

2022 PDA



# BIOMANUFACTURING CONFERENCE

[pda.org/EU/BioMan2022](http://pda.org/EU/BioMan2022)

**20-21 SEPTEMBER 2022**  
**AMSTERDAM, THE NETHERLANDS**  
EXHIBITION: 20-21 SEPTEMBER 2022  
TRAINING: 22-23 SEPTEMBER 2022

**REGISTER BEFORE 24 JULY 2022**  
**AND SAVE UP TO €200!**



# WELCOME FROM THE CHAIRS

Dear Colleagues,

We welcome you to the next **2022 PDA BioManufacturing Conference**.

This year, the committee has joined forces with the Lyophilization Conference to offer a full experience including emerging trends in biomanufacturing and regulatory focus areas. We will come together as a three-track conference face-to-face in **Amsterdam / The Netherlands on 20-21 September 2022**.

Over the last years, we have seen a tremendous acceleration in all aspects of biopharmaceutical development, due to the health emergency, which revealed many opportunities for exploring new technologies, development approaches, and regulatory frameworks to support rapid access to vaccines and biotherapeutics as well as sustainable life cycle management. The conference will provide the opportunity to discuss all these aspects: the theme of this edition will be Biopharmaceutical Solutions to Prepare for Healthcare Challenges.

The 2022 PDA BioManufacturing Conference will emphasize topics including product, process and analytical development, aseptic manufacturing, supply chain challenges, lifecycle strategies, new technologies, environmental sustainability, and regulatory approaches.

You will have the opportunity to expand your network, interacting with professionals from Industry, Academia, Research Institutes, and Health Agencies.

We look forward to seeing you in September!

Sincerely,  
The Chairs



**Cristiana Campa,**  
*GSK*



**Raf De Dier,**  
*Janssen*

## SCIENTIFIC PROGRAM PLANNING COMMITTEE

**Cristiana Campa,** *GSK, Chair*

**Raf De Dier,** *Janssen, Chair*

**Marta Antunes,** *MSD*

**Thomas Beutler,** *GEA Lyophil*

**Michael De Felippis,** *Eli Lilly*

**Thierry Gastineau,** *Sanofi*

**Sabine Hauck,** *Leukocare*

**Susanne Joerg,** *ten23 health*

**Julian Lenger,** *Bayer*

**Yves Mayeresse,** *GSK*

**Arnaud Paris,** *BioMerieux*

**Elisabeth Vachette,** *Sartorius*

**Josh Eaton,** *PDA*

**Falk Klar,** *PDA Europe*

**Sabine Hartmann,** *Manager Programs & Events, PDA Europe*



# WELCOME TO BIOMANUFACTURING CONFERENCE



## COVID-19 PERSONAL PRECAUTIONARY MEASURES

PDA is committed to deliver safe and secure in-person events. In conjunction with the venue and vendors supporting our event, PDA strictly adheres to all national, provincial and local government regulations.

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**TUESDAY, 20 SEPTEMBER 2022**

**09:00 – 18:30**

<b>09:00</b>	<b>Welcome and Introduction</b>	Falk Klar, <i>PDA Europe</i>
<b>09:05</b>	<b>Welcome by the Chairs</b>	Cristiana Campa, <i>GSK</i> Raf De Dier, <i>Janssen</i>
<b>OPENING PLENARY: Biopharmaceutical Solutions to Prepare for Healthcare Challenges</b>		<i>Moderators: Cristiana Campa, GSK</i> <i>Raf De Dier, Janssen</i>
	<b>EMA CMC Toolbox on Early Access: Applicability to COVID-19 and Beyond</b>	<i>EMA</i>
	<b>CMC Innovations to Achieve CEPI's 100 Days Mission – Lessons Learned from COVID-19 and Plans for the Future</b>	<i>CEPI</i>
<b>10:15</b>	<b>COFFEE BREAK, POSTER SESSION &amp; EXHIBITION</b>	
	<b>Current ICH Topics and Specification Setting Strategies</b>	<i>Medicine Products Agency</i> <i>Sweden</i>
	<b>Q&amp;A; Discussion</b>	

