**SUNDAY, 24 MARCH**

14:00 – 19:00 | Registration Open  
*Beat the Monday rush and enjoy light welcome refreshments when picking up your materials on Sunday afternoon!*

18:30 – 21:30 | PDA Awards Dinner *Ticketed Event – Cocktail Attire*  
*New this year – PDA has opened the annual Awards Dinner to all attendees! Purchase your ticket to join in the celebration and recognition of PDA’s world-class volunteers. Start your PDA Week with food, fun, and networking!*

**MONDAY, 25 MARCH**

07:00 – 19:00 | Registration Open

**08:00 – 10:00 | Hot Topic Breakfast Roundtables *Ticketed Event***

You asked and PDA listened! Kick-off your Annual Meeting experience with PDA subject matter experts in these brand-new breakfast roundtables. Participation is limited to ensure a robust and engaging discussion. The Roundtables are guaranteed to sell out, so don’t miss your chance to weigh in on these important hot topics!

|---|---|---|---|
| **Moderator:** Amanda McFarland, MS, Senior Consultant, ValSource, Inc.  

Industry is often asked the ever-important question, “What regulatory changes would help companies speed drug products to the patients that need them and actively prevent drug shortages?”  

As the current process requires multiple, repetitive reviews between regulatory authorities (regional or local), significant delays often slow the | **Moderator:** Kate Malachowski, PhD, Associate Director, MS&T, Novavax  

The world continues to change with the implementation of greater digitalization and automation, as well as a changing workforce with differing learning styles. With all these changes, what will the training of the future look like? This roundtable will explore these questions and will attempt to answer this very elusive question. | **Moderator:** Susan J. Schniepp, Distinguished Fellow, Regulatory Compliance Associates Inc.  

It’s been just over 10 years since legislation went into effect that provided the U.S. FDA more oversight responsibility for 503B compounding facilities. Much has changed within this part of the industry, from evolving business models to new guidance and evolving expectations.  

This roundtable will focus on the challenges 503B compounders are facing today. It is a chance to come together, have open | **Moderator:** Divyang Patel, Senior Specialist, Commissioning, Qualification & Validation (CQV), AtkinsRealis  

Discussion Leader: Ira Mann, President, IQ Referrals  

**Question:** When should early career and mid-career professionals start thinking about their career and the steps they can take to enable and prepare for future opportunities?  

**Answer:** Now, and always!  

As the saying goes, if you don’t know where you’re going, don’t be surprised if you get lost. Careers |
introduction of novel, lifesaving products and the implementation of manufacturing innovation. Is there a better way to accomplish the scientific review required for new product applications and post-approval changes? discussions, and learn from one another. The roundtable will start with a 15-20 min presentation on how the industry in this area is evolving to set the stage for the roundtable discussion. can take different paths, some in the way you desire and some in unexpected ways. Preparing early is the best approach and, while it is never too late to act, it is best to begin preparing early in one’s career.

13:00 – 15:00 | P1: Opening Plenary
Moderator: Amanda McFarland, MS, Senior Consultant, VolSource, Inc.

13:00 | Welcome from PDA Leadership and Meeting Co-Chairs
Anil Sawant, PhD, Chair, PDA Board of Directors and Senior Vice President, Global Quality Compliance, Merck & Co., Inc.
Glenn E. Wright, MA, President and CEO, PDA
Kenneth Paddock, Quality Director, Sterility Assurance, Baxter Healthcare
Susan J. Schniepp, Distinguished Fellow, Regulatory Compliance Associates Inc. and Immediate Past Chair, PDA Board of Directors

13:30 | Rich Horgan, MBA, Founder, President, and CEO, Cure Rare Disease

14:10 | Pat Gavit, MS, Head of Manufacturing Sciences, Takeda

14:30 | Q&A

15:00 – 15:30 | Refreshment Break

15:30 – 17:00 | Concurrent Sessions

<table>
<thead>
<tr>
<th>ATMP/Biopharmaceutical</th>
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This session will look at the future of the pharmaceutical industry, the different types of novel drug products, and how combination
products will continue to evolve to serve the needs of patients. Discussions on how PDA has and will continue to support the next wave of industry innovation.

