Sunday, March 18

1:00 p.m. – 5:00 p.m.
Biopharmaceutical Advisory Board (BioAB) Meeting (Invitation Only)

1:00 p.m. – 7:00 p.m.
Exhibitor Set Up

4:00 p.m. - 7:00 p.m.
Registration Open

4:00 p.m. - 7:00 p.m.
Speaker Ready Room Open

6:30 p.m. - 9:30 p.m.
PDA Awards Dinner (Invitation Only)

Monday, March 19

9:00 a.m. – 4:00 p.m.
Exhibitor Set Up

9:00 a.m. – 10:00 a.m.
2018 PDA Annual Meeting Program Planning Committee Meeting (Invitation only)

9:00 a.m. – 12:00 p.m.
Quality Culture Metrics Task Force Meeting (Invitation Only)

9:00 a.m. – 12:00 p.m.
Science Advisory Board (SAB) Meeting (Invitation Only)

9:00 a.m. - 5:00 p.m.
Registration Open

9:00 a.m. - 5:00 p.m.
Speaker Ready Room Open

10:00 a.m. – 11:30 a.m.
PDA Chapter Council Meeting (Invitation Only)

11:30 a.m. – 12:45 p.m.
Orientation Lunch (Invitation only): Sponsored by Amgen

12:00 p.m. - 1:00 p.m.
Advisory Board Mix & Mingle Lunch (Invitation Only)

1:00 p.m. - 1:30 p.m.
Welcome and Opening Remarks from the Chair of the PDA Board of Directors, PDA’s President and, the Meeting Program Planning Committee Co-Chairs
Rebecca Devine, PhD, Biopharmaceutical Consultant
Richard Johnson, President and CEO, PDA
Ghada Haddad, MBA, Executive Director, Global cGMP & Compliance Auditing Organization, Merck & Co., Inc.
Morten Munk, Global Technology Partner, NNE
1:30 p.m. - 3:00 p.m.  
**P1: Patient Perspective - Future Visions**  
**Moderator:** Morten Munk, Global Technology Partner, NNE

**Session Description:** All delegates at this conference are in some way involved in the path of providing pharmaceuticals to patients. It is a privilege and offers a clear purpose to be part of a community that have the possibility to make an instrumental difference to the individual patient as well as to the society in general. This option to make a difference, comes with substantial responsibility to ensure that we do our outmost to meet the expectations of the patients and health care professionals, who rely on us in providing safe and effective pharmaceuticals. During a busy workday with numerous daily challenges, the outcome of our work might be a bit out of focus, and maybe not the first thing we think about when we start working in the morning. This session offers to give a clear perspective of the individuals that ultimately are benefiting from our daily efforts.

1:30 p.m. - 2:00 p.m.  
**Clinician Perspective on Future Patient Therapies**  
**Stephen Kingsmore, MD,** President and CEO, *Rady Children’s Institute for Genomic Medicine*

2:00 p.m. - 2:30 p.m.  
**Patient Perspective**  
**Lori Richter,** Senior Consultant, *ValSource LLC*

2:30 p.m. - 3:00 p.m.  
**Questions and Answers/Discussion**

3:00 p.m. - 3:30 p.m.  
**Refreshment Break**

3:10 p.m. - 3:30 p.m.  
**Press Conference (Invitation Only)**

3:30 p.m. - 5:00 p.m.  
**P2: Disruptive Technology and the Future of Medicine**  
**Moderator:** Tia Bush, Vice President, Quality, *Amgen, Inc.*

**Session Description:** Today’s healthcare is not sustainable due to the rising costs of treatment, ageing populations, and healthcare worker shortages. The future of medicine will be innovative, patient focused, and digital. Our industry and the regulatory framework that governs our products and services must overcome technical and cultural challenges by embracing disruptive technologies that make healthcare more effective, by putting patients in the center of healthcare strategies, by digitizing information to grow our understanding of disease and treatment and shifting the healthcare from a “break and fix” mentality to one of prevention. This session will explore the trends in technology and how they will alter our current view of the healthcare system and the medicines we make to improve the lives of patients. We will also explore how companies must build their culture of innovation in order to deliver on this promise.

