | Workshop Wrap-Up

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*

12:00 – 12:45

Speed Networking

Lobby

13:00 – 15:00

Agenda

PDA Week 2026

P1: From Manufacturing Excellence to Patient Impact: The Future of GLP-1 Therapies (Oasis Hall 1)

Oasis Hall 1

This opening plenary will examine the evolving landscape of GLP-1 therapies as both a market and technology disruption, combining insights into innovative manufacturing advancements alongside the important patient perspective. The presenters will explore how disruptive technologies are transforming the production of GLP-1 products, ensuring greater efficiency and quality, while also addressing the real-world impact of these therapies on patients' everyday lives. The discussion will highlight opportunities to improve outcomes through collaboration between manufacturers, healthcare professionals, patients, and their providers.

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

13:00 – 13:25

Welcome from PDA Leadership and the PDA Week 2025 Co-Chairs

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

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

The Evolution of GLP-1 Therapies: Empowering Patients and Transforming Diabetes and Obesity Management

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

14:15 – 14:40

Evolving Quality Strategies and Innovations to Ensure Global Patient Access

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

Lobby

15:30 – 17:00

A1: Disruptive Therapies (Primrose A)

Primrose A

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**, President & Lead Toxicologist, *Toxicology Allies*

15:50 – 16:10

It's Just Dilute Liquid (Or Is It?): Why Understanding the Risks Matters in Antibody-Drug Conjugate Processes

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

16:10 – 16:30

Microbial Marvels: Live Biotherapeutic Products 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 (Primrose B)

Primrose B

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 (Primrose C)

Primrose C

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, Director, Global Quality Sterility Assurance, *Merz Aesthetics*

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/CMC Strategies in Contamination Control (Primrose D)

Primrose D

This session will explore effective preparation strategies for GxP audits and inspections, including mock inspections and past audit reviews, while gaining insight into integrated CMC strategy and quality risk management (QRM) for contamination control. Participants will hear 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

Grand Opening Happy Hour in the Exhibit Hall

Oasis Hall 3-4

18:30 – 21:00

Opening Reception

Jackie Lee Houston Plaza

Immediately following the Grand Opening Happy Hour in the Exhibit Hall, keep the good vibes going outdoors under the Palm Springs night sky at the PDA Week 2025 Opening Reception! Join us **Monday night** for a mix of **great beats, good eats, and even better company** as we turn up the volume on networking.

- A DJ spinning the perfect soundtrack
- Refreshing drinks and tasty bites to keep you fueled
- Networking that hits all the right notes
- A laid-back, festival-style atmosphere—your PDA Week badge is your all-access pass!

Whether you're here to make industry moves, vibe with colleagues, or just enjoy the desert night, this reception is music to your ears! Don't miss out—**let's get PDA Week 2025 started on a high note!**

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

Agenda

PDA Week 2026

Tuesday, 8 April

06:00 – 06:30

Morning Wellness Walk
Departs from Renaissance Lobby

Rise and refresh!

Start your day with a refreshing Morning Wellness Walk from 06:00-06:30 in beautiful Palm Springs. Enjoy the crisp desert air, take in the stunning sunrise, and connect with fellow attendees on a light, invigorating outing. It's the perfect way to energize your mind and body before a full day of learning and networking. All fitness levels welcome, and participation is free!

Meet in the Renaissance Lobby—walkers will depart promptly at 6:00 AM. After your morning stroll, stop by the PDA Member Lounge for a well-earned cup of coffee!

06:30 – 07:30

PDA Member Lounge Open
Santa Rosa (Renaissance)

The member lounge is a spacious and inviting area designed for relaxation and socializing among PDA members. Members can enjoy coffee and refreshments while engaging in conversations. The lounge is a vibrant hub for networking, community-building and member recognition. With free Wi-Fi and charging stations available, it's the perfect spot to unwind or collaborate with fellow members.

