



PDA Week 2026

Agenda

Sunday, 22 March

MDT Daylight Time (UTC -6:00)

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)
14:00 – 19:00	Presenter Ready Desk Open
14:00 – 19:00	Registration Open
18:30 – 21:30	PDA Industry and Honor Awards Ceremony (Ticket Required – Cocktail Attire)

Monday, 23 March

MDT Daylight Time (UTC -6:00)

07:00 – 19:00	Registration Open
	Mini-Workshop 1: Generative AI for Pharmaceutical Quality: Literacy, Oversight, and Implementation Pathways (Ticket Required)
08:00 – 10:30	Workshop Leader: Chris Dayton , Co-Founder/CEO, <i>Quality Assured AI</i> Workshop Leader: Adam B. Pinkert ME Senior Advisor, Quality and Regulatory <i>Quality Assured AI</i>
	Roundtable 3: The Future is Here: Is Your Quality Organization Ready? (Ticket Required) Discussion Leader: Denyse Baker PE, RAC , Associate Vice President, External Engagement and Advocacy/Global Quality Compliance, <i>Eli Lilly and Company</i>
08:00 – 09:30	Discussion Leader: Miguelina Matthews PhD Head Quality, Intelligence, Advocacy & Pharmacopoeia Affairs <i>Sanofi</i> Discussion Leader: Danielle Duran MA Director, GxP Compliance and Training <i>Nestlé Health Science</i>
	Roundtable 2: AI Implementation in Biopharma: A Hands-On Roundtable on People-Centric Training and Knowledge Parallelization (Ticket Required) Discussion Leader: David J. Jaenisch , Director of Technology, <i>PICLLC</i> Discussion Leader: Richard Jaenisch MPH Senior Director of Education, Outreach and Digital Experience <i>Open Biopharma Research and Training Institute</i>
	Roundtable 1: From Constraint to Catalyst: Turning Regulatory Challenges into Drivers of Aseptic Innovation (Ticket Required) Discussion Leader: Julian Petersen , Head of Business Development Pharma, <i>groninger & co gmbh</i> Discussion Leader: Richard Denk Senior Consultant Aseptic Processing <i>SKAN AG</i>
	Student and Early Career Professional Skill-Building Studio: Communicating and Networking with Confidence (Ticket Required)

Discussion Leader: Rozhin Derakhshandeh , Senior Scientist in Drug/Device Combination Products, *Merck & Co., Inc.*

08:00 – 09:30

Discussion Leader: Renee T. Morley MBA Senior Technical Services Specialist *Contec Inc.*

Discussion Leader: Tita Tavares Head of Strategic Marketing and Communication *PDA*

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

09:00 – 17:00 **Presenter Ready Desk Open**

09:45 – 10:45 **PDA Rapid Connect Speed Networking**

P1: Leading Through Transformation: Building Smarter, Human-Centered Organizations

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

Welcome from PDA Leadership and the PDA Week 2026 Co-Chairs

- **President & CEO: Glenn E. Wright MA**, President and CEO, *PDA*
- **Board Chair: Melissa S. Seymour MBA**, EVP and Chief Quality Officer, *Eli Lilly and Company*
- **Co-Chair: Kate Malachowski PhD**, Director, MS&T, *Novavax*
- **Co-Chair: Malav Parikh ME**, Director, Quality Risk Management, Global Quality Compliance and Systems, *Takeda*

The Smart Mission: NASA's Lessons for Managing Knowledge, People, and Projects

11:30 – 12:30

- **Presenter: Edward J Hoffman PhD**, CEO, *Knowledge Strategies*

12:30 – 13:00 **Fireside Chat**

13:15 – 15:15 **Exhibit Hall Open**

Grand Opening Lunch in the Exhibit Hall

13:15 – 15:15

13:15 – 15:15 **Poster Presentations**

13:15 – 15:15 **Solution Partner Tours**

Lightning Talks

Moderator: Michelle Dennis , QC Microbiology Application Specialist, North Carolina, *MilliporeSigma*

Freeze with Care: Navigating the Complexities of Lyophilizing Antibody Drug Conjugates

14:00 – 14:07

- **Presenter: Sarah Lanning PE**, Process Engineer, *CRB*

Integrating and Formalizing Generative AI in Laboratory Workflows

14:10 – 14:17

- **Presenter: David J. Jaenisch** , Director of Technology, *PICLLC*

Unlocking Access: A Low-Cost, Low-Waste Alternative to Auto-Injectors for Reliable Emergency and Routine Medication Delivery