3:30 p.m. - 4:00 p.m.  
**Discovering your Way to Greatness**  
**Steven Spear, PhD,** Senior Lecturer, System Dynamics, *Massachusetts Institute of Technology (MIT)*

4:00 p.m. - 4:30 p.m.  
**Emerging Technology: A Key Enabler to Meet the Needs of the Patient**  
**Sharmista Chatterjee, PhD,** Director, Division of Process Assessment II, CDER, *FDA*

4:30 p.m. - 5:00 p.m.  
**Questions and Answers/Discussion**

5:00 p.m. - 6:30 p.m.  
**Grand Opening Celebration in Exhibit Hall**
Tuesday, March 20

7:30 a.m. - 5:30 p.m.
Registration Open

7:30 a.m. - 5:30 p.m.
Speaker Ready Room Open

7:30 a.m. - 8:30 a.m.
Continental Breakfast

8:30 a.m. - 10:00 a.m.
P3: Genomic Profiling
Moderator: Austin Caudle, MSc, Associate Director, Business Development, IQVIA

Session Description: Our understanding of genomics is dramatically changing healthcare, leading the way to personalized care. Advances in the field of DNA sequencing and the ability to collect and analyze large amounts of data quickly has played a critical role in the evaluation of research. Using genomic profiling it is possible to map an individual’s unique genomic profile, providing physicians with invaluable information to help determine the best treatment. It can be used to find out why certain people get diseases while others do not, or why people react differently to the same drug. Likewise, this data can help biotech companies make informed decisions in their R&D investments. This session will explore the role of genomic profiling as a tool for identifying the potential risk of certain health conditions and application of treatment strategies/therapies that are tailored to the genetic profile of each patient.

8:30 a.m. - 9:00 a.m.
Learning from Kymriah, a CAR-T Therapy Which Targets B Cell Malignancies
Vadim V. Romanov, MD, MPhil, FFPM, Executive Medical Director, CAR-T, Novartis Pharmaceuticals Corporation

9:00 a.m. - 9:30 a.m.
Genomic Profiling from the Perspective of B2C
Victor Weigman, PhD, Director, Translational Genomics, IQVIA

9:30 a.m. - 10:00 a.m.
Questions and Answers/Discussion

8:30 a.m. - 10:00 a.m.
PDA Publications Meeting (Invitation Only)

9:45 a.m. - 6:30 p.m.
Exhibit Hall Open

10:00 a.m. - 10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall

Poster Presentations
The following posters will be presented during refreshment breaks on Tuesday and Wednesday

1 - Non-Destructive CCIT (Leak Detection) of Assembled Auto Injectors - Challenges and Successes
Paul Bilotti, North America Sales Manager, Wilco-USA

2 - The Prats and Pitfalls of Assessing Cell Viability After Cryopreservation
Brian Hawkins, PhD, Senior Application Scientist, BioLife Solutions

3 - Case Studies in Bacterial Spore and Fungal Spore Excursions in Cleanrooms and Oral Solid Dose Operations
Jim Polarine, Senior Technical Services Manager, STERIS Corporation

4 - Current Regulatory Considerations for Continuous Manufacturing of Pharmaceuticals in Japan
Issei Takayama, Reviewer, Pharmaceuticals and Medical Devices Agency

