

An event in collaboration with:

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

Event location:

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

Your contact to Biotechnologieverbund Berlin-Brandenburg e. V.

Tel.: +49 (0) 3302 494 5315
Fax: +49 (0) 3302 494 5316
Mail: info@biotech-verbund.de

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



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

8 December 2022 | Potsdam, Germany

Whether in the fields of regenerative medicine, cell or gene therapy – driven by remarkable research success, innovative therapy and product concepts for advanced therapy medicinal products (ATMP) are increasingly in the focus of interest. Several products have already reached marketing approval. In addition, multitude 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 are translated to safe and effective medicines for patients, the intensive exchange of expertise between involved stakeholders in research, clinical, industrial and regulatory affairs is required.

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

and requirements including authority representatives. It is organized in collaboration with 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 Cluster Healthcare Industries Cluster Berlin Brandenburg and Berlin Partner für Wirtschaft und Technologie GmbH.

Program 8 December 2022 | 9 a.m. - 5 p.m.

9.00 - 9.15 a.m.

Welcome Address

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

9.15 - 9.45 a.m.

Development of advanced therapies targeting neurodegenerative diseases – where do we stand?

Prof. Steven A. Goldman, University of Rochester Medical Center, USA

9.45 - 10.15 a.m.

Induced Pluripotent Stem Cell (iPSC)-derived tissue-engineered human myocardium for heart failure repair

Prof. Wolfram-Hubertus Zimmermann, Institute of Pharmacology and Toxicology, University Medical Center Göttingen, Germany

10.15 - 10.30 a.m.

Discussion

10.30 - 11.00 a.m.

Coffee break

11.00 - 11.30 a.m.

Key Aspects on CMC development, qualification and life cycle management of stem cell banking systems in a GMP context

Craig Beasley, Bluerock Therapeutics, Cambridge, USA

11.30 a.m. - 12.00 p.m.

Formulation of ATMPs: Lipid Nanoparticles and nano-based drug delivery systems

Dr. Martin Rabel, Precision Nano Systems Inc, Vancouver, Canada

12.00 - 12.15 p.m.

Discussion

12.15 - 1.30 p.m.

Lunch

1.30 - 2.00 p.m.

EC Revision of the EU legislation on blood, tissues and cells

Deirdre Fehily PhD, DG Santé, European Commission, Brussels, Belgium

2.00 - 2.30 p.m.

ATMP Development in Germany: Shortfalls + Future Perspectives

Prof. Christopher Baum, Berlin Institute of Health / Charité, Berlin, Germany

2.30 - 3.00 p.m.

Discussion

3.00 - 3.30 p.m.

Coffee break

3.30 - 4.00 p.m.

ATMP Manufacturing: Comparison of EMA, US-FDA & PIC/S ATMP guidance from a global stakeholder's perspective

Jasna Curak, Hoffmann-La Roche Ltd, Mississauga, Canada

4.00 - 4.30 p.m.

Quality control of ATMP: Potency assays revisited

Dr. Christopher Bravery, Advanced Biologics Ltd, London, United Kingdom

4.30 - 5.00 p.m.

Discussion

5.00 p.m.

Résumé and End of Symposium