

2022 PDA



# ADVANCED THERAPY MEDICINAL PRODUCTS CONFERENCE

FROM PROOF OF CONCEPT TO COMMERCIAL MANUFACTURING:  
MOVING TOWARDS BEST PRACTICES

[pda.org/EU/ATMP2022](http://pda.org/EU/ATMP2022)

**22-23 JUNE 2022**

**BRUSSELS, BELGIUM**

*EXHIBITION: 22-23 JUNE*



# WELCOME FROM THE CHAIRS

Dear Colleagues,

On behalf of the Scientific Program Planning Committee and PDA, we proudly present you to the **Advanced Therapy Medicinal Products Conference** and warmly welcome you to **Brussels, Belgium!**

It's wonderful and exciting that we are able to meet in person after two long years of virtual-only meetings. Despite the Covid-19 pandemic, the cell-and-gene therapy (CGT) pipeline continues to grow, expand, advance, and diversity in the last two years. The 2022 Conference aims to set a special focus on the specific considerations for the manufacture of ATMPs, to build a bridge between proof of concept and commercial manufacturing. During the opening, we will have a Patient talk, Regulatory Lifecycle, and Regulatory Framework of ATMPs including the attendance of GMP Inspectors. In total, six sessions will focus on Manufacturing with Lessons Learned, Solutions for Products and Hospital, Novel Applications, and the Control and Understanding of Critical Reagents.

Attendees can expect an interactive program and sessions including a panel discussion at the end of the Conference. Don't miss valuable take-home messages and the important opportunity to engage with industry peers and experts on ATMPs.

We are excited to finally return to a live event, including an exhibition, poster session, and networking opportunities. We look forward to seeing you soon in Brussels!

Sincerely,  
The Chairs



**Dayue Chen,**  
*Genentech/Roche*



**Richard Denk,**  
*SKAN*

## SCIENTIFIC PROGRAM PLANNING COMMITTEE

**Dayue Chen,** *Genentech/Roche, Chair*

**Richard Denk,** *SKAN, Chair*

**Christopher Bravery,** *Advanced Biologicals*

**Manuel Carrondo,** *ibet*

**Fabio D'Agostino,** *Claris Ventures*

**Marco Fadda,** *Comecer*

**Irving Ford,** *Adaptimmune Therapeutics*

**Renske ten Ham,** *University Medical Center Utrecht*

**Josh Eaton,** *PDA*

**Falk Klar,** *PDA*

**Caroline Lynar,** *Junior Manager Programs & Events, PDA*

The background of the page is a photograph of the Atomium structure in Brussels, Belgium. It features a central vertical column with six horizontal arms extending outwards, each ending in a spherical module. The spheres are made of a grid of metal and are highly reflective, mirroring the sky and surrounding environment. The sky is a clear, pale blue, suggesting a bright day. The overall composition is symmetrical and geometric.

# WELCOME TO ADVANCED THERAPY MEDICINAL PRODUCTS 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.

**WEDNESDAY, 22 JUNE 2022**

**09:00 – 17:20**

<b>09:00</b>	<b>Welcome and Introduction</b>	Falk Klar, <i>PDA</i>
	<b>Welcome from the Chairs</b>	Dayue Chen, <i>Genentech/Roche</i> Richard Denk, <i>SKAN</i>

**OPENING PLENARY: FOCUS ON THE PATIENT** *Moderator: Richard Denk, SKAN*

	<b>Keynote :</b> <b>Haemophilia Gene Therapy - A Personal Perspective</b>	<i>Irish Haemophilia Society</i>
	<b>From Development to the Patient:</b> <b>The Regulatory Lifecycle of ATMPs</b>	<i>Utrecht Science Park</i>
	<b>Innovations in ATMPs and the Regulatory Framework</b>	<i>AGES</i>
	<b>Q&amp;A, Discussion</b>	

**11:15 COFFEE BREAK, POSTER SESSION & EXHIBITION**

**SESSION 1: Building a Growing Market of Cell and Gene Therapy Products** *Moderator: Fabio D'Agostino, Claris Ventures*

The potential of C&GT products to target diseases considered uncurable has fueled billions of investments in just the past years. While this is great news for patients, the biopharmaceutical industry had to face unprecedented challenges ranging from manufacturing process to logistics and reimbursement models.

