

# PDA Good Aseptic Manufacturing Conference 2026 Agenda



**Thursday, 11 June**

CEST Daylight Time (UTC +2:00)

09:00 – 09:10	<p><b>Welcome and Introduction</b></p> <p><b>Committee Member:</b> Falk Klar PhD, General Manager, Vice President Europe, <i>Parenteral Drug Association</i></p>				
09:10 – 09:20	<p><b>Welcome from the Co-Chairs</b></p> <p><b>Co-Chair:</b> David Keen , Director Pharmaceutical Microbiology &amp; Consulting, <i>Ecolab Life Sciences</i></p> <p><b>Co-Chair:</b> Tarik Cheema PhD Asset Excellence Lead - Pre-Filled Syringe Line <i>F. Hoffmann-La Roche AG</i></p>				
09:20 – 10:35	<p><b>Opening Session-Part I</b></p> <p><b>Moderator:</b> Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i></p> <table border="1"> <tr> <td>09:45 – 10:10</td> <td> <p><b>Morning Coffee Chat</b></p> <ul style="list-style-type: none"> <li><b>Regulatory Panelist:</b> Daniel Mueller PhD, Head of GMDP-Inspectorate, <i>Regierungspraesidium Tuebingen, Germany</i></li> <li><b>Panelist:</b> Richard Denk , Senior Consultant Aseptic Processing, <i>SKAN AG</i></li> </ul> </td> </tr> <tr> <td>10:10 – 10:35</td> <td> <p><b>Quality Maturity as a Competitive Advantage: What the FDA Is Really Signaling to Aseptic Manufacturers</b></p> <ul style="list-style-type: none"> <li><b>Keynote Speaker:</b> John Claud JD, Partner, <i>Nelson Mullins Riley &amp; Scarborough LLP</i></li> </ul> </td> </tr> </table>	09:45 – 10:10	<p><b>Morning Coffee Chat</b></p> <ul style="list-style-type: none"> <li><b>Regulatory Panelist:</b> Daniel Mueller PhD, Head of GMDP-Inspectorate, <i>Regierungspraesidium Tuebingen, Germany</i></li> <li><b>Panelist:</b> Richard Denk , Senior Consultant Aseptic Processing, <i>SKAN AG</i></li> </ul>	10:10 – 10:35	<p><b>Quality Maturity as a Competitive Advantage: What the FDA Is Really Signaling to Aseptic Manufacturers</b></p> <ul style="list-style-type: none"> <li><b>Keynote Speaker:</b> John Claud JD, Partner, <i>Nelson Mullins Riley &amp; Scarborough LLP</i></li> </ul>
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10:35 – 11:05	<p><b>Networking Coffee Break, Poster Session &amp; Exhibition</b></p>				
11:05 – 12:00	<p><b>Opening Session-Part II</b></p> <p><b>Moderator:</b> Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i></p> <table border="1"> <tr> <td>11:05 – 11:20</td> <td> <p><b>Current and Recent Projects Governed by the PDA Science Advisory Board</b></p> <ul style="list-style-type: none"> <li><b>Presenter:</b> Julian Petersen , Head of Business Development Pharma, <i>groninger &amp; co gmbh</i></li> </ul> </td> </tr> <tr> <td>11:20 – 12:00</td> <td> <p><b>Panel Discussion on the Recent Status of Implementation of EU GMP Annex 1: 2022 from Different Perspectives</b></p> <ul style="list-style-type: none"> <li><b>Moderator:</b> Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i></li> <li><b>Panelist:</b> David Keen , Director Pharmaceutical Microbiology &amp; Consulting, <i>Ecolab Life Sciences</i></li> </ul> </td> </tr> </table>	11:05 – 11:20	<p><b>Current and Recent Projects Governed by the PDA Science Advisory Board</b></p> <ul style="list-style-type: none"> <li><b>Presenter:</b> Julian Petersen , Head of Business Development Pharma, <i>groninger &amp; co gmbh</i></li> </ul>	11:20 – 12:00	<p><b>Panel Discussion on the Recent Status of Implementation of EU GMP Annex 1: 2022 from Different Perspectives</b></p> <ul style="list-style-type: none"> <li><b>Moderator:</b> Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i></li> <li><b>Panelist:</b> David Keen , Director Pharmaceutical Microbiology &amp; Consulting, <i>Ecolab Life Sciences</i></li> </ul>
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- **Panelist: John Claud JD**, Partner, *Nelson Mullins Riley & Scarborough LLP*
- **Panelist: Julian Petersen**, Head of Business Development Pharma, *groninger & co gmbh*

