



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 Room 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
08:00 – 09:30	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	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>
08:00 – 09:30	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>
08:00 – 10:30	Mini-Workshop 1: Generative AI for Pharmaceutical Quality: Literacy, Oversight, and Implementation Pathways (Ticket Required) 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>
08:00 – 09:30	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, <i>Merck & Co., Inc.</i> Discussion Leader: Renee T. Morley MBA Senior Technical Services Specialist <i>Contec Inc.</i>

09:00 – 17:00 **Presenter Ready Room 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

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

Fireside Chat

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

13:15 – 15:15 **Exhibit Hall Open**

13:15 – 15:15 **Grand Opening Lunch in the Exhibit Hall**

13:15 – 15:15 **Poster Presentations in the Exhibit Hall**

Lightning Talks

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

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

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

Integrating and Formalizing Generative AI in Laboratory Workflows

- **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

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

Q&A

A1: Building a Culture of Compliance

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

Strengthening GMP Audit Readiness for Emerging Technologies: Oversight, Regulation, and Enforcement Trends

- **Presenter: Brian Trdina MS**, GQA Director of Emerging Technology, *AstraZeneca*

Bridging the Gap: Human Centered Strategies for Successful Knowledge Transfer	
15:50 – 16:10	<ul style="list-style-type: none">• Presenter: Renee Jesser MS, Lead Bioprocess Engineer, <i>Novavax</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)

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

Workshop Leader: James P. Wabby MTOPRA Head of Global Regulatory *AbbVie*

Workshop Leader: Juan Cheng PhD, RAC Principal Scientist *Merck & Co., Inc.*

IG1: Filtration

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

B1: Digital Twins and AI: Transforming Bioprocessing Through Secure, Compliant, and Scalable Digital Innovation

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

15:30 – 15:50	Digital Twin-Driven Continuous Process Verification: Securing Data Integrity and Compliance <ul style="list-style-type: none">• Presenter: Srividya Narayanan MDS MSc, Graduate Student, <i>Northeastern University</i>
15:50 – 16:10	BioScAI: Advancing Digital Twins with Embedded AI for Fast and Effective Bioprocess Scale-Up <ul style="list-style-type: none">• Presenter: Toni Manzano PhD, CSO and Compliance Officer, <i>Aizon</i>
16:10 – 16:30	Q&A

B2: Radiopharmaceuticals: A Rapidly Expanding Modality with High Potential

Moderator: Virginia Boldt , Associate Director, Supply Chain Lead, *Fusion Pharmaceuticals*

16:45 – 17:05	The Progression of Nuclear Medicine <ul style="list-style-type: none">• Presenter: Stephen Judd CEng, FIChemE FIEI, European Director of Process Technology, <i>Arcadis</i>
17:05 – 17:25	Shaping the Future of Radiopharma Manufacturing <ul style="list-style-type: none">• Presenter: Jack Bauers , Market Lead, Nuclear Medicine, <i>CRB</i>
17:25 – 17:45	Q&A

A2: Driving Change Across Boundaries

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

16:45 – 17:05	So Your Lab Needs an Upgrade? Here’s How It’s Done <ul style="list-style-type: none">• Presenter: Stacey Ramsey MSc, Senior Manager - Microbial Applications Lab, <i>Charles River Labs</i>
17:05 – 17:25	Global Tech Transfer in a Fragmented World <ul style="list-style-type: none">• Presenter: Katherine Windham , Director, External Manufacturing Operations, <i>Novavax Inc.</i>