	<b>Contamination Control Strategy for Cell Therapy Start-Up</b>	<i>DPS &amp; Takeda</i>
	<b>Unlocking Market Access for ATMPs</b>	<i>University Medical Center Utrecht</i>
	<b>Building on Non-Gene Edited Approaches to Develop Allogeneic, Off-The-Shelf CAR-T Cells</b>	<i>Celyad</i>
	<b>Q&amp;A, Discussion</b>	

**13:15 LUNCH BREAK, POSTER SESSION & EXHIBITION**

**SESSION 2: ATMP Manufacturing** *Moderator: Christopher Bravery, Advanced Biologicals*

ATMP continue to pose difficulties and challenges in various areas of manufacturing. This session will explore some of those challenges, such as sterility control when the product cannot be sterilized and biosafety. Whether autologous products are best manufactured locally or centrally remains a topic of debate, but to be successful likely needs automation to ensure consistency. Our panel of speakers will discuss how they are trying to solve some of these issues.

	<b>Interactive Questionnaire</b>	<i>Via Mentimeter</i>
	<b>Bio-Safety and GMP Manufacturing Requirements</b>	<i>SKAN</i>
	<b>Overcoming Autologous Manufacturing by Adaptive Culturing. Metabolic and Environmental Control-based Automation, Machine Learning and IA with the Adva X3</b>	<i>Adva Biotechnology</i>

**15:25 COFFEE BREAK, POSTER SESSION & EXHIBITION**

## SESSION 3: ATMP Manufacturing Continued

Moderator: **Christopher Bravery**,  
*Advanced Biologicals*

**Factors Holding Back Lights-out Manufacture of ATMPs**

*Takeda*

**Regulatory Considerations for  
Decentralized Manufacture of ATMPs at POCare**

*Orgenesis*

**Points to Consider for Microbial Control in ATMP Manufacturing -  
A New PDA Guidance Document**

*Genentech/Roche*

**Q&A, Discussion**

**17:20 END OF CONFERENCE DAY 1 & NETWORKING EVENT**



# CONFERENCE AGENDA

**THURSDAY, 23 JUNE 2022**

**09:00 – 17:00**

**SESSION 4: Solutions for Products in Hospital and Decentralized Scalable Settings**

Moderator: **Renske ten Ham**, University Medical Center Utrecht

Advances in manufacturing and logistics of ATMPs are bringing new point-of-care and closed system solutions, especially for use in hospital and small scale settings. In this session we explore the experience and needs of smaller scale ATMP development setting and discuss opportunities and implications of several platforms.

**Development and Manufacturing of ATMPs at Academia**

*Leiden University Medical Center*

**Routine Automated Manufacture of ATMPs in a Closed, Single Platform**

*Miltenyi*

**The GEN2 Cocoon® Platform with Integrated Magnetic Selection**

*LONZA*

**10:30 COFFEE BREAK, POSTER SESSION & EXHIBITION**

**SESSION 5: Emerging Technologies and Novel Applications**

Moderator: **Marco Fadda**, Comecer

Technological advancements are making possible opening new therapeutic approaches. On one side, we gain trust in new manufacturing capabilities, on the other side, they made possible exploring new fields. In this session, you'll learn about an example for each of these two emerging aspects.

**Personalized Tissue Engineering that will Revolutionize Future Medicine**

*VERIGRAFT*

**Novel Concept for Isolators to Manufacture ATMPs and Biologics**

*SKAN*

**Q&A, Discussion**

**12:30 LUNCH BREAK, POSTER SESSION & EXHIBITION**

**SESSION 6: Control and Understanding of Critical Reagents**

Moderator: **Dayue Chen**, Genentech/Roche

The quality of gene-editing reagents (i.e., Cas9 nuclease, guide RNA) is critical for ensuring product safety and process consistency. Two presentations in this session provide new insights into our understanding of these reagents as well as potential measures to better control and monitor the gene-editing process.

**Physicochemical and Functional Characterization of Differential CRISPR-Cas9 Ribonucleoprotein Complexes**

*Genentech/Roche*

**Improving Precision and Specificity of CRISPR Gene Editing with RGEN-seq and RGEN-mod**

*Merck*

**Q&A, Discussion**

**15:00 COFFEE BREAK, POSTER SESSION & EXHIBITION**

## CLOSING PLENARY: Take Home Dreams for Fulfillment

Moderator: **Manuel Carrondo,**  
*ibet*

The last talk will be on biopharmaceutical regulatory evaluation. Then, out of the presentations and broad talks that took place during breaks and meals, the session moderators, chairs and the audience will revise lessons learned and dream of future directions to keep us doing the good work for the years to come.

**Toolbox Guidance on Scientific Elements and Regulatory Tools to Support Quality Data Packages for Early Access Approaches with a Focus on ATMP**

*MEB*

**Summary from the Session Moderators and Chairs**

**Panel Discussion**

**Closing Remarks & Farewell**

Falk Klar,  
*PDA*

## 17:00 END OF CONFERENCE

*Agenda is subject to change without notice*

### VENUE

#### TANGLA HOTELS BRUSSELS


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51200 Brussels/Belgium  
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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 CONFERENCES AND EVENTS



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## 2022

06. May 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