12:00 – 12:30 **LIVE Guided Poster Walk**

12:30 – 13:20 **Networking Lunch Break, Poster Session, Exhibition**

**Session 1 Track A: Airflow and Isolator Design for First Air Integrity in Aseptic Processing**

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

**Behind the Isolator: Design and Operational Challenges in Meeting Regulatory Expectations**

- 13:20 – 13:40
- **Presenter: Anna Campanella PhD**, Global Aseptic Processing & Sterility Assurance Lead, *Takeda Pharmaceuticals International AG*

**Protective Airflow in Aseptic Manufacturing - Ensuring First Air Integrity**

- 13:40 – 14:00
- **Presenter: Hussein Bachir PhD**, Senior Scientist - GMP Compliance, *Franz Ziel GmbH*

**Q&A, Discussion**

- 14:00 – 14:30
- **Moderator: Julian Petersen**, Head of Business Development Pharma, *groninger & co gmbh*
  - **Panelist: Anna Campanella PhD**, Global Aseptic Processing & Sterility Assurance Lead, *Takeda Pharmaceuticals International AG*
  - **Panelist: Hussein Bachir PhD**, Senior Scientist - GMP Compliance, *Franz Ziel GmbH*

**Session 1 Track B: Automation Meets Microbiology: The Future of EM and Disinfection Validation**

**Moderator: Vanessa A. Figueroa MA**, Chief Microbiologist, *VVF Science*

**Transforming Environmental Monitoring: Automation Solutions for the Pharmaceutical Industry**

- 13:20 – 13:40
- **Presenter: Stephanie Kremser**, Innovation Product Manager, *Merck*

**Future of Disinfection Efficacy Testing: Aligning Validation to Regulatory Landscapes**

- 13:40 – 14:00
- **Presenter: Laura Brennan**, Director of Technical Consulting, *Ecolab*

**Q&A, Discussion**

- 14:00 – 14:30
- **Moderator: Vanessa A. Figueroa MA**, Chief Microbiologist, *VVF Science*
  - **Panelist: Stephanie Kremser**, Innovation Product Manager, *Merck*

14:30 – 15:00 **Networking Coffee Break, Poster Session & Exhibition**

**Session 2 Track A: Towards Human-Free Aseptic: Robotics, Automation & Gloveless Systems**

**Moderator: Klaus Ullherr Dipl.-Ing. (FH)**, Senior Product Manager, *Syntegon Technology GmbH*

**Cycle Development on a Fully Gloveless Isolator**

- 15:00 – 15:20
- **Co-Presenter: Theresa Ladwig**, Sterility Assurance Service Manager, *SKAN AG*
  - **Co-Presenter: Bianca Bohrer Dipl Ing**, Managing Director, *PSM GmbH*

15:00 – 16:10	<p><b>Innovative Microbiological Sampling Strategies in Grade A Gloveless Isolators for ATMP Manufacturing</b></p> <p>15:20 – 15:40</p> <ul style="list-style-type: none"> <li>• <b>Co-Presenter: Valentina Casalone Master Degree</b>, Sterility Assurance Senior Quality Manager, <i>Thermo Fisher</i></li> <li>• <b>Co-Presenter: Alessandra Benassi PharmD</b>, Laurea specialista in Farmacia industriale, <i>Università di Bologna (Italy)</i></li> </ul>
	<p><b>Q&amp;A, Discussion</b></p> <p>15:40 – 16:10</p> <ul style="list-style-type: none"> <li>• <b>Moderator: Klaus Ullherr Dipl.-Ing. (FH)</b>, Senior Product Manager, <i>Syntegon Technology GmbH</i></li> <li>• <b>Panelist: Theresa Ladwig</b>, Sterility Assurance Service Manager, <i>SKAN AG</i></li> <li>• <b>Panelist: Bianca Bohrer Dipl Ing</b>, Managing Director, <i>PSM GmbH</i></li> <li>• <b>Panelist: Valentina Casalone Master Degree</b>, Sterility Assurance Senior Quality Manager, <i>Thermo Fisher</i></li> <li>• <b>Panelist: Alessandra Benassi PharmD</b>, Laurea specialista in Farmacia industriale, <i>Università di Bologna (Italy)</i></li> </ul>

