# Tuesday - March 18

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>10:30am – 10:45am</td>
<td><strong>Welcome and Opening Remarks</strong>&lt;br&gt;Richard M. Johnson, President, PDA</td>
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<td>10:45am – 12:15pm</td>
<td><strong>Session P1: Industry Trends and Regulatory Expectations</strong>&lt;br&gt;Moderator: Hal Baseman, Chief Operating Officer, ValSource, LLC&lt;br&gt;<strong>Session description</strong>&lt;br&gt;Sterile biopharmaceutical product manufacturing remains a dynamic and challenging segment of our industry. This session will bring regulators and industry together to discuss expectations and explore trends focused on the use of technology, risk based decision making, process capability, and quality systems needed to achieve the objective of manufacturing excellence.&lt;br&gt;<strong>Session schedule:</strong>&lt;br&gt;10:45am – 11:15am: Presentation: Regulatory Expectations – Pharmaceutical Manufacturing&lt;br&gt;Speaker: Richard L. Friedman, Associate Director, Office of Compliance, CDER, FDA&lt;br&gt;11:15am – 11:45am: Presentation: Driving Manufacturing Excellence&lt;br&gt;Speaker: Michael Long, PhD, Director &amp; Principal Consultant, ConcordiaValSource, LLC&lt;br&gt;11:45am – 12:15 pm: Q&amp;A/Discussion</td>
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<td>12:15pm – 1:45pm</td>
<td><strong>PDA Education Program Lunch</strong> (Show Floor)</td>
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<td>1:45pm – 3:15pm</td>
<td><strong>Session P2: Biopharmaceutical and Sterile Manufacturing</strong>&lt;br&gt;Moderator: Maik Jornitz, Chief Operating Officer, G-Con Manufacturing LLC&lt;br&gt;<strong>Session description:</strong>&lt;br&gt;Most biopharmaceutical drug products cannot be heat sterilized and therefore a high reliance on aseptic processing is required. New technologies, single-use technologies for example, support aseptic processing efforts, and elevate the safety and security of the process activities. This session will address aseptic processing tasks, points to consider, and new technologies which enable process safety expansion and economic efficiencies.&lt;br&gt;<strong>Session schedule:</strong>&lt;br&gt;1:45pm – 2:15pm: Presentation: Aseptic Spray Drying – A Valid Alternative to Lyophilization&lt;br&gt;Speaker: Andrew P. Birkmire, Process Development Manager, GEA Process Engineering&lt;br&gt;2:15pm – 2:45pm: Presentation: When Secure Becomes Safe in Aseptic Processing – Single-Use Technologies as an Enabler&lt;br&gt;Speaker: Maurice Phelan, BioProcess Services Leader, GE Healthcare Life Sciences&lt;br&gt;2:45pm – 3:15pm: Q&amp;A/Discussion</td>
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<td>3:15pm – 3:30pm</td>
<td><strong>Break</strong> (PDA Education Program Area)</td>
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<td>3:30pm – 5:00pm</td>
<td><strong>Session P3: PDA Facilities/Engineering Interest Group Meeting</strong>&lt;br&gt;Moderator: Christopher Smalley, PhD, Director, BioSterile Validation, Merck &amp; Co., Inc.&lt;br&gt;<strong>Session description:</strong>&lt;br&gt;This session is intended to explore techniques and designs to make our facilities more flexible. We are leaving the era where massive facilities capable of producing large quantities of a block-buster drug made sense. Now, we need to build with smaller, less costly footprints to facilitate shorter distribution lines for products that have fragile stability; smaller, less costly clean environments by embracing isolators and RABS effectively; achieving flexibility and shorter turn-around by using Single Use Components. These facilities need to incorporate new technologies for PAT and Continuous Verification seamlessly, and at the same time be able to quickly shift to new products and processes to meet rapidly changing market demands with no risk of cross contamination. Make your manufacturing process a competitive advantage to your firm.&lt;br&gt;<strong>Session schedule:</strong>&lt;br&gt;3:30pm – 4:00pm: Presentation: Market Influence on Facility Design&lt;br&gt;Speaker: Matt Roberge, Senior Director, Global Supply, Pfizer, Inc.&lt;br&gt;4:00pm – 4:30pm: Presentation: Innovative Use of Isolators in Bulk Vaccine Product Handling&lt;br&gt;Speaker: David Moyle, Senior Specialist, Global Engineering Services, Merck &amp; Co., Inc.&lt;br&gt;4:30pm – 5:00pm: Q&amp;A/Discussion</td>
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<td>Time</td>
<td>Session P4: Prefilled Syringe/Drug Delivery Technology</td>
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| 10:30am – 10:40am | Presentation: Challenges and Opportunities for the Prefilled Syringe/Drug Delivery Technology  
Speaker: Michael F. Chiappetta, PhD., Research Advisor-DDR&D Advanced Development - Eli Lilly and Company |
| 10:40am – 11:00am | Presentation: Improvements in Needle Technology for Prefilled Syringes  
Speaker: Kevin Constable, Director of Technology Development, Terumo Medical Corporation |
| 11:00am – 11:20am | Presentation: Next generation of Plastic Syringes and Lubricants  
Speaker: Kevin Turney, PhD, Senior Application Development Scientist, SiO2 Medical Products |
| 11:20am – 11:40am | Presentation: Novel Approaches to Flexible Syringe Filling Lines  
Speaker: Wenzel Novak, PhD, Director of Pharmaceutical R&D, Groninger & Co. gmbh |
| 11:40am – 12:00pm | Q&A/Discussion |

