



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)
08:00 – 09:30	Discussion Leader: Denyse Baker PE, RAC , Associate Vice President, External Engagement and Advocacy/Global Quality Compliance, <i>Eli Lilly and Company</i> Discussion Leader: Miguelina Matthews PhD Head Quality, Intelligence, Advocacy & Pharmacopoeia Affairs <i>Sanofi</i> Discussion Leader: Danielle Duran MA Director IS Training Strategy and Enablement <i>Revolutions Medicines</i>
	Roundtable 2: AI Implementation in Biopharma: A Hands-On Roundtable on People-Centric Training and Knowledge Parallelization (Ticket Required)
08:00 – 09:30	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)
08:00 – 09:30	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*

11:00 – 13:00

11:00 – 11:30

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*

11:30 – 12:30

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

- **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 and Passport Game

13:15 – 15:15

13:15 – 15:15

Poster Presentations

13:15 – 15:15

Solution Partner Tours

13:30 – 14:00

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

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

14:00 – 14:45

Lightning Talks

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

14:00 – 14:07

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

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

14:10 – 14:17

Integrating and Formalizing Generative AI in Laboratory Workflows

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

14:20 – 14:27

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*

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

15:30 – 15:50

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

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

15:50 – 16:10

Bridging the Gap: Human Centered Strategies for Successful Knowledge Transfer

- **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, *Merck & Co., Inc.*

Interest Group Leader: Magnus Stering SME Filter Integrity Testing *Sartorius*

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

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

15:30 – 16:30

15:30 – 15:50

Digital Twin-Driven Continuous Process Verification: Securing Data Integrity and Compliance

- **Presenter: Jason Tugman**, ,

15:50 – 16:10

BioScAI: Advancing Digital Twins with Embedded AI for Fast and Effective Bioprocess Scale-Up

- **Presenter: Kevin Baughman MS**, VP of Aizon Consulting Services, *Aizon*

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, *GessNet*

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

Workshop Leader: Joe Bravo Director, Device System - Data Management *Merck & Co., Inc.*

IG2: Packaging Science

16:45 – 17:45

Interest Group Leader: Ana Kuschel PhD, Principal Scientific Affairs, *West Pharmaceutical Services*

Interest Group Leader: Tony A. Perry Regional Director of Quality *SCHOTT Pharma*

B2: Radiopharmaceuticals: A Rapidly Expanding Modality with High Potential

Moderator: Virginia Boldt, Associate Director Supply Chain, *AstraZeneca*

16:45 – 17:45

16:45 – 17:05

The Progression of Nuclear Medicine

- **Presenter: Stephen Judd CEng, FICHEM FIEI**, European Director of Process Technology, *Arcadis*

	<p>Implementing Grade A Radiopharmaceutical Manufacturing: Turnkey Automated Hot Cells for Radiopharmaceutical Production</p> <p>17:05 – 17:25</p> <ul style="list-style-type: none"> • Presenter: Jeffrey Siterlet MBA, Sales Director, <i>PBL (Performing Beyond Limits)</i>
	<p>17:25 – 17:45 Q&A</p>
	<p>A2: Driving Change Across Boundaries</p> <p>Moderator: Kate Malachowski PhD, Director, MS&T, <i>Novavax</i></p>
16:45 – 17:45	<p>So Your Lab Needs an Upgrade? Here's How It's Done</p> <p>16:45 – 17:05</p> <ul style="list-style-type: none"> • Presenter: Stacey Ramsey MSc, Senior Manager - Microbial Applications Lab, <i>Charles River Labs</i>
	<p>Global Tech Transfer in a Fragmented World</p> <p>17:05 – 17:25</p> <ul style="list-style-type: none"> • Presenter: Katherine Windham, Director, External Manufacturing Operations, <i>Novavax</i>
	<p>17:25 – 17:45 Q&A</p>
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 – 07:45	<p>Interpreting Sterile Manufacturing Expectations Across Manufacturing Approaches</p> <p>Moderator: Josh Eaton MS, Senior Director, Scientific and Regulatory Affairs, <i>PDA</i></p> <p>Presenter: Richard Denk Senior Consultant Aseptic Processing <i>SKAN AG</i></p> <p>Presenter: Andrew C. Chang Sr Quality & Regulatory Compliance Director <i>Novo Nordisk</i></p>
	<p>07:00 – 08:00 Continental Breakfast</p>
	<p>07:30 – 16:30 Presenter Ready Desk Open</p>
08:00 – 10:30	<p>Mini-Training Course 1: Environmental Monitoring – The Full Story, From Requirements to Reports (Ticket Required)</p> <p>Instructor: Mark C. Hallworth, Senior GMP Scientist, <i>Particle Measuring Systems</i></p>
08:00 – 09:00	<p>IG3: Visual Inspection of Parenterals</p> <p>Interest Group Leader: John G. Shabushnig PhD, Principal Consultant, <i>Insight Pharma Consulting, LLC</i></p>
	<p>A3: Elevating Quality System Performance Through AI Integration</p> <p>Moderator: Christopher Lewis, Head of Quality, <i>Umoja Biopharma</i></p>
08:00 – 09:00	<p>AI and Behavioural Compliance: Reduction of Human Error Using AI, Behavioural Sciences, Persuasive Technology, Nudge and Large Group Gamification</p> <p>08:00 – 08:20</p> <ul style="list-style-type: none"> • Presenter: Deepa Rachel MBA, Founder, <i>Eidolon Learning Pvt Ltd</i>
	<p>A Case Study on AI Implementation in Quality Management</p>