**12:00 LUNCH BREAK, POSTER SESSION & EXHIBITION**

<b>SESSION 1:</b>	<b>Track A:</b> <i>Moderator:</i> <b>Thierry Gastineau, Sanofi</b>	<b>Track B:</b> <i>Moderator:</i> <b>Yves Mayeresse, GSK</b>	<b>Track C:</b> <i>Moderator:</i> <b>Julian Lenger, Bayer</b>
	<b>ACCELERATION &amp; LEANINGS FROM PANDEMICS</b>	<b>FACILITIES</b>	<b>LYOPHILIZATION – PROCESS &amp; CHARACTERIZATION</b>
	<b>Strategies for Rapid Development and Commercialization of MAbs Therapies for COVID-19</b> <i>GSK</i>	<b>Aseptic Processing - A Paradigm Shift</b> <i>PM Group</i>	<b>Process Modeling and Process Analytical Technology for Primary Drying Design and Optimization</b> <i>TU Clausthal</i>
	<b>How to Accelerate the Supply of Vaccines to all Populations Worldwide - A Regulatory Perspective</b> <i>Merck</i>	<b>Solutions to Multi-Modal, Flexible, and Sustainability Facility Design</b> <i>DPS Group</i>	<b>The Effect of Nesting and Neighboring Vials in Freeze-Drying</b> <i>LMU Munich</i>
	<b>How has Biomanufacturing Changed from a Supply Chain Integrity Standpoint Because of the Pandemic</b> <i>Rx-360</i>	<b>Designing Flexible and Multi-Entity RNA Production Facilities</b> <i>DPS Group</i>	
	<b>Q&amp;A; Discussion</b>	<b>Q&amp;A; Discussion</b>	<b>Q&amp;A; Discussion</b>

**14:30 COFFEE BREAK, POSTER SESSION & EXHIBITION**

<b>SESSION 2:</b>	<b>Track A:</b> <i>Moderator:</i> <b>Sabine Hauk, Leukocare</b>	<b>Track B:</b> <i>Moderator:</i> <b>Thierry Gastineau, Sanofi</b>	<b>Track C:</b> <i>Moderator:</i> <b>Thomas Beutler, GEA Lyophil</b>
	<b>VACCINE PLATFORMS AND CONTROL STRATEGIES</b>	<b>SUSTAINABILITY</b>	<b>LYOPHILIZATION EQUIPMENT</b>
	<b>Quality by Digital Design for RNA Vaccine and Therapeutic Production</b> <i>The University of Sheffield</i>	<b>Designing for Patients and the Planet: Sustainable Solutions for Pharmaceutical Products</b> <i>Johnson &amp; Johnson</i>	<b>GMP-Ready Continuous and Controlled Freeze-Drying</b> <i>Ghent University</i> <i>Rhea Vita</i>

# CONFERENCE AGENDA

<p><b>Platform to Accelerate the Development of Vaccines Against Bacterial Pathogens</b> <i>GSK</i></p>	<p><b>Sustainable Innovative Solutions for a New Agile Manufacturing Facility</b> <i>Sanofi</i></p>	<p><b>Evolution of Vision Technologies for Contaminants Characterization: How to Improve the Detection Rate and Reduce False Reject in Lyophilized Products Inspection</b> <i>S.P.A.M.I.</i></p>
<p><b>How Integrity Testing of Single-Use Systems in Vaccine Manufacturing Can Help to Secure the Fast and Reliable Availability of Vaccines During a Pandemic – and Beyond</b> <i>Sartorius</i></p>	<p><b>Collaboration, Standardization, and Innovation – Steppingstones to Net Zero in Biopharma</b> <i>PM Group Sartorius</i></p>	<p><b>Shelf Temperature Mapping- Easy Test or Miracle?</b> <i>Bayer</i></p>
<p><b>Q&amp;A; Discussion</b></p>	<p><b>Q&amp;A; Discussion</b></p>	<p><b>Q&amp;A; Discussion</b></p>