5 - Pediatric Formulation Development of Epinephrine Injection: A Child’s Play?
Nicolas Thurin, PhD, Manager, Analytical Product Development, Catalent Pharma Solutions
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<td>6</td>
<td>How to Safely Handle and Transport Bulk Drug Substances? Case Study: Extensive Qualification Test for Enhanced Confidence in Liquid BDS Handling Strategies</td>
<td>Elisabeth Vachette, Senior Global Product Manager, Sartorius Stedim FMT SAS</td>
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<td>7</td>
<td>A Time-Saving Recombinant Factor C (rFC) Endotoxin Test Including a Novel Microplate Pre-Coated with Control Standard Endotoxin (CSE) Concentrations and Positive Product Controls</td>
<td>Gregory Devulder, PhD, Endotoxin Program Director, Hyglos GmbH - a bioMérieux company</td>
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<td>8</td>
<td>Determining Performance Improvements by Quality by Design Plungers for Syringes in Auto-Injector Systems</td>
<td>Page McAndrew, PhD, Director, Scientific Communications</td>
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<td>9</td>
<td>Maximizing Sterility Assurance using Aseptic Component Wrapping Systems</td>
<td>Aaron Mertens, Technical Service Specialist, West Pharmaceutical Services</td>
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<td>10</td>
<td>Evolution of Container Closure Integrity Testing: 5 Case Studies on Prefilled Syringes</td>
<td>Lisa Caralli, Senior Director of Pharmaceuticals, Catalent Pharma Solutions</td>
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<td>11</td>
<td>Process Validation Risk-Based Lifecycle Approach - Oral Solid and Semi-Solid Dosages</td>
<td>Igor Gorsky, Senior Consultant, ValSource, LLC</td>
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<td>12</td>
<td>Feasibility Evaluation of Blow Fill Seal Process and Compatibility with Aluminum Phosphate Adjuvanted Recombinant RSV F Vaccine</td>
<td>Yen-Huei Lin, PhD, Senior Director, Formulation and Drug Product Development, Novavax</td>
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<td>13</td>
<td>Incorporating Diverse Patient Needs and Preferences into a Medical Device Offering</td>
<td>Aditya Ravi, Product Manager, North America and Europe, BD Medical – Pharmaceutical Systems</td>
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<td>14</td>
<td>Striving for Zero Visible Particles: Practical Implementation in Elastomer Closure Manufacturing and Quality Control</td>
<td>Rahul Thakar, PhD, Technical Manager, Datwyler Pharma Packaging</td>
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<td>15</td>
<td>Impact of Selected Elements on the Accelerated Stability of Human Lysozyme</td>
<td>Erica Tullo, PhD, Technology Manager, Extractables and Leachables, West Pharmaceutical Services</td>
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<td>16</td>
<td>Improving Product Quality During Technical Transfers</td>
<td>Eric Good, PhD, Director, Compliance Services, ProPharma Group</td>
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<td>17</td>
<td>Developing a High-Throughput Formulation Development Platform for High-Concentration, Therapeutic Monoclonal Antibodies</td>
<td>Jessica Ripley, MS, Scientist, Process and Formulation Development, Catalent Biologics</td>
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<td>18</td>
<td>A Continuous Improvement Metric for Pharmaceutical Manufacturing</td>
<td>Ajay Babu Pazhayattil, Associate Director, Apotex Inc.</td>
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<td>19</td>
<td>Understanding the Science Behind Liquid Leak and Microbial Ingress Mechanisms as the Foundation for Single Use Container Closure Integrity (SU-CCI)</td>
<td>Marc Hogreve, Senior Engineer Integrity Testing Solutions, Sartorius Stedim Biotech GmbH</td>
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<td>20</td>
<td>A Proactive Approach to the Particulate Management Lifecycle in Parenteral Drug Products</td>
<td>David Exline, President, Gateway Analytical</td>
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**Authors:**
- Elisabeth Vachette
- Gregory Devulder, PhD
- Page McAndrew, PhD
- Aaron Mertens
- Lisa Caralli
- Igor Gorsky
- Yen-Huei Lin, PhD
- Aditya Ravi
- Rahul Thakar, PhD
- Erica Tullo, PhD
- Eric Good, PhD
- Jessica Ripley, MS
- Ajay Babu Pazhayattil
- Marc Hogreve
- David Exline

**Companies:**
- Sartorius Stedim FMT SAS
- Hyglos GmbH - a bioMérieux company
- West Pharmaceutical Services
- Novavax
- BD Medical – Pharmaceutical Systems
- Datwyler Pharma Packaging
- Catalent Biologics
- Apotex Inc.
- Sartorius Stedim Biotech GmbH
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<tr>
<td>10:45 a.m.</td>
<td>Insights on the Manufacturing Floor</td>
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<tr>
<td>10:45 a.m.</td>
<td><em>Michele D’Alessandro</em>, Vice President and Chief Information Officer, Manufacturing IT, Merck &amp; Co., Inc.</td>
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<tr>
<td>10:45 a.m.</td>
<td>Strategies and Complexities around Outsourcing of Labs</td>
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<td></td>
<td><em>Jeffrey T. Gelwicks</em>, PhD, Senior Director, Global Quality Labs, <em>Eli Lilly and Company</em></td>
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### Concurrent Sessions