	17:25 – 17:45 Q&A
	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>
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 Room Open
08:00 – 09:00	IG3: Visual Inspection of Parenterals Interest Group Leader: Antonio Burazer , Global Head Visual Inspection & Particle LCM, <i>Takeda</i>
08:00 – 09:00	A3: Elevating Quality System Performance Through AI Integration Moderator: Christopher Lewis , Head of Quality, <i>Umoja Biopharma</i>
	<div> <div>08:00 – 08:20</div> <div> A Case Study on AI Implementation in Quality Management <ul style="list-style-type: none"> Presenter: Brian Chviruk , Quality Systems Innovation Lead, <i>Takeda</i> </div> </div>
	<div> <div>08:20 – 08:40</div> <div> AI and Behavioural Compliance: Reduction of Human Error Using AI, Behavioural Sciences, Persuasive Technology, Nudge and Large Group Gamification <ul style="list-style-type: none"> Presenter: Deepa Rachel MBA, Founder, <i>Eidolon Learning Pvt Ltd</i> </div> </div>
	<div> <div>08:40 – 09:00</div> <div>Q&A</div> </div>
08:00 – 09:00	B3: Innovative Contamination Control: Far-UVC Technology and Risk-Based Approaches Moderator: Ryan Murray MS , Senior Consultant, <i>ValSource, Inc.</i>
	<div> <div>08:00 – 08:20</div> <div> Continuous Cleanroom Decontamination: Implementation of Far-UVC <ul style="list-style-type: none"> Presenter: Jordi Amagat Molas PhD, Segment Project Manager, Life Science and Pharma, <i>UV Medico</i> </div> </div>
	<div> <div>08:20 – 08:40</div> <div> Global Implementation of Risk-Based Contamination Control Strategies to Prevent Bioprocess Contamination <ul style="list-style-type: none"> Presenter: Hilary Chan MS, Global Sterility Assurance and Microbiology Lead, <i>Takeda</i> </div> </div>
	<div> <div>08:40 – 09:00</div> <div>Q&A</div> </div>
	B4: Next-Generation Aseptic Operations: Traceability, Gloveless Filling, and Real-Time Monitoring Moderator: Robin Usselman , Senior Business Development Manager, USA & Canada, <i>PBL (Performing Beyond Limits)</i>
	<div> <div></div> <div>RFID-Based Unit Level Traceability: A Case Study for Visual Inspection</div> </div>

09:15 – 10:15	09:15 – 09:35	<ul style="list-style-type: none">• Presenter: Adithya Balasubramanian MS, Senior Director, <i>ten23 health</i>
	09:35 – 09:55	Future Forward: Implementing and Validating Gloveless Isolators with Real-Time Biofluorescent Particle Counting <ul style="list-style-type: none">• Presenter: Brent N. Lieffers , Senior Director, Innovation Advocacy, <i>Cytiva</i>
	09:55 – 10:15	Q&A

09:15 – 10:15	A4: Turning Signals into Strategy	
	Moderator: Kate Malachowski PhD , Director, MS&T, <i>Novavax</i>	
	09:15 – 09:35	From Fragmented Data to Predictive Quality: Integrating Internal and External Signals to Predict Supply Chain Risk <ul style="list-style-type: none">• Presenter: Alison Sathe , Senior Vice President of Data Strategy & Analytics, <i>Redica Systems</i>
	09:35 – 09:55	From Data to Decisions: Enhancing Yield and Quality in Pharmaceutical Manufacturing with Advanced Analytics <ul style="list-style-type: none">• Presenter: Ranran Dong PhD, Principal Data Scientist, <i>Genentech, Inc.</i>
	09:55 – 10:15	Q&A

09:15 – 10:15	IG4: Early Career Professionals	
	Interest Group Leader: Renee T. Morley MBA , Senior Technical Services Specialist, <i>Contec Inc.</i>	

10:30 – 12:00	P2: Every Body Counts: Innovation That Reaches Everyone	
	Moderator: Kate Malachowski PhD , Director, MS&T, <i>Novavax</i>	
	10:30 – 11:00	From the Ground Up: Innovation in Women's Health <ul style="list-style-type: none">• Presenter: Amy Beckley PhD, MBA, Owner & CEO, <i>Proov</i>
	11:00 – 11:30	Industry Representative Invited
	11:30 – 12:00	Q&A