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.*

08:00 – 09:00

Continuous Cleanroom Decontamination: Implementation of Far-UVC
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)**

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)*

09:15 – 10:15

RFID-Based Unit Level Traceability: A Case Study for Visual Inspection
09:15 – 09:35 • **Presenter: Adithya Balasubramanian MS**, Senior Director, *ten23 health*

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**

A4: Turning Signals into Strategy

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

09:15 – 10:15

From Fragmented Data to Predictive Quality: Integrating Internal and External Signals to Predict Supply Chain Risk
09:15 – 09:35 • **Presenter: Yelena Ionova PharmD**, Senior Manager, Data Strategy and Analytics, *Redica Systems*

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**

P2: Every Body Counts: Innovation That Reaches Everyone

10:30 – 12:00	From the Ground Up: Innovation in Women's Health 10:30 – 11:00 <ul style="list-style-type: none">• Presenter: Amy Beckley PhD, MBA, Owner & CEO, <i>Proov</i>
	Representation Matters: Equity as a Foundation for Clinical Research 11:00 – 11:30 <ul style="list-style-type: none">• Presenter: Jenny Garcia, Associate Director, Trial Equity and Representation, <i>Takeda</i>
	11:30 – 12:00 Q&A

12:15 – 17:30 **Exhibit Hall Open**

12:15 – 13:45	Networking Lunch and Passport Game in the Exhibit Hall 12:15 – 13:45 Poster Presentations
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Exhibitor Tech Talks	
12:25 – 13:05	Aseptic Material Transfer into Isolator Filling Lines by Rapid Decontamination 12:25 – 12:35 <ul style="list-style-type: none">• Tech Talk Presenter: Hussein Bachir PhD, Senior Scientist - GMP Compliance, <i>Franz Ziel GmbH</i>
	Nitrogen Dioxide: Advancing Sterilization Beyond EO 12:40 – 12:50 <ul style="list-style-type: none">• Tech Talk Presenter: Michael Maust, Laboratory Manager for Customer Projects, <i>Noxilizer, Inc.</i>
	Revolutionize Your Lab Workflow 12:55 – 13:05 <ul style="list-style-type: none">• Tech Talk Presenter: Meg Provenzano, Product Manager Biodetection, <i>Veolia</i>
	TOC for Clean-In-Place and Cleaning Validation 13:10 – 13:20 <ul style="list-style-type: none">• Tech Talk Presenter: John W. Moir, <i>Beckman Coulter Life Sciences</i>
	Optimizing PS Labels in Cryogenic Applications 13:25 – 13:35 <ul style="list-style-type: none">• Tech Talk Presenter: Cory Keller, Sr. Product Manager, Pharma, <i>Avery Dennison</i>

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	Optimizing PS Labels in Cryogenic Applications 13:25 – 13:35 <ul style="list-style-type: none">• Presenter: Cory Keller, Sr. Product Manager, Pharma, <i>Avery Dennison</i>

IG5: Drug Compounding

14:00 – 15:00 **Interest Group Leader: Arie Avery MS**, Global Head of Operations, *Regulatory Compliance Associates Inc.*
Interest Group Leader: David Short Chief Quality Officer *QuVa Pharma*

IG6: Microbiology/Environmental Monitoring and Quality Risk Management

14:00 – 15:00 **Interest Group Leader: Kurt Jaecques MA**, Global Quality Technical Senior Lead, *GSK*
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: Kim Sobien MBA Senior Microbiology Consultant *ValSource, Inc.*

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

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

14:00 – 14:20	Innovative Design and Testing Strategy for an Autoinjector to Precisely Determine Leaks in the Pre-Filled Syringe <ul style="list-style-type: none">• Presenter: Matthias Kahl, Head of R&D and Lab Services, <i>WILCO AG</i>
14:20 – 14:40	Cell and Gene Therapies: Navigating Extractable and Leachable Testing Challenges for Life-Saving Treatments <ul style="list-style-type: none">• Presenter: Sam Albeke, Chromatography Manager, <i>Element Materials Technology</i>
14:40 – 15:00	Q&A

