

An event in collaboration with:

- Biotechnologieverbund Berlin-Brandenburg e.V. (bbb)
- Paul-Ehrlich-Institut (PEI)
- German ZLG
- German Stem Cell Network (GSCN)
- HealthCapital Berlin - Brandenburg
- Berlin Partner für Wirtschaft und Technologie GmbH

Event location:

Investitionsbank des Landes Brandenburg (ILB)
Babelsberger Straße 21
14473 Potsdam

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Further information and events:
<https://biotech-verbund.de>



ATMP Symposium

»The Product is the Process – Is it?« Manufacturing and Translation of ATMPs and Tissue- & Cell-based products

20 November 2025 | Potsdam, Germany

Whether in regenerative medicine, cell or gene therapy – driven by remarkable research and clinical success, innovative therapy and product concepts for advanced therapy medicinal products (ATMPs) are increasingly in the focus of interest. Several products have meanwhile achieved marketing approval and some ATMPs even reached broad clinical application. In addition, another multitude of product

approaches are in the early development phase or in clinical trials. Concomitantly, a complex and dynamic regulatory environment has emerged in this modern biotechnological area. To facilitate that ideas and development approaches can be translated to safe and effective medicines for patients, the intensive exchange of expertise between involved stakeholders in research, clinical, industrial as well as regula-

ry affairs is required. This also includes aspects of manufacturing and testing as essential part. Thus, discussing regulatory requirements together with entrepreneurial aspects, medical needs and possible technical solutions is an important way of making information and expectations transparent and counteracting erroneous trends. This symposium offers a forum for information and intensive exchange of current

developments, experiences and requirements including authority representatives. The symposium is organized in collaboration with the bbb, the Paul-Ehrlich-Institut (PEI), the German ZLG (Central Authority of the States for Health Protection Regarding Medicinal Products and Medical Devices), the German Stem Cell Network (GSCN), HealthCapital – the Healthcare Industries Cluster Berlin-Brandenburg and Berlin Partner.

Programme 20 November 2025 | 9 a.m. - 5 p.m.

9.00 - 9.15 a.m.

Welcome address

Dr. Ralf Sanzenbacher,
Paul-Ehrlich-Institut, Langen

9.15 - 9.45 a.m.

Beta cell replacement therapies for Diabetes:

Where do we stand?

Prof. Dr. Heiko Lickert,
Helmholtz Zentrum Munich and
Technical University Munich

9.45 - 10.15 a.m.

Beremagene geperpavec: First approved topical gene therapy for dystrophic epidermolysis bullosa

Prof. Dr. Caspar Franzen,
Krystal Biotech, Amsterdam/Berlin

10.15 - 10.30 a.m.

Discussion

10.30 - 11.00 a.m.

Coffee break

11.00 - 11.30 a.m.

SoHO and Implementation in Germany: Update and Perspective

Janina Hahnloser / Dr. Irina Bosman,
German Ministry of Health, Berlin

11.30 a.m. - 12.00 a.m.

Decentralized ATMP manufacturing: Opportunities and challenges

Dr. Bernd Schröder,
Miltenyi Biotec B.V. & Co. KG,
Bergisch Gladbach

12.00 - 12.15 p.m.

Discussion

12.15 - 1.30 p.m.

Lunch

1.30 - 2.00 p.m.

TIL-based cancer therapy and state of the art manufacturing of TILs

Prof. Dr. Markus Mäurer,
Champalimaud Foundation and Botton-
Champalimaud Pancreatic Cancer
Center, Lisboa Portugal / Johannes
Gutenberg University of Mainz

2.00 - 2.30 p.m.

GMP Manufacturing of Cell and Gene Therapy Drugs at Point of Care – Suitable Facility Concepts and Scalable Solutions

Dr. Hans-Georg Eckert,
Valicare GmbH Frankfurt/Main

2.30 - 3.00 p.m.

Discussion

3.00 - 3.30 p.m.

Coffee break

3.30 - 4.00 p.m.

Solutions for rapid bioburden, sterility and endotoxin testing: Update and general requirements

Stefan Gärtner, Labor L&S,
Bad Bocklet

4.00 - 4.30 p.m.

Comparison of interactions and submission pathways for ATMP in the US and EU: From pre-IND to marketing application

Dr. Thorsten Meyer,
Granzer Regulatory Consulting &
Services GmbH, Munich

4.30 - 5.00 p.m.

Discussion

5.00 p.m.

Résumé and end of symposium