February 27, 2025
Rahel Hirsch Center, Luisenstraße 65, 10117 Berlin

Register for free:

Preliminary agenda

Moderator: Leila Amini (Head of Regulatory Affairs, Berliner Centrum for Advanced therapies [BeCAT], Junior Group Leader Process Development for Cell and Gene therapy, BIH Center of Regenerative Therapies [BIH-CRT])

Time	Topic	Speaker
08:30	Registration	
09:00	Introduction	Leila Amini (BeCAT, BIH-CRT), Elke Luger (Elke Luger – National Network Office GCT Germany), Daniel Besser (German Stem Cell Network)
09:10	Keynote Lecture: Cell and gene therapy - challenges for academic research, development and translation into the clinic	Petra Reinke (Founding Director of the BeCAT, Head of GMP-Facility BIH-CRT)
09:50	*Coffee break*	
10:15	*Introduction talks pre-GMP/GMP* 1. The GMP challenge at the interface between laboratory research and "first in human"	Sven Stegemann (DWI Leibniz Institutes for Interactive Materials, Aachen, Germany)
10:35	2. ATMP development @Miltenyi and company interests in industry/academic co-developments	Michael Apel (Miltenyi)
10:55	3. Introduction to planned QP network	Martin Hildebrandt (Head of the apheresis unit, TU München)
11:15	4. GMP Development of an allogeneic off-the-shelf MSC preparation for steroid-refractory GvHD	Halvard Bönig (Goethe University Faculty of Medicine, Institute for Transfusion Medicine and immunohematology, and German Red Cross Blood Donor Service (DRK-BSD) BaWüHe, Institute Frankfurt, Department of Cellular Therapeutics/GMP)
11:35	5. IPSC process (heart patches)	Wolfram Hubertus Zimmermann (Director, Institute of Pharmacology and Toxicology, University Medical Center Göttingen)
11:55	*Coffee break*	
12:15	Introduction to the Workshop format	Leila Amini
12:20	*Workshop GMP*: 3 *Breakout Sessions* Warm up Breakout Session: Definition of a developed product: process vs. Cell Breakout sessions: in parallel 40'	Leila Amini

RegMed Forum 2025 –
Process development and
translation of ATMP
projects

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Time	Topic	Moderator / Speaker
	1. How can we train urgently needed personnel better? (And educate scientists about the importance of GMP processes) 2. Challenges in manufacturing tackled early in the development process (Good translational practice concept) 3. Special considerations for clinical trials with ATMPs	Moderator: Jasmin Podufall, Berlin Partner & Cluster HealthCapital Berlin-Brandenburg Moderator: Andy Römhild, BIH-CRT Moderator: Tobias Winkler, BIH-CRT
13:00	Analysis Workshops GMP	Moderator / Member Break out session
13:20	*Networking-Lunch*	
14:15	Panel discussion: Overcoming GMP bottlenecks (CMO vs. Company vs. Academic GMP unit)	Moderator: Gady Goldsobel 1. Academic GMP unit: Paul Franz (Fraunhofer Institute for Cell Therapy and Immunology IZI) 2. CMO: Christian Ebel (Tetec GmbH) 3. Company, in-house production: Guilietta Roel (co.don AG) 4. Company, using a CMO (TBA)
14:55	*Introduction talks Translation* 1. From the idea to the patient: Translational Challenges and Technology Transfer of ATMPs 2. German National Strategy of GCTs & GeneNovate: Insight into Workshop series 3. Regional and National Incubator Structures (Reimbursement, legal advice) 4. Introduction of the National Regulation Support Unit @BIH 5. „Forschungsstrukturbereich ATMPs" at Charité	 Daniel Forler (Bayer AG) Elke Luger (National Network Office GCT Germany) & N.N. Garima Bhardwaj (Head of Clinical Incubator, Berlin Institute of Health) Christoph Conrad (Head of Regulatory Affairs, Berlin Institute of Health) Annette Künkele-Langer (Project coordinator Join4 ATMP, Department of Pediatrics, Division of Oncology and Hematology Charité Universitätsmedizin Berlin)
16:05	*Coffee break*	
16:30	Panel discussion: What are challenges during translation?	Moderator: Garima Bhardwaj ATMP developer from industry: Matthias Lutolf, Roche (TBC) ATMP developer from academia: Georg Hansmann, Medizinische Hochschule Hannover (TBC) Start-up: MyoPax, Verena Schöwel-Wolf Regulatory body: Ralf Sanzenbacher, Paul-Ehrlich-Institut
17:10	Wrap up and closing words	Leila Amini, Elke Luger, Daniel Besser
17:20	End of the Program	