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<tr>
<th>Time</th>
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<tr>
<td>15:30</td>
<td>Challenges and Solutions to Manufacturing Ultra-High Concentration Antibody Formulations</td>
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<td>Ashley Harp, PE, Process Engineer, CRB</td>
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<td>15:50</td>
<td>A Path Though the Sustainable Manufacturing Forest</td>
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<td>Ankur K. Shah, PE, Lead Process Engineer, Arcadis DPS Group</td>
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<tr>
<td>16:10</td>
<td>Challenges and Solutions to Manufacturing of Ultra-High Concentration Antibody Formulations: Downstream Process to Fill-Finish Processing</td>
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<td>Vaibhav Deokar, Principal Scientist, Lupin Limited</td>
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<tr>
<td>16:30</td>
<td>Q&amp;A</td>
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17:00 – 18:30 | Happy Hour in the Exhibit Hall

18:30 – 21:00 | Opening Reception
*The Opening Reception is included with all Full Conference registrations. Guest tickets are available for purchase for $75.*

**TUESDAY, 26 MARCH**

07:00 – 18:30 | Registration Open
07:00 – 8:00 | Continental Breakfast

08:00 – 09:30 | P2: AI and Machine Learning
Moderator: Peter J. Makowenskyj, Director of Design Consulting, G-CON

08:00 | Ravi Starzl, PhD, Adjunct Professor, Language Technologies Institute, Carnegie Mellon University
08:25 | Sara Cook, PhD, President and Founder, IliaCook Consulting
08:50 | Q&A

09:30 – 10:30 | Refreshment Break, Poster Presentations, and Guided Poster Walk in the Exhibit Hall
On the Guided Poster Walk, poster presenters will give a 3-5 minute "Speedy Talk" about their project or research. Once completed, the poster presenters will have an opportunity to talk with attendees throughout the rest of the break.

10:30 – 12:00 | Concurrent Sessions

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<tr>
<td>A2</td>
<td>B2 Moderator: Malav Parikh, ME, Director, Global Quality Compliance and Systems, Takeda</td>
<td>C2: Innovations in cGMP Facility Design and Digitization Moderator: Kate Malachowski, PhD, Associate Director, MS&amp;T, Novavax</td>
<td>D2: Designing the Products and Processes of Tomorrow Moderator: Susan J. Schniepp, Distinguished Fellow, Regulatory Compliance Associates Inc. The world keeps changing and with it the complexity of the formulations, manufacturing floor operations, and quality expectations. This session will look at some of the challenges facing our industry and approaches being developed to overcome them.</td>
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<td>Moderator: Ryan Murray, MS, Senior Consultant, ValSource, Inc.</td>
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10:30 | Answering the Call for Flexibility: Adaptive Robotics for ATMP Drug Products Josh Russell, Vice President of Sales and Marketing, AST
10:30 | Bringing Pharmaceutical Quality Auditing into the Digital Age Melanie McIntosh, ASQ-CQE, CQA, CSSGB, Senior Quality Assurance
10:30 | Designing cGMP Facilities with Operations in Mind Jason E. Smith, PE, MBA, PMP, Director, Barry-Wehmiller Design Group
10:30 | Two Steps Forward and One Step Back: Advances in Nanoparticle Delivery Vehicle Development
10:50 | Next Generation of Platform ATMP-
10:50 | Accelerating Biopharmaceutical Development Through Data-Driven Strategies, Platforms, and Technology Enablers
Nitin Rathore, Associate Vice President, Amgen Inc.

11:10 | A Collaborative Approach to Agile Manufacturing
Peter J. Makowenskyj, Director of Design Consulting, G-CON

10:50 | How AI Can Reveal Enforcement Trends in Data Integrity
Michael de la Torre, CEO, Redica Systems

11:10 | Compliant Implementation of AI/ML Models in Commercial GMP
Ulrich Köllisch, Partner, GxP-CC GmbH

10:50 | Leveraging AI for Optimal cGMP Manufacturing Facility Design
Patrick Traver, AIA, US Director Process Architecture, Arcadis DPS Group

11:10 | The BioPhorum Digital Plant Maturity Model (DPMM), version 3.0
James Colley, IT Phorum Director, BioPhorum

11:30 | Q&A

12:00 – 13:30 | Lunch, Tech Talks, and Poster Presentations in the Exhibit Hall

13:30 – 14:15 | Concurrent Interest Groups

IG1: Data Governance, Management, Integrity, and Digitalization
IG Leaders
- Kir F. Henrici, Chief Executive Officer, The Henrici Group
- Ulrich Köllisch, Partner, GxP-CC GmbH

IG2: Annex 1 Implementation and Quality Risk Management
- Annex 1 IG Leaders
  o Marcia Baroni, MBA, VP Enterprise GxP Compliance & Systems, Emergent BioSolutions
  o Rebecca Brewer, VP Strategic Practices, Quality Executive Partners, Inc.
  o Gabriele Gori, SVP Global Quality and Chief Quality Officer, Biogen
  o Stephen Langille, PhD, Senior Microbiology Consultant, ValSource, Inc.
- QRM IG Leaders
  o Amanda McFarland, MS, Senior Consultant, ValSource, Inc.
  o Malav Parikh, ME, Director, Global Quality Compliance and Systems, Takeda