14:20 – 14:27

- **Presenter: Robert Halvorsen MIIPS**, Chief Technology Officer, *Pacto Medical*

14:30 – 14:45 **Q&A**

A1: Building a Culture of Compliance

Moderator: Rebecca C. Walden MSc, Senior Quality Systems Specialist, *Irish Blood Transfusion Service*

15:30 – 16:30	Strengthening GMP Audit Readiness for Emerging Technologies: Oversight, Regulation, and Enforcement Trends	
	15:30 – 15:50	<ul style="list-style-type: none"> • Presenter: Brian Trdina MS, GQA Director of Emerging Technology, AstraZeneca
	15:50 – 16:10	<ul style="list-style-type: none"> • Presenter: Drew Bundschuh MS, Lead Bioprocess Engineer, MS&T, Novavax
16:10 – 16:30 Q&A		
IG1: Filtration		
15:30 – 16:30	Interest Group Leader: William Peterson , Director, Global QA, <i>Merck & Co., Inc.</i>	
	Interest Group Leader: Magnus Stering SME Filter Integrity Testing <i>Sartorius Stedim FMT S.A.S.</i>	
B1: Digital Twins and AI: Transforming Bioprocessing Through Secure, Compliant, and Scalable Digital Innovation		
Moderator: Sebastian B. Teitz PhD , Senior Development Scientist, <i>Novo Nordisk</i>		
15:30 – 16:30	Digital Twin-Driven Continuous Process Verification: Securing Data Integrity and Compliance	
	15:30 – 15:50	<ul style="list-style-type: none"> • Presenter: Srividya Narayanan MDS MSc, Graduate Student, <i>Northeastern University</i>
	15:50 – 16:10	<ul style="list-style-type: none"> • Presenter: Kevin Baughman MS, VP of Aizon Consulting Services, <i>Aizon</i>
16:10 – 16:30 Q&A		
Mini-Workshop 2: Systems and Safety Engineering Approach for Safe, Effective, and Reliable Drug–Device Combination Products (Ticket Required)		
15:30 – 18:00	Workshop Leader: Fubin Wu MS , Co-founder and President, <i>GessNet</i>	
	Workshop Leader: James P. Wabby MTOPRA Head of Global Regulatory <i>AbbVie</i>	
	Workshop Leader: Juan Cheng PhD, RAC Principal Scientist <i>Merck & Co., Inc.</i>	
IG2: Packaging Science		
16:45 – 17:45	Interest Group Leader: Ana Kuschel PhD , Principal Scientific Affairs, <i>West Pharmaceutical Services</i>	
	Interest Group Leader: Tony A. Perry Regional Director of Quality <i>SCHOTT Pharma</i>	
B2: Radiopharmaceuticals: A Rapidly Expanding Modality with High Potential		
Moderator: Virginia Boldt BS , Associate Director Supply Chain, <i>AstraZeneca</i>		
16:45 – 17:45	The Progression of Nuclear Medicine	
	16:45 – 17:05	<ul style="list-style-type: none"> • Presenter: Stephen Judd CEng, FICHEM FIEI, European Director of Process Technology, <i>Arcadis</i>
	17:25 – 17:45	Q&A
A2: Driving Change Across Boundaries		
Moderator: Kate Malachowski PhD , Director, MS&T, <i>Novavax</i>		

So Your Lab Needs an Upgrade? Here's How It's Done

16:45 – 17:45

16:45 – 17:05 • **Presenter: Stacey Ramsey MSc**, Senior Manager - Microbial Applications Lab, *Charles River Labs*

Global Tech Transfer in a Fragmented World

17:05 – 17:25 • **Presenter: Katherine Windham**, Director, External Manufacturing Operations, *Novavax*

17:25 – 17:45 **Q&A**

18:30 – 21:00 **The Welcome Reception – Flannel Fest!**

Tuesday, 24 March

MDT Daylight Time (UTC -6:00)

07:00 – 18:30 **Registration Open**

07:00 – 08:00 **Continental Breakfast**

07:30 – 16:30 **Presenter Ready Desk Open**

Mini-Training Course 1: Environmental Monitoring – The Full Story, From Requirements to Reports (Ticket Required)

08:00 – 10:30 **Instructor: Mark C. Hallworth**, Senior GMP Scientist, *Particle Measuring Systems*