07:00 – 08:00

Continental Breakfast
Lobby

07:00 – 18:30

Registration Open
Oasis Hall 2

07:30 – 16:30

Presenter Ready Pavilion Open
Oasis Hall 2

08:00 – 09:30

P2: Sustainability at Scale: Transforming Facilities and Mindsets in Pharma (Oasis Hall 1)
Oasis Hall 1

Pharmaceutical manufacturing is one of the industries leading the charge toward a sustainable future and setting a new standard for environmental responsibility. In this plenary session, Jane Zhang will illustrate how procurement and supply chain innovation will drive transformative behavioral change within organizations. Phil Duncanson will unveil AstraZeneca's ambitious sustainability journey, from modernizing aging facilities to creating a groundbreaking carbon-neutral site in Singapore. Attendees will gain actionable strategies to champion sustainability as a cornerstone of industry progress.

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

Agenda

PDA Week 2026

08:00 – 08:25

Driving Behavioral Change: Unlocking Sustainability Through Procurement and Supply Chain Innovation

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

08:25 – 08:50

From Labs to Leadership: A Vision for Carbon-Neutral Pharma Operations

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

08:50 – 09:30

Q&A

09:30 – 10:30

Networking Break in the Exhibit Hall (Oasis Hall 3-4)

Oasis Hall 3-4

09:30 – 10:30

Poster Showcase and Voting

09:45 – 10:15

Meet the Presenters | P1: From Manufacturing Excellence to Patient Impact: The Future of GLP-1 Therapies

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

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

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

09:45 – 10:15

Technical Report Live | Points to Consider No. 11: Development, Classification, Manufacture, Control, and Testing of Plasmids and Vectors Used in ATMP Production

09:30 – 11:00

PDA Press Conference

Mesquite G

09:30 – 16:15

Exhibit Hall Open

Oasis Hall 3-4

Agenda

PDA Week 2026

10:30 – 12:00

A2: Data Management and Lifecycle Strategies for Advanced Therapies (Primrose A)

Primrose A

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 Consultant & Project Manager, *AtkinsRéalis*

10:30 – 11:00

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*

11:00 – 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

B2: Advancing Quality Control: Automated Visual Inspection in Parenterals (Primrose B)

Primrose B

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 (Primrose C)

Primrose C

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*

10:30 – 10:50

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

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

10:50 – 11:10

A Digital Transformation Path for Better Technology Transfers

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

11:10 – 12:00

Q&A

10:30 – 12:00

D2: Regulatory Insights and Challenges: Annex 1, PUPSIT, and Drug Compounding (Primrose D)

Primrose D

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 Visual Inspection Regulatory Framework Ensure the Safety of Compounded Drugs?

Presenter: Vivian Nguyen, Quality Visual Inspection Manager (Corporate), *QuVa Pharma*

11:10 – 11:30

Results Summary of the PDA 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 (Oasis Hall 3-4)

Oasis Hall 3-4

12:00 – 13:30

Poster Presentations and Voting

12:30 – 13:00

Technical Report Live | PDA Technical Report No. 33, Revised 2013 (TR 33) Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods

12:15 – 12:55

Exhibitor Tech Talks (Oasis Hall 3-4)

Oasis Hall 3-4

12:15 – 12:25

Navigating USP 382: Ensuring Compliance and Safety in Pharmaceutical Packaging with Aptar Pharma

Tech Talk Presenter: Arnaud Fournier, Regional Market Development Manager, *Aptar Pharma*

12:30 – 12:40

EZ-Fill Smart™: Advancing Sustainable RTU Packaging

Tech Talk Presenter: Mitchell J. Brasher, Global Product Manager, *Gerresheimer*

12:45 – 12:55

Defect Detection Lifecycle Approach

Tech Talk Presenter: Karen Granzow, Senior Consultant, *Koerber Pharma, North America*