IG3: Visual Inspection of Parenterals
IG Leader: John G. Shabushnig, PhD, Principal Consultant, Insight Pharma Consulting, LLC

13:30 – 14:15 | Lighting Presentations: Session 1
Moderator: Kenneth Paddock, Quality Director, Sterility Assurance, Baxter Healthcare

Join PDA’s first ever Lightening Presentations session! These exciting 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. The Lightening Presentations will have 20 slides set to automatically advance after only 20 seconds of commentary per slide for a total presentation time of just 6 minutes and 40 seconds.
Mandy Gervasio, MS, Vice President, QA & Compliance, Comanche Biopharma

13:37 | Delivering Value Through Quality External Engagement  
Cindy Capeloto, Head of Quality External Engagement, Takeda

Cheryl Norder, Vice President Global Quality, Phillips-Medisize, A Molex Company

13:51 | Cessation of In Vivo Lot Release Testing  
Stephanie P. Kurtz, MS, Strategic Account Executive, SQA Services

13:58 | Pre-Filled Syringe Considerations for VHP Sterilization  
Juha P. Mattila, MEng, Director, Sterilization Technologies, STERIS Corporation

14:05 | Q&A

13:30 – 15:00 | Mini Training Course: PDA TR70 Fundamentals of Cleaning and Disinfection for Aseptic Manufacturing  
Ticketed Event

14:15 – 14:30 | Transition to Next IG

14:30 – 15:15 | Concurrent Interest Groups

IG4: Advanced Manufacturing and Applied Process Digitalization  
IG Leader: Peter J. Makowenskyj, Director of Design Consulting, G-CON

IG5: Packaging Science  
IG Leaders:  
- Ana Kuschel, PhD, Principal Scientific Affairs, EU, West Pharmaceutical Services Deutschland GmbH & Co. KG  
- Anthony A. Perry, Regional Quality Director, Schott AG  
- Xu Song, MS, Director Process Engineering and Packaging, AstraZeneca

IG6: Vaccines  
IG Leaders:  
- Jane L. Halpern, PhD, Executive Director, International AIDS Vaccine Initiative  
- Sabrina Restrepo, PhD, Director, Global Vaccines Technical Operations, Merck & Co., Inc.

IG7: Process Validation  
IG Leader: Robert F. Dream, Principal, HDR Company, LLC

14:30 – 15:15 | Lighting Presentations: Session 2  
Moderator: Lisa Bennett, GMP Senior Consultant and Trainer, SeerPharma

PDA’s Lightening 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 just 6 minutes and 40 seconds.

14:30 | Sterility Testing of Cell and Gene Therapies
14:37 | Digitizing Process Specifications to Expediate Tech Transfers  
Zachary Beck, Senior Microbiologist, Group Leader III, Eurofins Lancaster Laboratories

14:44 | Trends Driving Container Closure Integrity Testing and Positive Controls  
Sergio Diaz, Product Marketing Manager, Emerson

14:51 | Analysis of a Robotic Airborne Disinfection System Utilizing Hydrogen Peroxide for Disinfecting Clean Rooms  
Ted Teitelman, North American Sales Manager, Oxford Lasers

14:58 | Improved Identification of Pharmaceutical Ingredients and Contaminants Using Artificial Intelligence and Machine Learning  
Prasanna K. Sistla, Technical Director, VM Sciences

15:05 | Q&A

15:00 – 16:00 | Refreshment Break, Tech Talks, and Poster Presentations in the Exhibit Hall

16:00 – 17:30 | Concurrent Sessions

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| Biopharmaceutical | Moderator: Jennifer Cheung, MS, Vice President, Quality Assurance and Regulatory Affairs, WuXi Advanced Therapies | Moderator: Catriona Murphy, MSc, Senior Advisor QA/Qualified Person, Eli Lilly and Company | Moderator: Michele Simone, Director, Corporate Quality Compliance, Risk Management, and Continual Improvement, Bracco | D3: The Case for Disruption: Challenging the Status Quo to Ensure a Viable Future  
Moderator: Josh Eaton, MS, Senior Director, Scientific and Regulatory Affairs, PDA  
Back by popular demand! This session will be an opportunity to discuss what needs to change in our industry and ideas for doing so, regardless of what, or how long, it would take to get there. The floor is open to topics including improvements to aseptic processing, updating regulatory requirements, and navigating post-approval changes (PAC) to next-generation |
technologies, and defining the ultimate desired state for sterile product manufacturing. A brief presentation will set the stage for an open forum to hear your views and ideas.