IG3: Visual Inspection of Parenterals

08:00 – 09:00 **Interest Group Leader: John G. Shabushnig PhD**, Principal Consultant, *Insight Pharma Consulting, LLC*

A3: Elevating Quality System Performance Through AI Integration

Moderator: Christopher Lewis, Head of Quality, *Umoja Biopharma*

AI and Behavioural Compliance: Reduction of Human Error Using AI, Behavioural Sciences, Persuasive Technology, Nudge and Large Group Gamification

08:00 – 09:00

08:00 – 08:20 • **Presenter: Deepa Rachel MBA**, Founder, *Eidolon Learning Pvt Ltd*

A Case Study on AI Implementation in Quality Management

08:20 – 08:40 • **Presenter: Brian Chviruk**, Quality Systems Innovation Lead, *Takeda*

08:40 – 09:00 **Q&A**

B3: Innovative Contamination Control: Far-UVC Technology and Risk-Based Approaches

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

Continuous Cleanroom Decontamination: Implementation of Far-UVC

08:00 – 09:00

08:00 – 08:20 • **Presenter: Jordi Amagat Molas PhD**, Segment Project Manager, Life Science and Pharma, *UV Medico*

Global Implementation of Risk-Based Contamination Control Strategies to Prevent Bioprocess Contamination

08:20 – 08:40 • **Presenter: Hilary Chan MS**, Global Sterility Assurance and Microbiology Lead, *Takeda*

08:40 – 09:00 **Q&A**

09:00 – 09:30 **Press Conference (Invite Only)**

A4: Turning Signals into Strategy

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

From Fragmented Data to Predictive Quality: Integrating Internal and External Signals to Predict Supply Chain Risk

09:15 – 09:35

- **Presenter: Matthew Oremland PhD**, Sr. Director, Data Strategy and Analytics, *Redica Systems*

09:15 – 10:15

From Data to Decisions: Enhancing Yield and Quality in Pharmaceutical Manufacturing with Advanced Analytics

09:35 – 09:55

- **Presenter: Ranran Dong PhD**, Principal Data Scientist, *Genentech, Inc.*

09:55 – 10:15 **Q&A**

IG4: Early Career Professionals

09:15 – 10:15

Interest Group Leader: Renee T. Morley MBA, Senior Technical Services Specialist, *Contec Inc.*

B4: Next-Generation Aseptic Operations: Traceability, Gloveless Filling, and Real-Time Monitoring

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

RFID-Based Unit Level Traceability: A Case Study for Visual Inspection

09:15 – 09:35

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

09:15 – 10:15

Future Forward: Implementing and Validating Gloveless Isolators with Real-Time Biofluorescent Particle Counting

09:35 – 09:55

- **Presenter: James Hathcock PhD**, Principal Director, *Cytiva*

09:55 – 10:15 **Q&A**

P2: Every Body Counts: Innovation That Reaches Everyone

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

From the Ground Up: Innovation in Women's Health

10:30 – 11:00

- **Presenter: Amy Beckley PhD, MBA**, Owner & CEO, *Proov*

10:30 – 12:00

Representation Matters: Equity as a Foundation for Clinical Research

11:00 – 11:30

- **Presenter: Jenny Garcia**, Associate Director, Trial Equity and Representation, *Takeda*

11:30 – 12:00 **Q&A**

12:15 – 13:45 **Exhibit Hall Open**

Networking Lunch in the Exhibit Hall

12:15 – 13:45

Poster Presentations

B5: Device Integrity and Therapeutic Safety: Advances in Testing Strategies

	Innovative Design and Testing Strategy for an Autoinjector to Precisely Determine Leaks in the Pre-Filled Syringe
14:00 – 14:20	• Presenter: Matthias Kahl , Head of R&D and Lab Services, <i>WILCO AG</i>
14:00 – 15:00	Cell and Gene Therapies: Navigating Extractable and Leachable Testing Challenges for Life-Saving Treatments
14:20 – 14:40	• Presenter: Sam Albeke , Chromatography Manager, <i>Element Materials Technology</i>
14:40 – 15:00	Q&A

Mini-Workshop 3: Hands-On Workshop: Data Governance (Ticket Required)