13:30 – 14:15

IG01: Combination Products

Primrose A

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

13:30 – 14:15

IG02: Drug Compounding

Primrose C

Interest Group Leader: Arie Anahory, **MS**, Global Head of Operations, *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

Primrose D

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

Primrose B

Interest Group Leader: Amanda McFarland, **MS**, Senior Consultant, *ValSource, Inc.*

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*

Agenda

PDA Week 2026

13:30 – 15:30

Mini-Training Course 1: Lyophilization (Ticket Required)

Mesquite A

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 Interest Group

14:30 – 15:15

IG05: Data Governance, Management, Integrity, and Digitalization

Primrose A

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

Primrose D

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

Primrose C

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

Primrose B

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

14:30 – 15:15

Lightning Session 1 (Mesquite B)

Mesquite B

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, Director, Global Quality Sterility Assurance, *Merz Aesthetics*

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 (Oasis Hall 3-4)

Oasis Hall 3-4

15:15 – 16:15

Poster Presentations and Voting

15:30 – 15:50

Technical Report Live | Enhancing Quality Management Maturity through Data-Driven Insights and Organizational Factors Shaping Quality Culture by KGI

15:30 – 16:00

Book Signing and Meet the Authors | Quality Risk Management: A Practical Guide

Author: Amanda McFarland, **MS**, Senior Consultant, *ValSource, Inc.*

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

16:15 – 17:45

A3: CMC Insights for Biosimilars and Container Closure Integrity Testing Advancements (Primrose A)

Primrose A

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 (Primrose B)

Primrose B

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 (Primrose C)

Primrose C

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 – 17:15

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 (Primrose D)

Primrose D

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

16:30 – 18:30

PDA Member Lounge Open

Santa Rosa (Renaissance)

The member lounge is a spacious and inviting area designed for relaxation and socializing among PDA members. Members can enjoy coffee and refreshments while engaging in conversations. The lounge is a vibrant hub for networking, community-building and member recognition. With free Wi-Fi and charging stations available, it's the perfect spot to unwind or collaborate with fellow members.

Agenda

PDA Week 2026

18:00 – 19:30

Supplier Think Tank: Aizon (Free for PDA Week Attendees - Advance Sign Up Required)

Chino (Renaissance)

Be part of a dynamic discussion where suppliers, innovators, and experts unite to explore strategies, trends, and solutions that matter most. Let's shape the future of our industry—together.

Ready to see real results from AI in pharma? Digital transformation in pharma often fails to deliver results where it matters most: the shop floor. Too many initiatives are pharaonic and disconnected from business outcomes. In this session, Geri Studebaker, CCO at Aizon and a transformational leader dedicated to enhancing global health through innovative business strategies, will reveal how GxP compliant AI can break that pattern: reducing downtime, improving yield, and accelerating value in just 100 days. Expect a dynamic discussion grounded in real-world application, not theory.

By signing up for this Think Tank, participants understand that their contact information will be shared with Aizon.

Aizon Think Tank Sign Up—Free for PDA Week Attendees

18:00 – 20:30

Architecture and Celebrity Homes Bicycle Tour (Ticket Required)

Departs from Renaissance Lobby

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.

Bicycles and helmets (required) will be provided.

18:15 – 20:00

Bar Trivia + Local Beer Tasting and Dinner (Ticket Required)

Departs from Renaissance Lobby

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 be broken up into teams for rounds of trivia. In between trivia, 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. A docent will be present to walk you through the beer tastings. Don't miss your opportunity to enjoy the laid-back desert lifestyle of Palm Springs while sipping craft beer with friends!

- **Price:** $70 per person – includes trivia, beer flight, and taco/nacho bar
- **Tickets:** 40 max.
- **Start:** 18:15 PT – participants to meet in the Renaissance hotel lobby to walk to brewery together (approx. 0.8 m/1.3 km) – group will depart from the hotel lobby promptly at 18:30 PT
- **End:** 20:00 PT – participants can return to their hotels at their leisure
- **Note:** All participants must be at least 21 years old. Comfortable shoes and a light layer are recommended.