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<tr>
<th>Session Time</th>
<th>Session Title</th>
<th>Presenter(s)</th>
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<tr>
<td>16:00</td>
<td>Ensuring Robustness in Combination Product Stability</td>
<td>Luis Montes, Product Quality Principal Lead, Amgen, Inc.</td>
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<td>16:20</td>
<td>Case Study on the Global Implementation of a Risk-Based Contamination Control Strategy</td>
<td>Elizabeth Brockson, MPH-VPH, Aseptic Processing and Sterility Assurance Lead, Takeda</td>
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<td>16:40</td>
<td>Analytical Tools to Support Quality and Consistency of mRNA Vaccines and Therapeutics</td>
<td>Diane McCarthy, PhD, Senior Director, Science and Standards, Global Biologics, USP</td>
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<tr>
<td>17:00</td>
<td>Q&amp;A</td>
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<td>16:00</td>
<td>Knowledge Management Best Practices for Preserving Biologic CQA Information</td>
<td>Beth Fulton, MS, Consultant, ValSource, Inc.</td>
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<td>16:20</td>
<td>The Integration of CSA into the CSV Projects</td>
<td>Orlando Lopez, Independent Consultant</td>
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<td>16:40</td>
<td>Methods for Measuring the Quality Management Maturity of a Manufacturing Network</td>
<td>Adam M. Caruso, Associate Director, Strategic Programs and Regulatory Intelligence, Merck &amp; Co., Inc.</td>
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<tr>
<td>17:00</td>
<td>Q&amp;A</td>
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<tr>
<td>16:00</td>
<td>Unlock the Potential: Integrated Development of High-Volume Drug/Device Combination Products</td>
<td>Adithya Balasubramanian, Director, ten23 Health AG</td>
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<tr>
<td>16:20</td>
<td>Embracing Innovation to Drive Operational Excellence</td>
<td>Scot Lindsey, Senior Vice President &amp; Information Officer, M&amp;Q, Eli Lilly and Company</td>
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<td>16:40</td>
<td>Lifecycle Management PAT Implementation for Process Intensification</td>
<td>Rui Almeida, Director Product Life Cycle Management, ValGenesis</td>
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<tr>
<td>17:00</td>
<td>Q&amp;A</td>
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<tr>
<td>17:00</td>
<td>Panel Discussion</td>
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16:00 – 17:30 | Mini Training Course: PDA TR13 Fundamentals of an Environmental Monitoring Program | Ticketed Event

18:00 – 21:00 | Evening Tours | Ticketed Event

19:00 – 22:00 | Documentary: Of Medicine and Miracles | Ticketed Event
Moderator: Kenneth Paddock, Quality Director, Sterility Assurance, Baxter Healthcare
Join PDA in their first-ever “documentary deep dive” session! A special guest from the documentary team will be there in person to introduce the film and facilitate the post-screening discussion. Tickets include the film, discussion, and light refreshments.

At the age of six, Emily Whitehead was diagnosed with leukemia and the lives of her and her parents were suddenly thrust into uncertainty. Through bracingly honest interviews and home videos, Of Medicine and Miracles details her family’s experience bouncing from hospital to hospital, trying to stay hopeful amidst hopelessness, and their fateful correspondence with a doctor whose research could hold the key to her survival. But time is of the essence.

A stunning feat of non-fiction filmmaking, Of Medicine and Miracles applies an acutely personal perspective to a highly publicized case, allowing Emily’s parents to speak candidly about the American healthcare system, experimental cancer treatments, and their overwhelming love for their daughter. Academy Award winner Ross Kauffman’s new documentary is a tear-jerking, heart-racing record of medical history that honors its subjects and their trauma while empowering future generations to attempt the impossible. – Cara Cusumano

WEDNESDAY, 27 MARCH

07:00 – 16:00 | Registration Open

08:00 – 09:00 | Continental Breakfast

08:30 – 10:30 | Mini Breakfast Training Course: Points to Consider for the Aseptic Processing of Sterile Pharmaceutical Products in Isolators  
Ticketed Event

09:00 – 10:30 | Concurrent Sessions

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<tr>
<td>A4</td>
<td>Moderator: Stephanie N. Lee, MBS, Operations Manager, Amgen Inc.</td>
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<tr>
<td>B4</td>
<td>Moderator: Ryan Murray, MS, Senior Consultant, ValSource, Inc.</td>
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<td>C4</td>
<td>Moderator: Divyang Patel, Senior Specialist, Commissioning, Qualification &amp; Validation (CQV), AtkinsRealis</td>
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| D4 | What is PDA Working On?  
Moderator: Josh Eaton, MS, Senior Director, Scientific and Regulatory Affairs, PDA | | |