Workshop Leader: Kir Henrici , President, *The Henrici Group*

14:00 – 16:30 **Workshop Leader: Ulrich Koellisch PhD** Partner *GxP-CC*

Workshop Leader: Peter Baker MS President *Live Oak Quality Assurance LLC*

A5: Practical Applications of AI in the Modern Pharmaceutical Workplace

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

	Human-AI Training Parallelization: AI Implementation in Biopharma Success Requires a People-Centric Approach to Training and AI Literacy
14:00 – 15:00	14:00 – 14:20 • Presenter: Richard Jaenisch MPH , Senior Director of Education, Outreach and Digital Experience, <i>Open Biopharma Research and Training Institute</i>
	Are We There Yet? A Digital Maturity Model for Enabling Process Monitoring and AI in Biologics Manufacturing
14:20 – 14:40	• Presenter: Jack Prior ScD , Head, MSAT Process Monitoring & Data Science/AI Strategy, <i>Sanofi</i>
14:40 – 15:00	Q&A

IG6: Microbiology/Environmental Monitoring and Quality Risk Management

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

14:00 – 15:00 **Interest Group Leader: Amanda McFarland MS** Senior Consultant *Val/Source, Inc.*

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

Interest Group Leader: Kim Sobien MBA Senior Microbiology Consultant *Val/Source, Inc.*

IG5: Drug Compounding

14:00 – 15:00 **Interest Group Leader: Arie Anahory MS**, Global Head of Operations, *Regulatory Compliance Associates Inc.*

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

A6: Accelerating Combination Product Development Through Platform Design and Lifecycle Excellence

Moderator: Rozhin Derakhshandeh , Senior Scientist in Drug/Device Combination Products, *Merck & Co., Inc.*

	Master-Platform for Drug-Device Combination Products: Maximizing Reuse and Minimizing Rework with Regulatory Rigor
15:15 – 15:35	

- **Presenter: Fubin Wu MS**, Co-founder and President, GessNet

15:15 – 16:15

Designing for the Future: Embedding Lifecycle Thinking in Early-Phase Development

15:35 – 15:55

- **Presenter: Priya Nataraj**, MS&T Associate Director, Novavax

15:55 – 16:15 **Q&A**

PDA Journal of Pharmaceutical Science and Technology—The Members' Journal

15:15 – 16:15

Moderator: Walter Morris, Senior Director, Publishing, PDA

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

B6: Breaking Boundaries: Rethinking Pyrogen Testing and Sterilization Risk in the Age of Innovation

Moderator: Julian Petersen, Head of Business Development Pharma, groningen & co gmbh

Out of the Endotoxin Box: Addressing Pyrogen Diversity Challenges Using the MAT

15:15 – 15:35

- **Presenter: Djikolngar Maouyo PhD**, Founder, Managing Director and President, *PyroDex LLC*

15:15 – 16:15

Comparative Study of Gamma and X-Ray Irradiation on CHO Cell Culture Growth: Risk Analysis and Performance Evaluation

15:35 – 15:55

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

15:55 – 16:15 **Q&A**

IG7: Annex 1 Implementation

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

15:15 – 16:15

Interest Group Leader: Gabriele Gori Vice President, Global GMP Compliance and Auditing Head *Chiesi Pharmaceuticals*

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

15:30 – 16:30

PDA Exhibit Committee Meeting (Invite Only)

Happy Hour in the Exhibit Hall

16:30 – 17:30

16:45 – 17:30

Technical Report Live: Technical Report No. 22 (Revised 2025): Process Simulation for Aseptically Filled Products

18:00 – 21:00

Optional Activity: PDA Battle of the Bags Cornhole Tournament (Ticket Required)

19:30 – 20:30

Optional Activity: Gentle Evening Slow-Flow Yoga (Ticket Required)

Wednesday, 25 March

MDT Daylight Time (UTC -6:00)

07:00 – 15:30 **Registration Open**

07:30 – 10:30 **Presenter Ready Desk Open**

Continental Breakfast in the Exhibit Hall

08:00 – 09:30

08:00 – 09:30 **Posters and Pastries**

08:00 – 13:45 **Exhibit Hall Open**

A7: Advancing AI-Driven Autonomy Across GxP Operations

Moderator: Christopher Lewis, Head of Quality, *Umoja Biopharma*

“Dark Facilities”: Is Autonomous Manufacturing the Future?