**Track: Innovative Manufacturing Strategies**

**A1: IT: So Much More than Technology**
- **Moderator:** Aaron R. Goerke, PhD, Director/Head of MSAT, Singapore Technical Operations, *F. Hoffmann-La Roche Ltd.*

**B1: In-House vs. CMO**
- **Moderator:** Marcia C. Baroni, Director, QC Microbiology & EM/Sterility Assurance, *Eli Lilly and Company*

**Interest Group**
- **IG1:** Process Validation
  - **Leader:** Scott Bozzone, PhD, Principal, *Pharm Lifecycle Validation, LLC*
- **IG2:** Filtration
  - **Leader:** Russell Madsen, President, *The Williamsburg Group, LLC*

**Session Description:**
- The IT revolution is evident all around us, but the emphasis has mostly been on the T, the technology. It is time to recast our gaze to focus on the I, the information. Perhaps this information really means insight. Has your company made this transition and began treating data as an asset and not a cost? Are you getting insight out of information? Responses vary across Pharma manufacturing as do their ability to harness information in novel ways to produce insights of significant value. This session will explore examples of where data is being put to new uses to solve difficult real-world problems. Different strategies, learning’s and challenges encountered, some of which might not have been overcome, will be key takeaways. There is a revolution underway in IT, but it is just as much in the information side of the acronym as in technology.

**Session Description:**
- The face of pharmaceutical manufacturing has changed drastically in the past two decades. Not only from a technological and science standpoint, but also with regards to the regulatory and political environment. Shorter patent protection, lower price premiums and increasing barriers to reimbursability have created a market where faster development, smaller volumes and increasing levels of customization are not only more common, but also more desirable. Deciding when to invest in house and when to leverage a third party has become a critical business decision, as limited resources must be carefully divided amongst a wider range of needs. Third party companies are being actively leveraged cross all stages of the product lifecycle, from development to launch and through product end of life; from the labs to manufacturing. This session will explore a few of those scenarios, sharing experiences and points to consider when making these critical decisions.

**Session Description:**
- This session will have short presentations on current issues in process validation (PV), followed with open discussion afterwards. A small panel of SMEs will be assembled to lead the open discussions.

**Session Description:**
- Annex 1 includes a controversial paragraph on the integrity test pre-use/post sterilization. This paragraph causes severe problems within the industry. Since the Annex I revision will be published, we require to review the paragraph posted in the revised Annex I and see what activities require to be taken.

We will also inform attendees on new initiatives regarding PUPSIT:
- Statement by filter manufacturers
- Blocking test proposal within PDA TRI
- MOU with BPOG to work together on PUPSIT

**Speakers:**
- **Ajay Pazhayattil**, PhD, Associate Director, *Anotep, Inc.*
- **Michael Long**, PhD, Senior Director, *ValSource LLC*

**Speaker:**
- **Maik W. Jornitz**, MS, CEO, *G-CON Manufacturing*
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| 11:15 a.m. -11:45 a.m. | Beyond the Product – Data, Insights, and Value  
Thomas Seewoester, PhD, Executive Director and Plant Manager, *Amgen Inc.*  
11:45 a.m. -12:15 p.m. | Questions and Answers/Discussion  
Jay Buchanan, Head of US Supply Chain and LATAM External Supply, *Takeda Pharmaceuticals*  
11:45 a.m. -12:15 p.m. | Questions and Answers/Discussion |
| 11:15 a.m. -11:45 a.m. | Contract Manufacturing/Supply Chain  
Jay Buchanan, Head of US Supply Chain and LATAM External Supply, *Takeda Pharmaceuticals*  
11:45 a.m. -12:15 p.m. | Questions and Answers/Discussion |
| 12:15 p.m. -1:45 p.m. | Networking Luncheon in Exhibit Hall  
12:15 p.m. -1:45 p.m. | Portfolio Steering Committee *(Invitation Only)*  
1:45 p.m. - 2:45 p.m. | 2019 Annual Meeting Exhibit Space Draw Meeting  
1:45 p.m. -3:15 p.m. | Concurrent Sessions |