We have the answers, and it is exciting! Join us for an inside look at PDA activities and initiatives with our Technical Advisory Boards (ABs), Interest Group (IGs) Leaders, the PDA Training and Education Team, and PDA’s Chapter Presidents.
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| 09:00  | Analytical Tools to Support the Production and Characterization of AAV Therapeutics  
Anthony Blaszczyk, PhD, Senior Scientist, USP |
| 09:20  | Developing an ATMP Regulatory Submission Strategy: Concepts That Work  
Janmeet S. Anant, Senior Regulatory Consultant, MilliporeSigma |
| 09:40  | What New Therapeutic Modality CMC Challenges Tell Us About Facility Design  
Paul Fleming, Project Manager, Genesis AEC |
| 10:00  | Q&A                                                                     |
| 09:00  | AI, DI, and Overregulation: Impact on QMS  
Karen Taylor, MSc, Owner, PCI Pharmaceutical Consulting Israel Ltd |
| 09:20  | Assessing the Quality Management Maturity of an ATMP CMO  
Londa Ritchey, MS, MBA, Quality Director, PharmaLex |
| 09:40  | Ensuring Patient Access to Medicines Through RAPID Root Cause Analysis  
Paul Hanson, PhD, Vice President, Head of Lifecycle Management, Innovation, and Strategy, Takeda |
| 10:00  | Q&A                                                                     |
| 09:00  | Embracing Innovation to Meet the Requirements of Annex 1  
Brent Lieffers, General Manager, Aseptic Filling, Cytiva |
| 09:20  | Robotics and Automation: Enabling Higher Quality and Annex 1 CCS Compliance  
Julian Petersen, Head of Business Development, proninger & co. gmbh |
| 09:40  | The End of an Era: Injectable Pharmaceuticals as a Relic of the Past  
Jessica Chiaruttini, PhD, Microbiology Consultant, ValSource, Inc. |
| 10:00  | Q&A                                                                     |
| 10:00-10:30 | Q&A  
10:30 – 11:30 | Refreshment Break, Tech Talks, and Poster Presentations in the Exhibit Hall  
11:30 – 12:15 | Concurrent Interest Groups  
**IG8: Microbiology/Environmental Monitoring**  
IG Leaders:  
- Kurt Jaecques, MA, Global Aseptic Technologies Lead Monitoring & Control, GSK Vaccines  
- Kim R. Sobien, Senior Consultant, ValSource, Inc.  
**IG9: Annex 1 Implementation and Sterile Processing/Parenteral Drug Manufacturing**  
**Annex 1 IG Leader: Marcia Baroni, MBA, VP Enterprise GxP Compliance & Systems, Emergent BioSolutions**  
**Sterile Processing IG Leader: Julian Petersen, Director of Business Development and Product Management, proninger & co. gmbh**  
**IG10: Management of Outsourced Operations**  
IG Leaders:  
- Maria Amaya, PhD, Lead External Advocacy North America (Quality Policy), Genentech  
- Morten Munk, Director - Global Alliance Management, Fujifilm Diosynth Biotechnologies  
**IG11: Quality Systems**  
IG Leaders:  
- Ghada N. Haddad, PhD, Executive Director, Global Quality Transformation, Merck & Co., Inc. |
• Michele Simone, Director, Corporate Quality Compliance, Risk Management, and Continual Improvement, Bracco
• Eva M. Urban, MSc, Head Internal Audit & Compliance, CSL Behring

IG12: Facilities and Engineering
IG Leaders:
• Shelley Preslar, MBA, PMP, President & COO, Azzur Training Center
• Joachim Regel, Account Manager Biotech Account, Merck Chemicals GmbH

12:15 – 13:45 | Networking Lunch, Tech Talks, Passport Drawings, and Poster Presentations in Exhibit Hall

13:45 – 15:30 | P3: Closing Plenary
Moderator: Kenneth Paddock, Quality Director, Sterility Assurance, Baxter Healthcare

13:45 | Derek A. Sabori, MBA, Senior Director, Communications, thinkPARALLAX and Founder and Lead Instructor, School of Understanding, The Underswell

14:05 | Massine Yanat, Technical Support Service and Sustainability, North America, SGD Pharma

14:30 | Margaret Faul, PhD, Vice President, Manufacturing and Clinical Supply, Amgen Inc.

14:55 | Q&A

15:25 | Closing Remarks from Meeting Co-Chairs