12:15 – 13:45	Exhibit Hall Open
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12:15 – 13:45	Networking Lunch in the Exhibit Hall
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12:15 – 13:45	Poster Showcase in the Exhibit Hall
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14:00 – 15:00	A5: Practical Applications of AI in the Modern Pharmaceutical Workplace	
	Moderator: Susan J. Schniepp , Distinguished Fellow, <i>Regulatory Compliance Associates Inc.</i>	
	14:00 – 14:20	Human-AI Training Parallelization: AI Implementation in Biopharma Success Requires a People-Centric Approach to Training and AI Literacy <ul style="list-style-type: none">• Presenter: Richard Jaenisch MPH, Senior Director of Education, Outreach and Digital Experience, <i>Open Biopharma Research and Training Institute</i>
	14:20 – 14:40	Are We There Yet? A Digital Maturity Model for Enabling Process Monitoring and AI in Biologics Manufacturing <ul style="list-style-type: none">• Presenter: Jack Prior ScD, Head, MSAT Process Monitoring & Data Science/AI Strategy, <i>Sanofi</i>

14:40 – 15:00 **Q&A**

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*

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

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

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, *WILCO AG*

Cell and Gene Therapies: Navigating Extractable and Leachable Testing Challenges for Life-Saving Treatments

14:20 – 14:40

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

14:40 – 15:00 **Q&A**

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

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

Workshop Leader: Ulrich Koellisch PhD Partner *GxP-CC*

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

IG6: Microbiology/Environmental Monitoring and Quality Risk Management

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

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

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*

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

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

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*

15:15 – 16:15	<i>BioSolutions</i> Interest Group Leader: Gabriele Gori Senior Quality Advisor <i>Consultant</i> Interest Group Leader: Stephen E. Langille PhD Senior Microbiology Consultant <i>ValSource, Inc.</i>						
15:15 – 16:15	PDA Journal of Pharmaceutical Science and Technology—The Members' Journal Moderator: Walter Morris , Senior Director, Publishing, <i>PDA</i> Presenter: Shanker Gupta PhD Editor-In-Chief <i>PDA Journal of Pharmaceutical Science and Technology</i>						
15:15 – 16:15	A6: Accelerating Combination Product Development Through Platform Design and Lifecycle Excellence Moderator: Rozhin Derakhshandeh , Senior Scientist in Drug/Device Combination Products, <i>Merck & Co., Inc.</i> <table><tr><td>15:15 – 15:35</td><td>Master-Platform for Drug-Device Combination Products: Maximizing Reuse and Minimizing Rework with Regulatory Rigor<ul style="list-style-type: none">Presenter: Fubin Wu MS, Co-founder and President, <i>GessNet</i></td></tr><tr><td>15:35 – 15:55</td><td>Designing for the Future: Embedding Lifecycle Thinking in Early-Phase Development<ul style="list-style-type: none">Presenter: Priya Nataraj , MS&T Associate Director, <i>Novavax</i></td></tr><tr><td>15:55 – 16:15</td><td>Q&A</td></tr></table>	15:15 – 15:35	Master-Platform for Drug-Device Combination Products: Maximizing Reuse and Minimizing Rework with Regulatory Rigor <ul style="list-style-type: none">Presenter: Fubin Wu MS, Co-founder and President, <i>GessNet</i>	15:35 – 15:55	Designing for the Future: Embedding Lifecycle Thinking in Early-Phase Development <ul style="list-style-type: none">Presenter: Priya Nataraj , MS&T Associate Director, <i>Novavax</i>	15:55 – 16:15	Q&A
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15:55 – 16:15	Q&A						
16:30 – 17:30	Happy Hour in the Exhibit Hall						
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 – 16:00	Registration Open				
07:30 – 10:30	Presenter Ready Room Open				
08:00 – 09:30	Posters and Pastries in the Exhibit Hall				
08:00 – 09:30	Continental Breakfast in the Exhibit Hall				
08:00 – 13:45	Exhibit Hall Open				
09:45 – 12:15	Mini-Training Course 2: Applied GMP Behaviors: Cleaning Conduct and Gowning (Ticket Required) Instructor: David B. Talmage MBA , Global Strategic Advisor – Education, <i>PDA</i>				
09:45 – 10:45	A7: Advancing AI-Driven Autonomy Across GxP Operations Moderator: Christopher Lewis , Head of Quality, <i>Umoja Biopharma</i> <table><tr><td>09:45 – 10:05</td><td>Dark Facilities: Is Autonomous Manufacturing the Future?<ul style="list-style-type: none">Presenter: Faryal Khan , Lead Process Engineer, <i>CRB</i></td></tr><tr><td>10:05 – 10:25</td><td>Assessing the Risk of AI in the GxP Environment<ul style="list-style-type: none">Presenter: Joseph A. Horvath PhD, Head, Quality Risk Management, <i>Takeda</i></td></tr></table>	09:45 – 10:05	Dark Facilities: Is Autonomous Manufacturing the Future? <ul style="list-style-type: none">Presenter: Faryal Khan , Lead Process Engineer, <i>CRB</i>	10:05 – 10:25	Assessing the Risk of AI in the GxP Environment <ul style="list-style-type: none">Presenter: Joseph A. Horvath PhD, Head, Quality Risk Management, <i>Takeda</i>
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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*