18:15 – 20:30

Palm Springs Aerial Tram and Dinner (Ticket Required)

Departs from Renaissance Lobby

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, transporting visitors to the pristine wilderness of the Mt. San Jacinto State Park and Wilderness Area. During the 10-min journey, 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°F cooler than the desert floor), guests will enjoy 180-degree views of the valley from the observation decks, watch two documentary films, visit the natural history museum, and enjoy dinner at Peaks Restaurant. This trek to the top of this famous mountain is truly a singular experience!

Dinner includes your choice of an appetizer, an entrée with two sides, and a soft drink or water. Alcohol is available for purchase.

- **Price:** $180 per person – includes tram ticket, dinner, and roundtrip transportation
- **Tickets:** 50 max.
- **Start:** 18:15 PT – participants to meet in the Renaissance hotel lobby to board the bus that will depart promptly at 18:30 PT
- **End:** 21:30 PT – participants will ride the bus back to the Renaissance hotel
- **Note:** The temperature at the Mountain Station can be up to 30°F cooler than in the valley, so a jacket and comfortable walking shoes are recommended. Participants will select from the following menu options:
  - Appetizers
    - Charred shrimp
    - Mediterranean bruschetta
  - Entrées
    - Pan Seared Salmon served with mango salsa, jasmine rice, and baby bok choy
    - Wild Mushroom Ravioli in a porcini cream sauce
    - Roasted half duck served with jasmine rice, baby bok choy, and blackberry gastrique
    - Filet of beef in a demi glaze served with red bliss potato puree and baby carrots

18:30 – 20:30

Wine and Watercolors (Ticket Required)

San Jacinto (Renaissance)

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).

- **Price:** $110 per person – includes two (2) glasses of wine or beer, charcuterie, professional watercolor painting instruction, and supplies
- **Tickets:** 50 max.
- **Start:** 18:30 PT – event will take place at the Renaissance hotel
- **End:** 20:30 PT
- **Note:** All participants must be at least 21 years old.

Wednesday, 9 April

06:00 – 06:30

Morning Wellness Walk

Departs from Renaissance Lobby

Rise and refresh!

Start your day with a refreshing Morning Wellness Walk from 06:00-06:30 in beautiful Palm Springs. Enjoy the crisp desert air, take in the stunning sunrise, and connect with fellow attendees on a light, invigorating outing. It's the perfect way to energize your mind and body before a full day of learning and networking. All fitness levels welcome, and participation is free!

Meet in the Renaissance Lobby—walkers will depart promptly at 6:00 AM. After your morning stroll, stop by the PDA Member Lounge for a well-earned cup of coffee!

06:30 – 07:30

PDA Member Lounge Open

Santa Rosa (Renaissance)

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Agenda

PDA Week 2026

07:00 – 07:45

FDA Complete Response Letters – A Growing Industry Challenge with Big Impacts (Primrose A)

Primrose A

This session will discuss the current challenge facing the industry related to manufacturing and facility related Complete Response Letters (CRLs). CRLs are issued at the end of the FDA review cycle for regulatory submission indicating that the submission (BLA/NDA) cannot be approved in its current form. Over the past several years the number of manufacturing and facility related CRLs has greatly increased, creating unprecedented challenges for the industry. This session will provide an update on the current issues and discuss the work being done by PDA on this topic area as well as work being done on behalf of PDA to better understand these CRLs and any predictors of which the industry should be aware.