A5: Practical Applications of AI in the Modern Pharmaceutical Workplace

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

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

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

14:00 – 16:30 **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*

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*
Presenter: Michael J. Sadowski Owner *Sterilexcellence*

Presenter: Ghada N. Haddad PhD Head of Global Quality Systems and Quality Processes *Kite Pharma*

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

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

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

15:15 – 16:15

15:15 – 15:35

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

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

15:35 – 15:55

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

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

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.*

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*

15:15 – 16:15

15:15 – 15:35

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

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

15:35 – 15:55

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

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

15:55 – 16:15

Q&A

15:30 – 16:30

PDA Exhibit Committee Meeting (Invite Only)

16:30 – 17:30

Happy Hour and Passport Game in the Exhibit Hall

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
	08:30 – 09:15	Technical Report Live: Manufacturing Technology Guide No. 1: Aseptic Filling, Engineering, and Operation
	09:15 – 09:30	Scavenger Hunt Winners Announcement

08:00 – 13:45 **Exhibit Hall Open**

A7: Advancing AI-Driven Autonomy Across GxP Operations

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

09:45 – 10:45	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>
	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 <ul style="list-style-type: none"> • Presenter: Josh Russell , Vice President of Technical Sales, <i>AST</i>
	10:05 – 10:25	Redesigning Pre-Filled Syringes: A Way to Increase Equitable Access, Decrease Costs, and Reduce Environmental Impact <ul style="list-style-type: none"> • Presenter: Ian Speers MPH, CPH, MedLog, CEO and Co-Founder, <i>Pacto Medical</i>
	10:25 – 10:45	Q&A

IG8: Process Validation

09:45 – 10:45 **Interest Group Leader: Robert Dream** , Managing Director, *HDR Company LLC*
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*

11:00 – 12:00	11:00 – 11:20	Digital Transformation in Cleaning Validation Use Cases: Key Benefits and Lessons Learned <ul style="list-style-type: none"> • Presenter: Thomas Altmann , Principal Global Technical Consultant, <i>Ecolab</i>
		Detection Disrupted: AI and the New Era of Predictive Contamination Control

11:20 – 11:40

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

11:40 – 12:00

Q&A

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

Revolutionizing Product Protection: Digital Collaboration to Combat Counterfeit Medicines

11:00 – 11:20

- **Presenter: Tommy Adler MBA**, Associate Director Global Product Protection Americas Region, *Takeda*

11:20 – 11:40

PDA Survey 2025: Transportation Validation Benchmarking Review and Analysis

- **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, *ValSource, Inc.*

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

Networking Lunch in the Exhibit Hall

12:15 – 13:45

13:15 – 13:40

Passport Drawing

13:15 – 13:40

Poster Award Winners Announcement

Exhibitor Tech Talks

12:25 – 13:05

12:25 – 12:35

TOC for Clean-In-Place and Cleaning Validation

- **Tech Talk Presenter: John W. Moir** , , *Beckman Coulter Life Sciences*

12:40 – 12:50

Optimizing PS Labels in Cryogenic Applications

- **Tech Talk Presenter: Cory Keller** , Sr. Product Manager, *Pharma, Avery Dennison*

12:55 – 13:05

The Intersection of Drug Product CCS and Primary Packaging CCS: How do Pharma and Supplier CCS Successfully Coexist

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

Spotlight Session 1: Why Good Enough Isn't: The Hidden Economics of the Value of Quality

14:00 – 15:00

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

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

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

Spotlight Session 2: Smarter, Faster, Safer: Transforming Fill-Finish Through Distributed Fleet Management

14:00 – 15:00

Presenter: Andrew C. Chang , Sr Quality & Regulatory Compliance Director, *Novo Nordisk*

Presenter: Steven Falcone VP, Complaints Inspections & Audits *Novo Nordisk*

P3: Decision-Making Under Uncertainty

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

The Role of QA in a Rapidly Evolving Regulatory Landscape

15:15 – 15:45

- **Presenter: Peter Baker MS**, President, *Live Oak Quality Assurance LLC*

15:15 – 16:45

From Uncertainty to Integrity: Building a Culture of Quality & Compliance

15:45 – 16:15

- **Presenter: Coleen Glessner MBA**, EVP, Chief Quality, Compliance and Risk Officer, *Emergent BioSolutions*

16:15 – 16:45

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

Aseptic Processing Essentials Workshop (PDA 374) (Separate Registration Required)

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

08:30 – 16:00

Contamination Control Strategy Essentials Workshop (PDA 293) (Separate Registration Required)

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

09:00 – 14:00

Optional Activity: Site Visit to Particle Measuring Systems (Ticket Required)