



**2022 PDA Advanced Therapy Medicinal Products Conference**  
*From Proof of Concept to Commercial Manufacturing: Moving Towards Best Practices*  
**Brussels/Belgium**  
**22-23 June 2022**

| <b>Wednesday, 22 June 2022</b>  |   | <b>09:00 – 17:20</b>  |
|---|---|---|
| 9:00  | Welcome and Introduction  | Falk Klar, <i>PDA</i>   |
|   | Welcome from the Chairs   | Dayue Chen, <i>Genentech/Roche</i><br>Richard Denk, <i>SKAN</i> |
| <b>Opening Plenary: Focus on the Patient</b>                                  |   | <b>Moderator:</b> Richard Denk, <i>SKAN</i>                     |
|   | Keynote<br>Haemophilia Gene Therapy - A Personal Perspective                            | <i>Irish Haemophilia Society</i>                                |
|   | From Development to the Patient: The Regulatory Lifecycle of ATMPs                      | <i>Utrecht Science Park</i>                                     |
|   | Innovations in ATMPs and the Regulatory Framework                                       | <i>AGES</i>   |
|   | <b>Q&amp;A, Discussion</b>  |   |
| <b>11:15</b>  | <b>Coffee Break, Poster Session &amp; Exhibition</b>                                    |   |
| <b>Session 1: Building a Growing Market of Cell and Gene Therapy Products</b> |   | <b>Moderator:</b> Fabio D'Agostino,<br><i>Claris Ventures</i>   |
|   | Contamination Control Strategy for Cell Therapy Start-Up                                | <i>DPS &amp; Takeda</i>   |
|   | Unlocking Market Access for ATMPs   | <i>University Medical Center Utrecht</i>                        |
|   | Building on Non-Gene Edited Approaches to Develop Allogeneic, Off-The-Shelf CAR-T Cells | <i>Celyad</i>   |



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|  | <b>Q&amp;A, Discussion</b>   |   |
| <b>13:15</b>                                   | <b>Lunch Break, Poster Session &amp; Exhibition</b>  |   |
| <b>Session 2: ATMP Manufacturing</b>           |  | <b>Moderator:</b> Christopher Bravery,<br><i>Advanced Biologicals</i> |
|  | Interactive Questionnaire  | <i>Via Mentimeter</i>   |
|  | Bio-Safety and GMP Manufacturing Requirements  | <i>SKAN</i>   |
|  | Overcoming Autologous Manufacturing by Adaptive Culturing.<br>Metabolic and Environmental Control-based Automation, Machine Learning and IA with the Adva X3 | <i>Adva Biotechnology</i>   |
| <b>15:25</b>                                   | <b>Coffee Break, Poster Session &amp; Exhibition</b>   |   |
| <b>Session 3: ATMP Manufacturing Continued</b> |  |   |
|  | Factors Holding Back Lights-out Manufacture of ATMPs   | <i>Takeda</i>   |
|  | Regulatory Considerations for Decentralized Manufacture of ATMPs at POCare   | <i>Orgenesis</i>  |
|  | Points to Consider for Microbial Control in ATMP Manufacturing - A New PDA Guidance Document   | <i>Genentech/Roche</i>  |
|  | <b>Q&amp;A, Discussion</b>   |   |
| <b>17:20</b>                                   | <b>End of Conference Day 1 &amp; Networking Event</b>  |   |

**Thursday, 23 June 2022**

**09:00 – 17:00**



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| <b>Session 4: Solutions for Products in Hospital and Decentralized Scalable Settings</b> |   | <b>Moderator:</b> Renske ten Ham,<br><i>University Medical Center Utrecht</i> |
|  | Development and Manufacturing of ATMPs at Academia  | <i>Leiden University Medical Center</i>                                       |
|  | Routine Automated Manufacture of ATMPs in a Closed, Single Platform                                     | <i>Miltenyi</i>   |
|  | The GEN2 Cocoon® Platform with Integrated Magnetic Selection  | <i>LONZA</i>  |
|  | <b>Q&amp;A, Discussion</b>  |   |
| <b>10:30</b>   | <b>Coffee Break, Poster Session &amp; Exhibition</b>  |   |
| <b>Session 5: Emerging Technologies and Novel Applications</b>                           |   | <b>Moderator:</b> Marco Fadda,<br><i>Comecer</i>                              |
|  | Personalized Tissue Engineering that will Revolutionize Future Medicine                                 | <i>VERIGRAFT</i>  |
|  | Novel Concept for Isolators to Manufacture ATMPs and Biologics  | <i>SKAN</i>   |
|  | <b>Q&amp;A, Discussion</b>  |   |
| <b>12:30</b>   | <b>Lunch Break, Poster Session &amp; Exhibition</b>   |   |
| <b>Session 6: Control and Understanding of Critical Reagents</b>                         |   | <b>Moderator:</b> Dayue Chen,<br><i>Genentech/Roche</i>                       |
|  | Physicochemical and Functional Characterization of Differential CRISPR-Cas9 Ribonucleoprotein Complexes | <i>Genentech/Roche</i>  |
|  | Improving Precision and Specificity of CRISPR Gene Editing with RGEN-seq and RGEN-mod                   | <i>Merck</i>  |



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|  | <b>Q&amp;A, Discussion</b>   |   |
| <b>15:00</b>   | <b>Coffee Break, Poster Session &amp; Exhibition</b>   |   |
| <b>Closing Plenary: Take Home Dreams for Fulfillment</b> |  | <b>Moderator:</b> Manuel Carrondo,<br><i>ibet</i> |
|  | Toolbox Guidance on Scientific Elements and Regulatory Tools to Support Quality Data Packages for Early Access Approaches with a Focus on ATMP | <i>MEB</i>  |
|  | <b>Summary from the Session Moderators and Chairs</b>  |   |
|  | <b>Panel Discussion</b>  |   |
|  | <b>Closing Remarks &amp; Farewell</b>  | Falk Klar, <i>PDA</i>                             |
| <b>17:00</b>   | <b>End of Conference</b>   |   |

*Agenda is subject to change without notice*