### Concurrent Sessions

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| A2: Control Strategies for Continuous Processing  
Moderator: Melissa Seymour, MBA  
Vice President, Corporate Quality, *Biogen*  
Session Description:  
Continuous manufacturing offers compelling benefits with respect to costs, process flexibility and capacity. In fact, the 21st Century Cures Act, enacted in December 2016, authorized grants to support studying Continuous Manufacturing of drugs and biological products. Control strategies for these processes must also continuously provide assurance of quality, mitigating any risk to product quality because of process variations over time. This session will focus on science and risk based approaches to control strategies that can be implemented to monitor and ensure appropriate understanding of process dynamics and their relation to process conditions and raw material. | B2: Aseptic Processing/Isolators  
Moderator: Shelley Preslar, MBA, PMP, General Manager, *Azzur Group*  
Session Description: The need for improved aseptic manufacturing capabilities has led to innovations in isolator technology. To meet increasing product demand while ensuring patient safety and product quality requires new thinking in implementing aseptic processes and capabilities. To continue to be effective it is necessary to look at systems that are reliable yet flexible. This session will showcase two different strategies for implementation of strategies to improve aseptic processing capabilities. Speakers will share innovative ways to implement robotics and environmental controls. | IG3: Quality Risk Management  
Leaders: Amanda Bishop McFarland, MS, Consultant, *ValSource, LLC* and Emma Ramnarine, Head, Global Biologics Quality Control, *Gentech, A Member of the Roche Group*  
Session Description: Surviving a QRM Program Audit: With new and evolving manufacturing strategies, QRM programs are also evolving to meet new demands and, in some cases, becoming more mature. This change in the environment, Regulatory Authorities are also changing and requiring more from the industry with respect to their QRM programs. In this session we will discuss strategies in presenting a QRM program to Health Authorities, with presenters who will provide actual examples and case studies. | IG4: Biopharmaceutical Manufacturing  
Session Description: BioAB has recently changed the name and scope for the Biotechnology IG. We renamed the IG to Biopharmaceutical Manufacturing as this focus better aligns with PDA’s overall mission to advance pharmaceutical manufacturing science and technology. This session represents the inaugural meeting for the newly formatted Biopharmaceutical Manufacturing IG. The session program includes:  
- Outline the objective and mission of the Biopharmaceutical Manufacturing IG  
- Solicit input from participants on future developments. |
material control. Tools including model-based control, multivariate monitoring, automation and real-time release testing will be discussed as well as identification and rejections of non-conforming segments.

considerations with regards to isolator technology.

Participants will also be working in teams to develop audit strategies and responses to practice scenarios. Examples will be presented that address both what the auditor is expecting as well as how the auditee should plan on responding. This will include both proper and improper use of QRM in audit responses. The session will end with lively dialogue involving both the participants and the presenters, as we work through the scenarios as a group.

directions and focus areas for the IG

Following this introductory discussion, the session will focus on the latest developments in manufacturing science and technology for biopharmaceutical products including advanced cell and gene therapies. The content will include both presentation and time for interactive dialogue addressing topics related to process optimization to streamline operations, improvements to increase efficiency and reduce costs, and approaches for achieving the highest level of biopharmaceutical product quality.

1:45 p.m. -2:15 p.m.
Continuous Manufacturing: Considerations on Controls of a Dynamic Process
Markus Krumme, PhD, Head, Continuous Manufacturing Unit, Novartis

2:15 p.m. -2:45 p.m.
Building Quality in Continuous API Manufacturing: Key Learnings
Erwin Irdam, Principal Engineer, Technical Development, Biogen

2:45 p.m. -3:15 p.m.
Questions and Answers/Discussion

Speakers:
Ghada Haddad, MBA, Executive Director, Global cGMP & Compliance Auditing Organization, Merck & Co., Inc.
Lori Richter, Senior Consultant, ValSource LLC

Speakers:
Weichang Zhou, PhD, Chief Technology Officer, Senior Vice President, Biologics Development and Manufacturing, WuXi Biologics
Peter Makowenskyj, Sales Engineer, G-CON Manufacturing, Inc.

