SPARK-BIH National Gene and Cell Therapies Webinar Lecture Series 2025

Thursday 19th June
3:30-4:30 CET

SPARK BIH

GCT
National Strategy
Gene- and Cell-Based Therapies
Project Funding

Understanding Regulatory Requirements for Gene and Cell Therapies

Dr. Barbara Volz

Bringing 25 years in translational research on ATMPs and Biologicals, **Barbara** has led GMP-compliant manufacturing of cell-based tumor vaccines and recombinant proteins. She also guided non-clinical development of immuno-oncology therapeutics. In April 2024 she joined the Regulatory Support Unit (RSU) at the Berlin Institute of Health (BIH) as a Regulatory Affairs Specialist for Biologicals.

Dr. Michael Moles

Michael holds a PhD in Cancer Studies and focused on CAR-T/NK cell therapies in his postdoc. In April 2024, he joined the BIH-RSU as a Regulatory Affairs Specialist, supporting academic ATMP developers and contributing to the EU Join4ATMP consortium and IRDiRC Task Force on regulatory convergence.

ATMP development is challenging, partly due to their unique characteristics and the regulatory requirements. Non-clinical development differs significantly from other drugs and is usually determined case-by-case. Therefore, a proactive and well-informed regulatory strategy is vital. In this webinar, you will learn about the European ATMP regulatory landscape, developer challenges, and global initiatives supporting their advancement. It focuses on the overarching guideline for investigational ATMPs in clinical trials (IMPD submission), including model selection, proof-of-concept, safety/toxicity, and dose-finding studies. A real-world case study will illustrate how these regulatory expectations are applied in practice for non-clinical development.

Online via MS Teams | Please register here!

Registration to the webinar is required in advance in order to receive MS Teams meeting link.
The event is hosted by SPARK-BIH at the Berlin Institute of Health at Charité, Berlin, Germany.

This lecture series is part of the Project Funding Program of National Strategy for Gene- and Cell-based Therapies

SPARK is an initiative created at Stanford University to overcome challenges associated with translation of academic discoveries.

The organizers reserve the right to change and update the topics and speakers

All webinars with automatic captioning.