**Session 2 Track B: Aseptic Process Simulations**

**Moderator: Hue Kwon PhD**, Global Head Quality External Operations, *SOBI*

15:00 – 16:10	<p><b>Reframing Aseptic Process Simulations: Modern Expectations Aligned with EU GMP Annex 1 &amp; PDA Technical Report 22</b></p> <p>15:00 – 15:20</p> <ul style="list-style-type: none"> <li>• <b>Presenter: Vanessa A. Figueroa MA</b>, Chief Microbiologist, <i>VVF Science</i></li> </ul>
	<p><b>APS Challenges and Proposed Solutions</b></p> <p>15:20 – 15:40</p> <ul style="list-style-type: none"> <li>• <b>Presenter: Alberto Gonzalez</b>, Global Sterility Assurance Associate Director, <i>Takeda</i></li> </ul>
	<p><b>Q&amp;A, Discussion</b></p> <p>15:40 – 16:10</p> <ul style="list-style-type: none"> <li>• <b>Moderator: Hue Kwon PhD</b>, Global Head Quality External Operations, <i>SOBI</i></li> <li>• <b>Panelist: Vanessa A. Figueroa MA</b>, Chief Microbiologist, <i>VVF Science</i></li> <li>• <b>Panelist: Alberto Gonzalez</b>, Global Sterility Assurance Associate Director, <i>Takeda</i></li> </ul>

16:10 – 17:40 **Interactive Round Table Session Track A**

16:10 – 17:40 **Interactive Round Table Session Track B**

17:40 – 17:40 **End of Conference Day 1 & Networking Event**

## Friday, 12 June

CEST Daylight Time (UTC +2:00)

**Session 3 Track A: From Development to Commercial Manufacturing**

**Moderator: Richard Denk**, Senior Consultant Aseptic Processing, *SKAN AG*

09:00 – 09:20	<p><b>Process Validation Strategy for Aseptic Drug Product Manufacturing: From New Product Introduction (NPI) to Process Performance Qualification (PPQ) and Continued Process Verification (CPV)</b></p>
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- **Presenter: Jaehyun Kim** , Lead Specialist, *Samsung Biologics*

09:00 – 10:10

09:20 – 09:40

**Aseptic Manufacturing of Antibody Drug Conjugates: Points to Consider in Process Development and Validation**

- **Presenter: Yuan-An Liu PhD**, Director Protein & ADC Drug Product, *BioNTech SE*

09:40 – 10:10

**Q&A, Discussion**

- **Moderator: Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG*
- **Panelist: Jaehyun Kim** , Lead Specialist, *Samsung Biologics*
- **Panelist: Yuan-An Liu PhD**, Director Protein & ADC Drug Product, *BioNTech SE*

**Session 3 Track B: Digital Immersion for Aseptic Technologies**

**Moderator: Peter J. Makowenskyj MEng**, Senior Director of Design Consulting, *G-CON*

09:00 – 09:20

**Augmented Reality Training for Sterile Filter Cartridge Manufacturing**

- **Presenter: Sofia Garcia Fracaro Dr**, Engineering Lead AR/VR, *Merck Life Science*

09:00 – 10:10

09:20 – 09:40

**VR Solution for Training Specific SOPs on Fill & Finish Machines**

- **Presenter: Michael Chudoba** , Product Manager Virtual Engineering, *Bausch+Ströbel SE + Co. KG*

09:40 – 10:10

**Q&A, Discussion**

- **Moderator: Peter J. Makowenskyj MEng**, Senior Director of Design Consulting, *G-CON*
- **Panelist: Sofia Garcia Fracaro Dr**, Engineering Lead AR/VR, *Merck Life Science*
- **Panelist: Michael Chudoba** , Product Manager Virtual Engineering, *Bausch+Ströbel SE + Co. KG*

10:10 – 10:40

**Networking Coffee Break, Poster Session & Exhibition**

**Session 4 Track A: Ready-to-Use**

**Moderator: Simone Biel PhD**, Senior Regulatory Consultant, *Merck KGaA*

10:40 – 11:00

**Particulate Burden in Ready-to-Use Containers for Biological Products**

- **Presenter: Dilara Ali MA**, PhD Student , *ten23 health*

10:40 – 11:50

11:00 – 11:20

**EU GMP Annex 1 and New Ready-to-Use Containers are Driving the Innovation for Fill/Finish Solutions**

- **Presenter: Klaus Ullherr Dipl.-Ing. (FH)**, Senior Product Manager, *Syntegon Technology GmbH*