09:45 – 10:05 • **Presenter: Faryal Khan**, Lead Process Engineer, *CRB*

Assessing the Risk of AI in the GxP Environment

10:05 – 10:25 • **Presenter: Joseph A. Horvath PhD**, Head, Quality Risk Management, *Takeda*

10:25 – 10:45 **Q&A**

B7: Smart Systems, Smarter Solutions: Reinventing Drug Manufacturing and Delivery

Moderator: Julian Petersen, Head of Business Development Pharma, *groninger & co gmbh*

The Future of Fill-Finish: Implementing Digital Twin Technology for Drug Product Manufacturing

09:45 – 10:05 • **Presenter: Josh Russell**, Vice President of Technical Sales, *AST*

Redesigning Pre-Filled Syringes: A Way to Increase Equitable Access, Decrease Costs, and Reduce Environmental Impact

10:05 – 10:25 • **Presenter: Ian Speers MPH, CPH, MedLog**, CEO and Co-Founder, *Pacto Medical*

10:25 – 10:45 **Q&A**

IG8: Process Validation

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

09:45 – 10:45

Interest Group Leader: Mauro Giusti MSc Executive Director, TSMS Technical Capabilities Training *Eli Lilly and Company*

Mini-Training Course 2: Applied GMP Behaviors: Cleanroom Conduct and Gowning (Ticket Required)

09:45 – 12:15

Instructor: David B. Talmage MBA, Global Strategic Advisor – Education, *PDA*

A8: Optimizing Product Safety Through AI and Digitalization

Moderator: Rebecca C. Walden MSc, Senior Quality Systems Specialist, *Irish Blood Transfusion Service*

Digital Transformation in Cleaning Validation Use Cases: Key Benefits and Lessons Learned

11:00 – 11:20 • **Presenter: Thomas Altmann**, Principal Global Technical Consultant, *Ecolab*

Detection Disrupted: AI and the New Era of Predictive Contamination Control

11:20 – 11:40 • **Presenter: Kim Sobien MBA**, Senior Microbiology Consultant, *Va/Source, Inc.*

11:40 – 12:00 **Q&A**

B8: Smart Supply Chains: Predictive Insights and Digital Defense for Product Integrity

	Revolutionizing Product Protection: Digital Collaboration to Combat Counterfeit Medicines
11:00 – 12:00	11:00 – 11:20 • Presenter: Tommy Adler MBA , Associate Director Global Product Protection Americas Region, <i>Takeda</i>
	PDA Survey 2025: Transportation Validation Benchmarking Review and Analysis
	11:20 – 11:40 • Presenter: Jahanvi Miller MBA , ,
	11:40 – 12:00 Q&A
	IG9: Quality Risk Management and Sterile Processing/Parenteral Drug Manufacturing
11:00 – 12:00	Interest Group Leader: Amanda McFarland MS , Senior Consultant, <i>Va/Source, Inc.</i>
	Interest Group Leader: Julian Petersen Head of Business Development <i>Pharma groningen & co gmbh</i>
12:15 – 13:45	Networking Lunch and Passport Drawing in the Exhibit Hall
12:15 – 13:45	Poster Awards in the Exhibit Hall
	Innovation Session 1: Why Good Enough Isn't: The Hidden Economics of the value of Quality
14:00 – 15:00	Presenter: Marcia C. Baroni MBA , VP Quality, Enterprise GxP Compliance & Systems, <i>Emergent BioSolutions</i>
	Presenter: Rebecca C. Walden MSc Senior Quality Systems Specialist <i>Irish Blood Transfusion Service</i>
14:00 – 15:00	Innovation Session 2
	P3: Decision-Making Under Uncertainty
	The Role of QA in a Rapidly Evolving Regulatory Landscape
15:15 – 16:45	15:15 – 16:15 • Presenter: Peter Baker MS , President, <i>Live Oak Quality Assurance LLC</i>
	16:15 – 16:40 Q&A
	16:40 – 16:45 Closing Remarks from the PDA Week 2026 Co-Chairs

Thursday, 26 March

MDT Daylight Time (UTC -6:00)

07:30 – 16:00	Registration Open
08:30 – 16:00	Contamination Control Strategy Essentials Workshop (PDA 293) (Separate Registration Required) Instructor: Frederic B. Ayers , Senior Consultant - Microbiology, <i>Va/Source, Inc.</i>
08:30 – 16:00	Aseptic Processing Essentials Workshop (PDA 374) (Separate Registration Required) Instructor: Hal Baseman MBA , Vice President, <i>Va/Source, Inc.</i>