



February 27, 2025

Rahel Hirsch Center, Luisenstraße 65, 10117 Berlin

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)*)

Preliminary agenda

Time	Topic (titles TBA)	Speaker
08:30	Registration	
09:00	Introduction	Leila Amini (<i>BeCAT, BIH-CRT</i>), Elke Luger (<i>National Network Office Gene and Cell Therapies</i>), Daniel Besser (<i>German Stem Cell Network</i>)
09:10	Keynote Lecture	Petra Reinke (<i>Founding Director of the BeCAT, Head of GMP-Facility BIH-CRT</i>)
09:50	Coffee break	
10:15	<i>Introduction talks pre-GMP/GMP</i>	
	1. Working group GMP from national strategy: What locations are there and what we can learn from each other?	Sven Stegemann (<i>DWI Leibniz Institutes for Interactive Materials, Aachen, Germany</i>)
10:35	2. ATMP development @Miltenyi and company interests in industry/academic co-developments	N.N. (<i>Miltenyi</i>)
10:55	3. Introduction to planned QP network	Martin Hildebrandt (<i>Head of the apheresis unit, TU München</i>)
11:15	4. DRK: MSCs (GvHD)	Halvard Bönig (<i>German Red Cross, DRK - Research and Development Department - Translational Cell Therapeutics Development/GMP</i>)



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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	<p>Workshop GMP: 3 Breakout Sessions</p> <p>Warm up Breakout Session: Definition of a developed product: process vs. Cell</p> <p>Breakout sessions: in parallel 40'</p> <ol style="list-style-type: none"> 1. How can we better train urgently needed personnel? (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 	<p>Leila Amini</p> <p>Moderator: Jasmin Podufall</p> <p>Moderator: Andy Römhild</p> <p>Moderator: Tobias Winkler</p>
13:00	Analysis Workshops GMP	Moderator / Member Break out session
13:20	Networking-Lunch	
14:15	<p>Panel discussion:</p> <p>Overcoming GMP bottlenecks (CMO vs. Company vs. Academic GMP unit)</p>	<p>Moderator: Gady Goldsobel</p> <ol style="list-style-type: none"> 1. Academic GMP unit 2. CMO 3. Company, in-house production



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14:55	<p><i>Introduction talks Translation</i></p> <ol style="list-style-type: none"> 1. Tech-Transfer/Business development for ATMPs 2. German National Strategy of CGTs <p>GeneNovate: Insight into Workshop series</p> <ol style="list-style-type: none"> 3. Regional and National Incubator Structures (Reimbursement, legal advice) 4. Introduction of the national Regulation Support Unit @BIH 5. Forschungsstrukturbereich ATMPs an der Charité 	<p>TBC</p> <p>Elke Luger (<i>Head of the National Network Office Gene and Cell Therapies</i>)</p> <p>Garima Bhardwaj (<i>Head of Clinical Incubator, Berlin Institute of Health</i>)</p> <p>Christoph Conrad (<i>Head of Regulatory Affairs, Berlin Institute of Health</i>)</p> <p>Annette Künkele-Langer (<i>Project coordinator Join4 ATMP, Department of Pediatrics, Division of Oncology and Hematology Charité Universitätsmedizin Berlin</i>)</p>
16:05	<i>Coffee break</i>	
16:30	<p>Panel discussion:</p> <p>What are challenges during translation and what would have helped me?</p>	<p>Moderator: Garima Bhardwaj</p> <p>ATMP developer panel (TBA)</p> <p>Academic Developers (TBA)</p> <p>Big Company (TBA)</p> <p>Start-up (TBA)</p>
17:10	Wrap up and closing words	Leila Amini, Elke Luger, Daniel Besser
17:20	End of the Program	