## 16:30 COFFEE BREAK, POSTER SESSION & EXHIBITION

<b>SESSION 3:</b>	<p><b>Track A:</b> <i>Moderator:</i> <b>Elisabeth Vachette, Sartorius</b></p>	<p><b>Track B:</b> <i>Moderator:</i> <b>Michael De Felippis, Eli Lilly</b></p>
	<p><b>SINGLE USE SYSTEMS</b></p>	<p><b>INTEREST GROUP VACCINES</b></p>
	<p><b>Single-Use Bioprocess Systems Sterilization by X-Ray: Challenges, Interchangeability, and Flexibility Outcomes</b> <i>Sartorius</i></p>	<p><b>Welcome from the Session Chairs</b> <i>Andrew Chang, Novo Nordisk Michael De Felippis, Eli Lilly</i></p>
	<p><b>End-to-End Single-Use Manufacturing at Pilot Plant for Early Development Clinical Material</b> <i>Janssen</i></p>	<p><b>Overview of PDA Vaccine Technical Report</b> <i>Consultant</i></p>
	<p><b>Extractables and Leachables from Single-Use Systems and Their Assessment in Cell and Gene Therapy Applications</b> <i>Sartorius</i></p>	<p><b>Vaccine Lifecycle Management: Regulatory Perspective</b> <i>US FDA</i></p>
	<p><b>Q&amp;A; Discussion</b></p>	<p><b>Lessons Learned from COVID-19 Pandemic on Vaccine Lifecycle Management</b> <i>AstraZeneca</i></p> <p><b>Vaccine Case Studies: Identification of Established Conditions (ECs) and Justification for Reporting Categories When Make Changes to the ECs</b> <i>Sanofi</i></p> <p><b>Q&amp;A; Discussion</b></p>

## 18:30 END OF CONFERENCE DAY 1 & NETWORKING EVENT



# CONFERENCE AGENDA

**WEDNESDAY, 21 SEPTEMBER 2022**

**08:00 – 16:30**

**08:00 – 08:45** Early Career Professional – Morning Coffee Chat

Cristiana Campa, GSK  
Julian Lenger, Bayer  
Falk Klar, PDA Europe

**09:00** Welcome Back by the Chairs & Summary Day 1

Cristiana Campa, GSK  
Raf De Dier, Janssen

SESSION 4:	Track A: Moderator: Raf De Dier, Janssen	Track B: Moderator: Cristiana Campa, GSK	Track C: Moderator: Marta Antunes, MSD
	<b>INNOVATIONS IN FORMULATION &amp; DRUG PRODUCT MANUFACTURING</b>	<b>ICH UPCOMING TOPICS - STABILITY &amp; SPECIFICATION</b>	<b>QUALITY CONTROL METHODS</b>
	<b>Quickly by Design: How New Methods Reshape the Selection and Formulation Development of Novel Therapeutic Proteins</b> <i>Ghent University</i>	<b>Using Stability Prior Knowledge From 'Like-Molecules' to Determine Shelf-Life</b> <i>Amgen</i>	<b>Superior Methods for the Assessment of Particulate Matter Risks when Applying Single-Use Systems: Moving Beyond the Force-Fit of USP</b> <i>Sartorius</i>
	<b>Overcoming Challenges in Co-Formulation of Proteins with Contradicting Stability Profiles – EPO plus G-CSF</b> <i>A. Menarini Research &amp; Service Business</i>	<b>Accelerated Stability Study: Kinetic or Statistical Models?</b> <i>GSK</i>	<b>Which Sustainable Innovative Solutions for a New Agile Manufacturing Facility?</b> <i>Obviotec</i>
	<b>Model Predictive Control for Automated Biologics Drug Product Manufacturing</b> <i>Janssen</i>	<b>Specifications Setting for Biopharmaceuticals in Accelerated Scenarios</b> <i>GSK</i>	
	<b>Q&amp;A; Discussion</b>	<b>Q&amp;A; Discussion</b>	<b>Q&amp;A; Discussion</b>