3:15 p.m. -4:00 p.m.
Refreshment Break and Poster Presentations in Exhibit Hall
### Concurrent Sessions

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<td><strong>A3: Agile Bioprocessing</strong>&lt;br&gt;Moderator: Morten Munk, Global Technology Partner, NNE</td>
<td><strong>B3: Trends in Digital Information and Automated Technology</strong>&lt;br&gt;Moderator: Tia Bush, Vice President, Quality, Amgen, Inc.</td>
<td><strong>IG5: Cell and Gene Therapy</strong>&lt;br&gt;Leaders: Michael Blackton, MBA, Vice President, Global Quality, Adapimmune, LLC</td>
<td><strong>IG6: Facilities and Engineering</strong>&lt;br&gt;Leader: Shelley M. Preslar, MBA, PMP, General Manager, Azzur Group</td>
</tr>
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**Session Description:** High production costs, patient affordability and accessibility, and maintaining an uninterrupted supply of product are primary concerns of the biopharmaceutical industry. To address these issues, the term *agile bioprocessing* might best describe the next evolution needed for biopharmaceutical manufacturing. Indeed, industry efforts are now being directed towards reducing the long development cycle times, increasing production flexibility and eliminating processing complexities all with an aim towards addressing current challenges. This session explores innovative approaches being considered for future biopharmaceutical manufacturing operations, with an emphasis on latest developments in continuous bioprocessing.

**Session Description:** The healthcare industry is experiencing unparalleled change. Millions of data points are generated throughout the end-to-end supply chain that can be converted to knowledge and understanding that leads to meaningful and timely action to improve manufacturing processes and drive organizational efficiency. A comprehensive digital strategy and structured data analytics can explore techniques such as visualization, modeling, automation, machine learning, and artificial intelligence to dematerialize manufacturing processes and facilities and drive productivity through fewer errors, higher output, and improved quality, safety, and speed. This session will explore case studies where companies have advanced their digital strategy to deliver meaningful value and advancements to the business.

**Session Description:** The session will introduce the first program for the Cell and Gene Therapy Interest Group. This session will:
- Outline the objective and mission of the Cell and Gene Therapy Interest Group.
- Provide a 30-minute presentation on risk assessment for aseptic processing for cell therapy. This presentation will be a case study and set of recommendations for the establishment of an effective aseptic processing verification program for these innovative products.

**Session Description:** The Facilities and Engineering Interest Group can cover many specific technical interests within the industry as they relate to Manufacturing Facilities and Engineering capabilities. There has been a tremendous amount of discussion around Aging Facilities the past couple of years, so for this meeting, the focus will shift to look at innovation. During the B2 session, we heard about two different approaches to improving aseptic manufacturing capabilities. In this IG session, we will continue to talk with those speakers to take a bit of a deeper dive into their presentations to learn more about their specific examples.

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**4:00 p.m. - 4:30 p.m.**  
**Continuous Processing Strategies - nextBioPharmDSP**<br>Gorazd Hribar, PhD Project Manager Next BioPharm DSP and Research Scientist, Lek, A Sandoz Company

** Speakers:**
- Marsha Steed (Hardiman), Senior Consultant, ValSource, LLC
- Darius Pillsbury, Head of Quality Lifecycle Management, Adapimmune LLC

**4:00 p.m. - 4:30 p.m.**  
**New Approaches to Harnessing Data at a Portfolio Level**<br>Patrick Gammel, PhD, Director, Process Development, Amgen, Inc.

** Speakers:**
- Guenther Gapp, PhD, Consultant, Gapp Quality GmbH
- Terrence E. Hollis, Process Engineering Manager, Patheon
4:30 p.m. - 5:00 p.m.  
**Streamlining Biopharmaceutical Decision-Making: Designing for Manufacturability, Facility Fit and Cost-Effectiveness**  
Suzanne Farid, PhD, CEng, FIChemE, Professor and Co-Director, Future Targeted Healthcare Manufacturing Hub, Department of Biochemical Engineering, University College London  
5:00 p.m. - 5:30 p.m.  
Questions and Answers/Discussion

4:30 p.m. - 5:00 p.m.  
**The Rise of Human Data Science in the Real World: Eight Environments for Innovation**  
Malcolm R. Postings, Vice President, Head of Innovation & Emerging Technologies, IQVIA  
5:00 p.m. - 5:30 p.m.  
Questions and Answers/Discussion

Panelist:  
Ute Schleyer, PhD, Project Manager, Plant and Site Development, Vetter Pharma-Fertigung GmbH & Company KG