| 12:00pm – 1:30pm | PDA Education Program Lunch (Show Floor) |

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<th>Time</th>
<th>Session P5: Supply Chain for the 21st Century</th>
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| 1:30pm – 2:00pm | Presentation: Track and Trace  
Speaker: Michael Blackton, AVP Validation Technical Services, Imclone Systems |
| 2:00pm – 2:30pm | Presentation: Patients are Counting on Us: It’s Time to Act  
Speaker: Brian Johnson, Senior Director, Supply Chain Security, Pfizer, Inc. |
| 2:30pm – 3:00pm | Q&A/Discussion |

| Time       | Break (PDA Education Program Area) |

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<tr>
<th>Time</th>
<th>Session P6: Parenteral Packaging</th>
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| 3:15pm – 3:45pm | Presentation: Container Closure Strategies for Parenteral Products, and the New Techniques that are Available  
Speaker: Akshay R. Kamdar, Ph.D., Senior Consultant Engineer, Packaging Development, Packaging and Device Design and Development, Eli Lilly and Company |
| 3:45pm – 4:15pm | Presentation: Ez-Ecopak and Equipment Fill-Finish Lines  
Speaker: Paolo Golfetto, Business Development & Customer Care Director, Nuova OMPI, Stevanato Group |
| 4:15pm – 4:45pm | Q&A/Discussion |
## Thursday - March 20

### 10:30am – 12:00pm

#### Session P7: PDA Pharmaceutical Water Interest Group Meeting

**Moderator:** Igor Gorsky, Senior Consultant, ConcordiaValSource, LLC

**Session description:**
The Water Interest Group addresses topics in pharmaceutical water quality, analytical and microbiological control, rouging and biofilm concerns, continued water monitoring and compendial issues. The interest group is providing for an on-going forum for the exchange and dissemination of information and ideas for the purpose of education, innovation, and compliance related to purified water science. In addition, the interest group is fostering scientific and technical activities through the development of guidelines, technical reports, and technical bulletins and recommendations of other activities such as conferences or training courses on subject of on-going purified water quality.

In a spirit of this mission the PDA Water interest group will be offering two presentations on the subjects of process oriented validation practices and state of the art controls that could improve water systems quality and greatly contribute to process consistency.

**Session schedule:**
- **10:30am – 11:00am**
  - Presentation: Monitoring and Continued Verification of Water Systems, Application of Lifecycle Approach
  - **Speaker:** Igor Gorsky, Senior Consultant, ConcordiaValSource, LLC

- **11:00am – 11:30am**
  - Presentation: Ultrapure Water – Quality and Technology to Support Advanced Industries’ Needs
  - **Speaker:** Vyacheslav (Slava) Libman, Water Lab Director, Air Liquide-Balazs Nanoanalsis

- **11:30am – 12:00 pm**
  - Q&A/Discussion on New Trends in Pharmaceutical Water Systems

### 12:00pm – 12:30pm

#### PDA Education Program Lunch (Show Floor)

### 12:30pm – 3:00pm

#### Session P8: Closing Plenary-Aging Facilities

**Moderator:** Richard M. Johnson, President, PDA

**Session description:**
Pharmaceutical manufacturing is dependent upon facility design and maintenance, and many companies are faced with decisions about aging facilities. This session will provide an update on the PDA Task Force that is discussing strategies and risk management of Aging Facilities, and discuss some specific examples of unique challenges that manufacturers must deal with these facilities to maintain Good Manufacturing Practice as well as decision tools for balancing upgrade/replacement.

**Session schedule:**
- **1:45pm – 2:15pm**
  - Presentation: PDA Aging Facility Task Force – Scope, Deliverables and Up-date
  - **Speaker:** Maik Jornitz, Chief Operating Officer, G-Con Manufacturing LLC

- **2:15pm – 2:45pm**
  - Presentation: Aging Facilities: Are They Being Asked to Do Something More or Different Than Designed For?
  - **Speaker:** Christopher Smalley, PhD, Director, BioSterile Validation, Merck & Co., Inc.

- **2:45pm – 3:00pm**
  - Q&A/Discussion

### 3:00pm

#### Closing Remarks

**Richard M. Johnson, President, PDA**

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**How to Register:** To register to attend the PDA Education@INTERPHEX Program, contact 203-840-5603, 888-745-2529 (toll free), or email inquiry@interphex.com. Or you can register online by clicking here and selecting which session/pass you would like to attend.