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

07:00 – 07:25

Unpacking FDA CRLs: Manufacturing Hurdles and Industry Response

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

Presenter: Michael de la Torre, CEO, *Redica Systems*

07:25 – 07:45

Q&A with Additional Panelists

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

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

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

07:00 – 08:00

Continental Breakfast

Lobby

07:00 – 15:30

Registration Open

Oasis Hall 2

07:30 – 10:30

Presenter Ready Pavilion Open

Oasis Hall 2

08:00 – 09:30

A4: Ensuring Quality and Potency in ATMP Manufacturing (Primrose A)

Primrose A

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 (Primrose B)

Primrose B

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 (Primrose C)

Primrose C

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 (Primrose D)

Primrose D

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

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

09:30 – 10:30

Networking Break in the Exhibit Hall (Oasis Hall 3-4)

Oasis Hall 3-4

09:30 – 10:30

Poster Presentations

09:45 – 10:15

Book Signing and Meet the Authors | Quality Risk Management: A Practical Guide

Author: Amanda McFarland, **MS**, Senior Consultant, *ValSource, Inc.*

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

09:45 – 10:15

Meet the Presenters | P2: Sustainability at Scale: Transforming Facilities and Mindsets in Pharma

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

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

09:45 – 10:15

Technical Report Live | PDA/ANSI Standard 06-2025: Assessment of Quality Culture Guidance Documents, Models, and Tools

Agenda

PDA Week 2026

09:30 – 13:45

Exhibit Hall Open
Oasis Hall 3-4

10:30 – 11:15

IG09: Advanced Manufacturing and Applied Process Digitalization
Primrose D

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
Primrose A

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

10:30 – 11:15

IG11: Facilities and Engineering
Primrose C

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

10:30 – 11:15

IG12: Quality Systems
Primrose B

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)
Mesquite A

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*

Agenda

PDA Week 2026

11:15 – 11:30

Transition to Next Interest Group

11:30 – 12:15

IG13: Annex 1 Implementation

Primrose B

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

Primrose D

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

Primrose A

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 (Mesquite B)

Mesquite B

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

11:30 – 12:15

PDA Journal of Pharmaceutical Science and Technology—The Members' Journal (Primrose C)

Primrose C

In this session, participants will learn about the latest content published in the 79-year-old, peer-reviewed PDA Journal of Pharmaceutical Science and Technology (JPST), including updates on the new submission and reviewer site as well as the new reviewer management and recognition program. Hear from the winning authors (invited) of the 2024 Frederick Simon D. Simon Paper of the Year Award. All current and potentially interested authors and reviewers are especially invited to attend.

Moderator: Walter Morris, Senior Director, Publishing, *PDA*

11:30 – 12:00

Editor's Perspective

Presenter: Shanker Gupta, **PhD**, Editor-In-Chief, *PDA Journal of Pharmaceutical Science and Technology*

12:00 – 12:15

Q&A

12:15 – 13:45

Networking Lunch in the Exhibit Hall (Oasis Hall 3-4)

Oasis Hall 3-4

12:15 – 13:45

Passport Drawing

12:15 – 13:45

Poster Awards and Presentations

12:30 – 13:00

Technical Report Live | PDA/ANSI Standard 03-2025: Standard Practice for Quality Risk Management of Aseptic Processes

13:45 – 15:15

P3: From Burnout to Breakthrough: Inspiring Person-Centered Care (Oasis Hall 1)

Oasis Hall 1

Every healthcare professional has a crucial impact on person-centered care – including those who do not have direct patient contact. By specifically recognizing the ways that their work is directly tied to a human being, Allison will generate a deeper connection to the patient experience for each participant. This closing plenary session will address how fostering a culture of compassion, engagement, and innovation can combat burnout and create breakthroughs in patient-centered care. Participants will leave with a renewed sense of purpose, empowered by the knowledge that their contributions improve patient outcomes, enhance company culture, and drive both personal and organizational success.

