

An event in collaboration with:

- Biotechnologieverbund Berlin-Brandenburg e.V.
- 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>



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

30 November 2023 | 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 ap-

proaches 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 regulatory 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. This workshop 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), Health Capital – the Healthcare Industries Cluster Berlin Brandenburg and Berlin Partner.

Program 30 November 2023 | 9 a.m. - 5 p.m.

9.00 - 9.15 a.m.

Welcome address

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

9.15 - 9.45 a.m.

Cell and gene therapy for inherited and acquired disease of the hematopoietic system

Prof. Dr. Marina Cavazzana, Necker-Enfants Malades Hospital/ Institut Imagine Paris, France

9.45 - 10.15 a.m.

Current results with first-in-class stem cell genome editing for treatment of hemoglobinopathies

PD Dr. Roland Meisel, Universitätsklinikum Düsseldorf, Germany

10.15 - 10.30 a.m.

Discussion

10.30 - 11.00 a.m.

Coffee break

11.00 - 11.30 a.m.

Regulatory trends and news in gene therapy

PD Dr. Matthias Renner, Paul-Ehrlich-Institut, Germany

11.30 a.m. - 12.00 a.m.

High grade plasmid and mini-circle DNA for gene therapy: key manufacturing and control settings

Dr. Martin Schleef, Plasmid Factory GmbH, Germany

12.00 - 12.15 p.m.

Discussion

12.15 - 1.30 p.m.

Lunch

1.30 - 2.00 p.m.

EU Pharm revision and impact on ATMPs

Dr. Matthias Wilken, Federal Association of the Pharmaceutical Industry e.V., Germany

2.00 - 2.30 p.m.

Decentralized manufacturing: new POCare strategies for ATMPs

Prof. Dr. Heiko von der Leyen, Orgenesis Inc, USA

2.30 - 3.00 p.m.

Discussion

3.00 - 3.30 p.m.

Coffee break

3.30 - 4.00 p.m.

Flow cytometry-based QC of cell-based products: development and validation of assays

PD Dr. Sabine Hünecke, Universitätsklinikum Frankfurt/Main, Germany

4.00 - 4.30 p.m.

How AI / ChatGPT will impact regulatory processes

Dr. Liam Childs, Paul-Ehrlich-Institut, Germany

4.30 - 5.00 p.m.

Discussion

5.00 p.m.

Résumé and end of symposium