09:45 – 10:45

09:45 – 10:05

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

- **Presenter:** Josh Russell , Vice President of Technical Sales, *AST*

10:05 – 10:25

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

- **Presenter:** Ian Speers MPH, CPH, MedLog, CEO and Co-Founder, *Pacto Medical*

10:25 – 10:45 **Q&A**

IG8: Process Validation

09:45 – 10:45

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

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

IG9: Quality Risk Management and Sterile Processing/Parenteral Drug Manufacturing

11:00 – 12:00

Interest Group Leader: Julian Petersen , Head of Business Development Pharma, *groninger & co gmbh*

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

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

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

11:00 – 12:00

11:00 – 11:20

Revolutionizing Product Protection: Digital Collaboration to Combat Counterfeit Medicines

- **Presenter:** Tommy Adler , , *Takeda*

11:20 – 11:40

PDA Survey 2025: Transportation Validation Benchmarking Review and Analysis

- **Presenter:** Jahanvi Miller MBA, Head of Global Quality External Affairs, *Baxter*

11:40 – 12:00 **Q&A**

A8: Optimizing Product Safety Through AI and Digitalization

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

11:00 – 12:00

11:00 – 11:20

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

- **Presenter:** Thomas Altmann , Principal Global Technical Consultant, *Ecolab*

11:20 – 11:40

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

- **Presenter:** Kim Sobien MBA, Senior Microbiology Consultant, *ValSource, Inc.*

11:40 – 12:00 **Q&A**

12:15 – 13:45 **Networking Lunch and Passport Drawing in the Exhibit Hall**

12:15 – 13:45	Poster Awards in the Exhibit Hall
14:00 – 15:00	Innovation Session 1
14:00 – 15:00	Innovation Session 3
14:00 – 15:00	Innovation Session 2
15:15 – 16:45	P3: Decision-Making Under Uncertainty
	<div><div>The Role of QA in a Rapidly Evolving Regulatory Landscape</div><div>15:15 – 16:15<ul style="list-style-type: none">• Presenter: Peter Baker MS, President, <i>Live Oak Quality Assurance LLC</i></div></div>
	16:15 – 16:40 Q&A
	16:40 – 16:45 Closing Remarks from the PDA Week 2026 Co-Chairs
17:30 – 22:00	Optional Wednesday Evening Activity

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>ValSource, Inc.</i>
08:30 – 16:00	Aseptic Processing Essentials Workshop (PDA 374) (Separate Registration Required) Instructor: Hal Baseman MBA , Vice President, <i>ValSource, Inc.</i>