What It Takes To Heal

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

13:45 – 14:30

From Burnout to Breakthrough: Inspiring Person-Centered Care

Presenter: Allison Massari, MFA, Burn Survivor, Patient-Advocate, and Interdisciplinary Artist, *allisonmassari.com*

14:30 – 15:00

Q&A

15:00 – 15:15

Closing Remarks from the PDA Week 2025 Co-Chairs

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

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

15:15 – 15:45

Meet the Presenter | P3: From Burnout to Breakthrough: Inspiring Person-Centered Care (Oasis Hall 1)

Oasis Hall 1

Presenter: Allison Massari, MFA, Burn Survivor, Patient-Advocate, and Interdisciplinary Artist, *allisonmassari.com*

15:30 – 17:00

Supplier Think Tank: Alliance for RTU (Free for PDA Week Attendees - Advance Sign Up Required)

Sierra/Ventura (Renaissance)

Be part of a dynamic discussion where suppliers, innovators, and experts unite to explore strategies, trends, and solutions that matter most. Let’s shape the future of

our industry—together.

Join the Alliance for RTU as they present, "Collaborating to Innovate: Advancing Quality and Efficiency with Ready-To-Use Vials and Cartridges." This Supplier Think Tank will explore how implementing a ready-to-use (RTU) industrial setup can streamline processes, lower contamination risks, and reduce the total cost of ownership. After hearing from pharma and contract manufacturing organization (CMO) industry experts, participants will have a chance to provide valuable user input through an interactive discussion.

- **Introduction and Opening Speech | Mr. Richard Johnson,** Immediate Past President and CEO, *PDA*
- **Strategic Advantages to Use RTU Containers as Primary Packaging Platform for Bio Drugs: The Perspective of a BioPharma | Mr. Victor Bradford,** Director PSDPE Drug Product, *Regeneron*
- **Flexibility and Speed to Market While Preserving High-End Quality in Pharma Fill&Finish Operations: The Perspective of a CDMO | Mrs. Mihaela Carmen Simian,** Vice President of R&D and Operations, *Singota Solutions*
- **RTU Packaging Benefits and Cost Savings in Pharma Fill&Finish Operations: The Perspective of a CDMO | Mr. Dhaval Patel,** Director MS&T, *INCOG BioPharma Services, Inc.*

By signing up for this Think Tank, participants understand that their contact information will be shared with the Alliance for RTU founding members (Gerresheimer, Schott Pharma, Stevanato Group).

Alliance for RTU Think Tank Sign Up—Free for PDA Week Attendees

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15:30 – 17:30

PDA Member Lounge Open

Santa Rosa (Renaissance)

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15:45 – 17:45

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

Mesquite A

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)

Departs from Renaissance Lobby

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 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*

Agenda

PDA Week 2026

Thursday, 10 April

06:00 – 06:30

Morning Wellness Walk

Departs from Renaissance Lobby

Rise and refresh!

Start your day with a refreshing Morning Wellness Walk from 06:00-06:30 in beautiful Palm Springs. Enjoy the crisp desert air, take in the stunning sunrise, and connect with fellow attendees on a light, invigorating outing. It's the perfect way to energize your mind and body before a full day of learning and networking. All fitness levels welcome, and participation is free!

Meet in the Renaissance Lobby—walkers will depart promptly at 6:00 AM. After your morning stroll, stop by the PDA Member Lounge for a well-earned cup of coffee!

07:00 – 08:30

PDA D/A/CH Chapter: Opportunities and Challenges for Start Ups Webinar

Santa Rosa (Renaissance)

Join the PDA D/A/CH Chapter Thursday, 10 April for coffee and connections at PDA Week 2025! Gather in person to watch the Chapter's *Opportunities and Challenges for Start Ups* webinar live, then stay to network and exchange ideas with fellow professionals. All PDA members, regardless of chapter, are welcome! Coffee and tea will be provided—please sign up in advance.

- **Where:** PDA Member Lounge at the Renaissance Hotel
- **When:** Thursday, 10 April, 07:00-08:30 PDT
- **Cost:** Free!
- **Attend In Person at PDA Week 2025:** Advance Sign Up

Join us for an engaging conversation where we will explore three captivating stories of innovation in biotechnology and IT. **Are you aware of the key differences between launching a new business idea in the biotech or IT sectors in the USA and Germany?**

Discover the contrasting approaches to launching new business ideas in Germany and the USA. Whether you choose to **join us online or attend in person at PDA Week 2025 in Palm Springs, CA**, this is a conversation you won't want to miss.

