

# 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" style="width: 100%;"> <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" style="width: 100%;"> <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: Daniel Mueller PhD**, Head of GMDP-Inspectorate, *Regierungspraesidium Tuebingen, Germany*
- **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**

Explore cutting-edge gloveless isolator solutions across two presentations: one detailing cycle development on fully gloveless isolators using VHP decontamination with biological and enzyme indicators and novel technologies to optimize robustness; the second presenting Thermo Fisher's CDMO approach for ATMPs, covering Grade A gloveless isolator deployment, risk-based environmental monitoring, automated VHP cycles, and validated sampling strategies aligned to EU GMP Annex 1. Leave with practical tactics to elevate contamination control and sampling confidence.

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

**Cycle Development on a Fully Gloveless Isolator**

	15:00 – 15:20	<ul style="list-style-type: none"> <li>• <b>Co-Presenter: Theresa Ladwig</b> , Sterility Assurance Service Manager, <i>SKAN AG</i></li> <li>• <b>Co-Presenter: Bianca Bohrer Dipl Ing</b>, Managing Director, <i>PSM GmbH</i></li> </ul>
15:00 – 16:10	15:20 – 15:40	<p><b>Innovative Microbiological Sampling Strategies in Grade A Gloveless Isolators for ATMP Manufacturing</b></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>
	15:40 – 16:10	<p><b>Q&amp;A, Discussion</b></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

This session starts with an overview of the latest expectations for Aseptic Process Simulations (APS) from the revised PDA TR22 and how they align with the intent of EU GMP Annex 1. It then moves into a practical, question-driven presentation focused on common APS challenges and potential solutions. This provides a natural starting point for an interactive Q&A, where we will exchange experiences and perspectives on the audience's APS issues.

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

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

Development to commercial manufacturing often presents the greatest challenge in pharmaceutical manufacturing. Processes that work very well in product development can prove challenging in commercial production. When the product is a highly potent substance, requiring consideration of both product protection in a multi-purpose facility and employee protection from the highly potent substance, a number of requirements come together. This session offers insights, and interesting discussions are guaranteed.

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

09:00 – 10:10

09:00 – 09:20	<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> <ul style="list-style-type: none"><li>• <b>Presenter: Jaehyun Kim</b> , Lead Specialist, <i>Samsung Biologics</i></li></ul>
09:20 – 09:40	<b>Aseptic Manufacturing of Antibody Drug Conjugates: Points to Consider in Process Development and Validation</b> <ul style="list-style-type: none"><li>• <b>Presenter: Yuan-An Liu PhD</b>, Director Protein &amp; ADC Drug Product, <i>BioNTech SE</i></li></ul>
09:40 – 10:10	<b>Q&amp;A, Discussion</b> <ul style="list-style-type: none"><li>• <b>Moderator: Richard Denk</b> , Senior Consultant Aseptic Processing, <i>SKAN AG</i></li><li>• <b>Panelist: Jaehyun Kim</b> , Lead Specialist, <i>Samsung Biologics</i></li><li>• <b>Panelist: Yuan-An Liu PhD</b>, Director Protein &amp; ADC Drug Product, <i>BioNTech SE</i></li></ul>

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

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

09:00 – 10:10

09:00 – 09:20	<b>Augmented Reality Training for Sterile Filter Cartridge Manufacturing</b> <ul style="list-style-type: none"><li>• <b>Presenter: Sofia Garcia Fracaro Dr</b>, Engineering Lead AR/VR, <i>Merck Life Science</i></li></ul>
09:20 – 09:40	<b>VR Solution for Training Specific SOPs on Fill &amp; Finish Machines</b> <ul style="list-style-type: none"><li>• <b>Presenter: Michael Chudoba</b> , Product Manager Virtual Engineering, <i>Bausch+Ströbel SE + Co. KG</i></li></ul>
09:40 – 10:10	<b>Q&amp;A, Discussion</b> <ul style="list-style-type: none"><li>• <b>Moderator: Peter J. Makowenskyj MEng</b>, Senior Director of Design Consulting, <i>G-CON</i></li><li>• <b>Panelist: Sofia Garcia Fracaro Dr</b>, Engineering Lead AR/VR, <i>Merck Life Science</i></li><li>• <b>Panelist: Michael Chudoba</b> , Product Manager Virtual Engineering, <i>Bausch+Ströbel SE + Co. KG</i></li></ul>

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 – 11:50

10:40 – 11:00	<b>Particulate Burden in Ready-to-Use Containers for Biological Products</b> <ul style="list-style-type: none"><li>• <b>Presenter: Dilara Ali MA</b>, PhD Student , <i>ten23 health</i></li></ul>
11:00 – 11:20	<b>EU GMP Annex 1 and New Ready-to-Use Containers are Driving the Innovation for Fill/Finish Solutions</b> <ul style="list-style-type: none"><li>• <b>Presenter: Klaus Ullherr Dipl.-Ing. (FH)</b>, Senior Product Manager, <i>Syntegon Technology GmbH</i></li></ul>

#### Q&A, Discussion

11:20 – 11:50

- **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*

#### Continuous and Controlled Freeze-Drying According to GMP

10:40 – 11:00

- **Presenter: Thomas De Beer PhD**, Professor, *Ghent University*

#### Efficient. Sustainable. Future-Proof: Rethinking Freeze-Drying Processes

10:40 – 11:50

11:00 – 11:20

- **Presenter: Fabian Plaum M.Eng.**, Sales Management, *HOF Sonderanlagenbau GmbH*

#### Q&A, Discussion

11:20 – 11:50

- **Moderator: Yuan-An Liu PhD**, Director Protein & ADC Drug Product, *BioNTech SE*
- **Panelist: Thomas De Beer PhD**, Professor, *Ghent University*
- **Panelist: Fabian Plaum M.Eng.**, Sales Management, *HOF Sonderanlagenbau GmbH*

11:50 – 12:50

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

#### Closing Plenary Part I

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

#### Interactive Questionnaire Session

12:50 – 13:05

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

#### Beyond Counting: How RFID-Enabled Unit-Level Traceability and Data Analytics Transform Aseptic Manufacturing

12:50 – 14:05

13:05 – 13:25

- **Co-Presenter: Thomas Hiltbrand MSc**, Founder and CEO, *Crypto Pharma Solutions AG*
- **Co-Presenter: Emilien Folzer PhD**, Principal scientist, *ten23 health*

#### Isolator or RABS? How to Combine the Best Features of Both Technologies

13:25 – 13:45

- **Presenter: Helen Sauter Dr**, Director Quality Assurance, *Vetter Pharma Fertigung GmbH & Co. KG*

#### Transforming Compliance: Digitization and Data in Aseptic Observations

13:45 – 14:05

- **Presenter: Serena Ambrosini PhD**, Global Business Process owner - director sterile manufacturing, *AstraZeneca*

14:05 – 14:35

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

#### Closing Plenary Part II

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

**Hype, Play, and First Principles: Turning AI Curiosity into Competence in Aseptic Manufacturing**

14:45 – 15:05

- **Presenter: Fabrizio Maniglio** , Industry and Business Development Director, *Honeywell*

**Q&A, Discussion**

14:45 – 15:35

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

- **Panelist: Thomas Hiltbrand MSc**, Founder and CEO, *Crypto Pharma Solutions AG*

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15:55 – 15:55 **End of Conference**