**10:45** COFFEE BREAK, POSTER SESSION & EXHIBITION

SESSION 5:	Track A: Moderator: Elisabeth Vachette, Sartorius	Track B: Moderator: Marta Antunes, MSD	Track C: Moderator: Yves Mayeresse, GSK
	<b>MAB NEW TRENDS</b>	<b>COMPARABILITY STRATEGIES &amp; TECHNICAL TRANSFERS</b>	<b>LYOPHILIZATION PRODUCT CONSIDERATIONS</b>
	<b>Strategic Modernization of a Commercial Monoclonal Antibody Process by the Introduction of a Next Generation Protein A Resin</b> <i>Eli Lilly</i>	<b>Comparability – How Similar is Similar? Lessons Learnt from Experience with Biosimilars</b> <i>HPRA</i>	<b>Protein Stability in the Freeze Concentrated Solution</b> <i>Coriolis Pharma</i>
	<b>Process Intensification and Connected Processing for Robust, Cost-Effective, and Fast Manufacturing of Monoclonal Antibodies</b> <i>Sartorius</i>	<b>Using Quality by Design to Accelerate the Biopharmaceutical Product Development Lifecycle: A Case Study</b> <i>GSK</i>	<b>Investigation on Solution Creeping in Vials after Filling -A Case Study</b> <i>Boehringer Ingelheim</i>
	<b>Q&amp;A; Discussion</b>	<b>Q&amp;A; Discussion</b>	<b>Q&amp;A; Discussion</b>

**12:25** LUNCH BREAK, POSTER SESSION & EXHIBITION

**13:10** POSTER WALK

## CLOSING PLENARY: DIGITALIZATION & INNOVATION

Moderator: **Sabine Hauck**, *Leukocare*

### INTERACTIVE SESSION

**Regulatory Perspective on Model-Based Approaches to Biomanufacturing**

*CBG meb  
Netherlands*

**Transformation to the Laboratory of the Future:  
Automation Technology, Digitalization, and Artificial Intelligence**

*Lonza*

### 14:35 COFFEE BREAK, POSTER SESSION & EXHIBITION

**Sustainability in Quality Control of Vaccines:  
Applying the 3R's Principle (Replace, Reduce, Refine) and Implementing the 4th R**

*Sciensano Belgium*

**Q&A & Final Panel Discussion**

*Moderators:  
Sabine Hauck,  
Leukocare  
Michael De Felippis,  
Eli Lilly*

**Chairs Conference Summary**

*Cristiana Campa, GSK  
Raf De Dier, Janssen*

**Closing Remarks & Farewell**

*Falk Klar, PDA Europe*

### 16:30 END OF CONFERENCE

*Agenda is subject to change without notice, all speaker are invited and pending confirmation*

## VENUE

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<https://bit.ly/3E6ZmlR>



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### SPECIAL REQUIREMENTS



If you require special assistance to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to [info@pda.org](mailto:info@pda.org).

# PDA EUROPE UPCOMING CONFERENCES



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## 2022

30 Jun 2022

26-27 APR 2022	2022 PDA Visual Inspection Forum	Berlin, Germany
16-17 MAY 2022	2022 PDA Medical Devices and Connected Health Conference	Dublin, Ireland
16-17 MAY 2022	2022 PDA Robotics and Automation Conference	Dublin, Ireland
18-19 MAY 2022	2022 PDA Annex 1 Workshop	Dublin, Ireland
01 JUN 2022	2022 PDA Pre-filled Syringes Workshop	Basel, Switzerland
01 JUN 2022	2022 PDA Packaging Science Workshop	Basel, Switzerland
02-03 JUN 2022	2022 PDA Parenteral Packaging Conference	Basel, Switzerland
20-21 JUN 2022	2022 PDA Virus Conference	Brussels, Belgium
22-23 JUN 2022	2022 PDA Advanced Therapy Medicinal Products Conference	Brussels, Belgium
20-21 SEP 2022	2022 PDA BioManufacturing Conference	Amsterdam, The Netherlands
22-23 SEP 2022	2022 PDA Annex 1 Workshop	Amsterdam, The Netherlands
05-06 OCT 2022	2022 PDA Quality and Regulations Conference	Amsterdam, The Netherlands
08 NOV 2022	2022 PDA Visual Inspection Workshop	Berlin, Germany