Meet the Presenters

- **Lara Denk,** a Master's student in Economics at Ludwig Maximilian University (LMU) in Munich, will present insights on this topic.
- **Bianca Bohrer,** CEO of PSM, a German CDMO, will discuss her experiences setting up a new Contract Development and Manufacturing Organization (CDMO) service that provides a comprehensive range of solutions from API to sterile pharmaceutical products, including the hurdles she faced.
- **Svetlana Kiseleva,** CPO and Co-Founder of Plair SA will introduce new technologies for manufacturing sterile medicines, specifically focusing on a Biofluorescent Particle Counter (BFPC) that aims to replace traditional monitoring methods using settle plates.

The webinar will conclude with an interactive session discussing how the PDA D/A/CH Chapter can support startups and accelerate the adoption of innovative technologies in the market.

We look forward to seeing you there!

07:00 – 16:00

PDA Member Lounge Open

Santa Rosa (Renaissance)

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Agenda

PDA Week 2026

07:30 – 16:00

Registration Open
San Jacinto (Renaissance)

08:30 – 16:00

Aseptic Processing Essentials Workshop - Separate Registration Required (Pueblo - Renaissance)
Pueblo (Renaissance)

This workshop is based on *PDA Technical Report No. 22: Process Simulations for Aseptically Filled Products*, as well as relevant topics from *PDA Points to Consider for Aseptic Processing: Part 2*, and the EMA draft Annex 1 revision. The workshop will address various elements required in the design and execution of aseptic process simulations to include personnel qualification, media selection and preparation, filling considerations, interventions, duration, and number of units filled, pre and post incubation inspections, incubation conditions, acceptance criteria and investigations and corrective actions. The use of risk-based decision making will be considered.

Participants will also receive a free copy of *PDA Technical Report No. 22: Process Simulation for Aseptically Filled Products*.

Workshop Information and Registration

Instructor: Hal Baseman, MBA, Vice President, *ValSource, Inc.*

08:30 – 16:00

Contamination Control Strategy Essentials Workshop - Separate Registration Required (Chino - Renaissance)
Chino (Renaissance)

Learn not only the theory of developing a great contamination control strategy (CCS), but also how to translate that theory into actual practice. Gain the skills you need to create holistic contamination control strategies covering all aspects of the manufacturing operation, including facility design and utilities, environmental control, validation and monitoring, quality systems, people, and processes.

This workshop is based on the *PDA Technical Report No. 90: Contamination Control Strategy Development in Pharmaceutical Manufacturing*, which will be provided free to each participant as a tool to prepare for the workshop. Jumpstart your CCS understanding and how to apply it to your manufacturing facilities and processes in this world-class interactive workshop – your hands-on solution to developing and implementing a successful CCS!

Workshop Information and Registration

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

Friday, 11 April

07:30 – 16:30

Registration Open
San Jacinto (Renaissance)

08:30 – 16:30

Fundamentals of Quality Risk Management Training Course - Separate Registration Required (Chino - Renaissance)
Chino (Renaissance)

This training course will provide an overview of the quality risk management (QRM) process with an emphasis on the principles in ICH Q9 and ICH Q10. A portion of the training course will be focused on how QRM can be integrated into the Pharmaceutical Quality System and the use of QRM principles throughout the product lifecycle.

Agenda

PDA Week 2026

This training course will further build on the conceptual lessons by teaching practical skills, covering a broad look at QRM tools, templates, facilitation tips, and managing teams and bias. Lastly, this training course will close out with evaluating the power of decision making in using a risk register and a best practice approach for building a QRM program at your company.

Participants will also receive a free copy of *PDA Technical Report No. 54: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations*.

Training Course Information and Registration

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

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