11:20 – 11:50

**Q&A, Discussion**

- **Moderator: Simone Biel PhD**, Senior Regulatory Consultant, *Merck KGaA*
- **Panelist: Dilara Ali MA**, PhD Student , *ten23 health*
- **Panelist: Klaus Ullherr Dipl.-Ing. (FH)**, Senior Product Manager, *Syntegon Technology GmbH*

**Session 4 Track B: Freeze-Drying**

**Moderator: Yuan-An Liu PhD**, Director Protein & ADC Drug Product, *BioNTech SE*

10:40 – 11:50	10:40 – 11:00	<b>Continuous and Controlled Freeze-Drying According to GMP</b> <ul style="list-style-type: none"><li>• <b>Presenter: Thomas De Beer PhD</b>, Professor, <i>Ghent University</i></li></ul>
	11:00 – 11:20	<b>Efficient. Sustainable. Future-Proof: Rethinking Freeze-Drying Processes</b> <ul style="list-style-type: none"><li>• <b>Presenter: Fabian Plaum M.Eng.</b>, Sales Management, <i>HOF Sonderanlagenbau GmbH</i></li></ul>
	11:20 – 11:50	<b>Q&amp;A, Discussion</b> <ul style="list-style-type: none"><li>• <b>Moderator: Yuan-An Liu PhD</b>, Director Protein &amp; ADC Drug Product, <i>BioNTech SE</i></li><li>• <b>Panelist: Thomas De Beer PhD</b>, Professor, <i>Ghent University</i></li><li>• <b>Panelist: Fabian Plaum M.Eng.</b>, Sales Management, <i>HOF Sonderanlagenbau GmbH</i></li></ul>

11:50 – 12:50 **Networking Lunch Break, Poster Session & Exhibition**

### Closing Plenary Part I

**Moderator: David Keen**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

12:50 – 14:05	12:50 – 13:05	<b>Interactive Questionnaire Session</b> <ul style="list-style-type: none"><li>• <b>Moderator: David Keen</b>, Director Pharmaceutical Microbiology &amp; Consulting, <i>Ecolab Life Sciences</i></li></ul>
	13:05 – 13:25	<b>Beyond Counting: How RFID-Enabled Unit-Level Traceability and Data Analytics Transform Aseptic Manufacturing</b> <ul style="list-style-type: none"><li>• <b>Co-Presenter: Thomas Hiltbrand MSc</b>, Founder and CEO, <i>Crypto Pharma Solutions AG</i></li><li>• <b>Co-Presenter: Emilien Folzer PhD</b>, Principal scientist, <i>ten23 health</i></li></ul>
	13:25 – 13:45	<b>Isolator or RABS? How to Combine the Best Features of Both Technologies</b> <ul style="list-style-type: none"><li>• <b>Presenter: Helen Sauter Dr</b>, Director Quality Assurance, <i>Vetter Pharma Fertigung GmbH &amp; Co. KG</i></li></ul>
	13:45 – 14:05	<b>Transforming Compliance: Digitization and Data in Aseptic Observations</b> <ul style="list-style-type: none"><li>• <b>Presenter: Serena Ambrosini PhD</b>, Global Business Process owner - director sterile manufacturing, <i>AstraZeneca</i></li></ul>

14:05 – 14:35 **Networking Coffee Break, Poster Session & Exhibition**

### Closing Plenary Part II

**Moderator: David Keen**, Director Pharmaceutical Microbiology & Consulting, *Ecolab Life Sciences*

14:45 – 15:35	14:45 – 15:05	<b>Hype, Play, and First Principles: Turning AI Curiosity into Competence in Aseptic Manufacturing</b> <ul style="list-style-type: none"><li>• <b>Presenter: Fabrizio Maniglio</b>, Industry and Business Development Director, <i>Honeywell</i></li></ul>
		<b>Q&amp;A, Discussion</b> <ul style="list-style-type: none"><li>• <b>Moderator: David Keen</b>, Director Pharmaceutical Microbiology &amp; Consulting, <i>Ecolab Life Sciences</i></li><li>• <b>Panelist: Thomas Hiltbrand MSc</b>, Founder and CEO, <i>Crypto Pharma Solutions AG</i></li></ul>

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15:55 – 15:55 **End of Conference**