5:30 p.m. - 6:30 p.m.  
Happy Hour in the Exhibit Hall

**Wednesday, March 21**

7:30 a.m. - 3:15 p.m.  
Registration Open

7:30 a.m. - 8:30 a.m.  
Continental Breakfast

7:30 a.m. - 1:45 p.m.  
2019 Annual Meeting Exhibit Space Draw Meeting

8:30 a.m. - 10:00 a.m.  
P4: Increasing Capacity and Capability without Increasing Costs  
Moderator: Maik W. Jornitz, MS, CEO, G-CON Manufacturing  
**Session Description:** In the past capacity and capability increases meant lengthy, but especially cost intensive expansions of rigid production and process infrastructures. New technology platforms, like single-use processes create the ability to increase or utilize the current capacity in a more flexible, but also efficient way. The new process technologies furthermore enable new process models like continuous processing. The factors listed will change our current thinking of investments to be made, capacity flexing and capacity location, to name a few. Examples of such innovative production and processing platforms will be presented as well as the benefits of such.

8:30 a.m. - 9:00 a.m.  
Transforming Operations with Next-Generation Biomanufacturing  
Arleen C. Paulino, Vice President, Singapore Site Operations, Amgen, Inc.

9:00 a.m. - 9:30 a.m.  
Improving Operational Performance Using a Resilience Engineering Approach: A Case Study  
Amy D. Wilson, PhD, Director, Global Human Performance, Biogen  
9:30 p.m. - 10:00 a.m.  
Questions & Answers/Discussion

9:45 a.m. - 1:45 p.m.  
Exhibit Hall Open

10:00 a.m. - 10:45 a.m.  
Refreshment Break and Poster Presentations in Exhibit Hall
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<th>Track: Handling Complexity in the Product Value Chain</th>
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<tr>
<td>A4: Implementing Manufacturing Innovation Moderator: Ursula Busse, PhD, Head Quality Intelligence, External Relations, Novartis</td>
<td>B4: Addressing Unique Challenges of Patient-Centric Supply Chain Needs Moderator: Karen Walker, Vice President, Quality, Seattle Genetics</td>
<td>IG7: Visual Inspection of Parenterals Leader: John G. Shabushnig, PhD, Principal Consultant, Insight Pharma Consulting, LLC and Richard (Rick) Watson, Director, Sterile &amp; Validation, COE, Merck &amp; Co., Inc.</td>
<td>IG8: Combination Products Leader: Lee Leichter, President, P/L Biomedical</td>
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</table>

**Session Description:**
Innovation in manufacturing should be at the heart of our efforts to ensure the sustained supply of better, safer medicines to patients. Yet our industry is very slow in adopting the wealth of new manufacturing technologies available. This session will discuss strategies for successful implementation of innovative technologies in pharmaceutical manufacturing, focusing on challenges, success factors and key learnings. Presentations will cover both the technical as well as the cultural and leadership aspects of implementation.

**Session Description:**
With the recent approval of CAR-T therapies in the US, and the explosion in the research into these types of therapies, there are over 300 trials listed on ClinicalTrials.gov, and over 40 active. CAR-T is not the only Patient Centric therapy being developed, and with this increase in active clinical studies, there is increased attention on managing the supply chain for these types of products. During this session, we will hear how the shift to a more patient-focused supply chain has impacted manufacturing models, price, cost, and complexity. We will also explore some proven solutions to the challenges posed.

**Session Description:**
This Interest Group session will focus on the inspection of injectable products, specifically those considered “difficult to inspect” such as lyophilized powders, suspensions and protein solutions, as well as those in amber glass or plastic containers. A review of the recently published PDA Technical Report on this subject will be included in the agenda. A brief presentation reviewing relevant recalls, warning letters and 483 observations will be given followed by a moderated discussion on inspection topics of interest to those in attendance. Past discussions have included current experience with USP <790> and <1790>, selection and training of inspectors who perform manual inspection, industry benchmarks for inspection practices and inspection results.

**Session Description:**
This session will include a discussion of the concepts, expertise, expectations, and requirements for a pharmaceutical company to develop, manufacture, and market a combination product. Topics will include areas, such as:
- Design Controls
- Mechanical/Electronic Engineering
- Risk Management
- Human Factors Engineering
- Device Software Engineering, validation and controls
- Mobile Medical Applications
- Medical Device Reports (MDRs)
- Device Purchasing Controls
- Change Management for devices
- Functional Stability
- Drug Compatibility

This session will help attendees gain an appreciation for the challenges of successfully developing, manufacturing, and marketing a combination product within the pharmaceutical company environment.
10:45 a.m. - 11:15 a.m.
Next Generation Advancements – Treatment Modalities, Innovative Manufacturing and Novel Attribute Assessments
Michael Abernathy, MS, RAC, Executive Director, Regulatory Affairs CMC, Amgen Inc.

11:15 a.m. - 11:45 a.m.
The Human Side of Innovation
Pierre Boulas, PhD, Senior Director, Pharmaceutical Development, Biogen

11:45 a.m. - 12:15 p.m.
Questions and Answers/Discussion

10:45 a.m. - 11:15 a.m.
Industry Perspective on Patient-Centric Supply Chain Needs
Kirstin Powel, Global Quality Head, CGTDM, Novartis Pharmaceuticals Corporation

11:15 a.m. - 11:45 a.m.
Intelligent Biomanufacturing and the Impact on Facility Design on the Factory of the Future
Jeffery Odum, Global Technology Partner, NNE

11:45 a.m. - 12:00 p.m.
Successful Commercialization of CAR T-Cell therapies: COG Versus Reimbursement Perspectives
Suzanne Farid, PhD, CEng, FIChemE, Professor and Co-Director, Future Targeted Healthcare Manufacturing Hub, Department of Biochemical Engineering, University College London

12:00 p.m. - 12:15 p.m.
Questions and Answers/Discussion

Speakers:
Viky Verna, MS, RAC, Senior Regulatory Affairs Consultant, Confinis AG
Susan Neadle, Head, Combination Products Center of Excellence and Sr. Director, Quality Engineering & Design-to-Value and Product Quality Management (PQM), Janssen Pharmaceuticals

12:15 p.m. - 1:30 p.m.
Interest Group Leaders Meeting (Invitation only)

12:15 p.m. - 1:45 p.m.
Networking Luncheon and Passport Raffle in Exhibit Hall

1:45 p.m. - 3:15 p.m.
P5: Personalized Medicine
Moderator: Ghada Haddad, MBA, Executive Director, cGMP & Compliance Auditing Organization, Merck & Co., Inc.

Session Description: Until now, most medical treatments have been designed for the “average patient.” Because of this “one-size-fits-all” approach, treatments can be very successful for some patients but not for others. Precision Medicine, on the other hand, is an innovative approach that considers individual differences in people’s genes, environments, and lifestyles. It gives medical professionals the resources they need to target the specific treatments of the illnesses we encounter, further develops our scientific and medical research, and keeps our families healthier. Advances in Precision Medicine have already led to powerful new discoveries and several new treatments that are tailored to specific characteristics, such as a person’s genetic makeup, or the genetic profile of an individual’s tumor. This is helping transform the way we can treat diseases such as cancer: Patients with breast, lung, and colorectal cancers, as well as melanomas and leukemias, for instance, routinely undergo molecular testing as part of patient care, enabling physicians to select treatments that improve chances of survival and reduce exposure to adverse effects.

In the last few years, we have seen a rapid development of new methods using immunotherapies in treating different types of cancer. By combining immunotherapy with other types of treatment, an increase of the effectiveness may be accomplished. Newer types of immune treatments are now being developed, and they will affect how we treat cancer in the future. This session will explore more about the status of where pharma development is today as well as example of a successful research.

1:45 p.m. - 2:15 p.m.
Personalized Cancer Vaccines
Rainer Mueller, PhD, Global Technical Head, Personalized Cancer Vaccine Project, Roche Diagnostics GmbH
2:15 p.m. - 2:45 p.m.
Cancer Immunotherapy and Update on Brain Tumor Trials
Matthias Gromeier, MD, Professor, Department of Neurosurgery, Duke University Medical School

2:45 p.m. - 3:15 p.m.
Questions and Answers/ Discussion

3:15 p.m.
Closing Remarks & Adjournment from Co-Chair of the 2019 PDA Annual Meeting Program Planning Committee
Ghada Haddad, MBA, Executive Director, Global cGMP & Compliance Auditing Organization, Merck & Co., Inc.
Melissa Seymour, MBA, Vice President, Corporate Quality, Biogen

7:00 p.m. - 10:00 p.m.
Closing Reception: A Night in Havana
Your full conference badge is required to access this reception.