Paul-Ehrlich-Institut

Paul-Ehrlich-Institut Workshop (HYBRID)

Scientific and Regulatory Aspects of Innovative Gene Therapy Medicinal Products

Tuesday, September 27th, 2022, 9:00 – 17:00

Town Hall Langen (Neue Stadthalle Langen)

Südliche Ringstraße 77, 63225 Langen

PROGRAMME

Time	Title	Chairs/Speaker
9:00	Welcome	K. Cichutek, President Paul-Ehrlich-Institut (PEI)
9:10 – 9:30	The life cycle management of Advanced Therapy Medicinal Products (ATMPs)	M. Schuessler-Lenz, PEI
9:30 – 12:00	PLENARY SESSION I Gene editing approaches of ATMPs	Session Chairs C. Buchholz, E. Flory, PEI
9:30 – 9:50	Gene editing – current state of clinical translation	T. Cathomen, Freiburg
9:50-10:10	Regulatory quality and manufacturing aspects of gene editing medicinal products	M. Renner, PEI
10:10– 10:30	Coffee	
10:30– 10:50	Regulatory non-clinical aspects of gene editing medicinal products	B. Anliker, PEI
10:50 -11:10	Bioinformatics aspects of gene editing	L. Childs, PEI
11:10 - 11:30	Clinical aspects of gene editing medicinal products	J. Rau, PEI
11:30– 12.00	Q & A	ALL

Paul-Ehrlich-Institut Workshop (HYBRID)

Scientific and Regulatory Aspects of Innovative Gene Therapy Medicinal Products

Time	Title	Chairs/Speaker
12:00– 12.50	PLENARY SESSION II mRNA –based gene therapy medicinal products	Session Chairs M. Renner, J. Scherer, PEI
12:00– 12:25	RNA nanoparticles in gene therapy	C. Buchholz, PEI
12:25– 12:50	RNA-loaded Lipid Nanoparticles: Introduction into critical quality attributes and analytical requirements	M. Rabel, Leipzig
12.50	Lunch	
13.50– 15:10	PLENARY SESSION III Hot topics part 1	Session Chairs B. Anliker, M. Renner, PEI
13.50 - 14:10	Guidelines on Good Manufacturing Practice specific to ATMPs – focus on GMP inspections	C. Liebold, Nürnberg
14.10 –14:30	Point-of-care production of CAR-T cells at an academic center: clinical experience in hematologic and autoimmune diseases	A. Mackensen, Erlangen
14:30 –14.50	Hot topics within the European Commission	Paschalia Koufokotsiou, European Commission
14:50-15:10	Q&A	ALL
15:10-15:30	Coffee	
15:30-16:55	PLENARY SESSION IV Hot topics part 2	Session Chairs M. Schuessler-Lenz, J. Scherer, PEI
15:30-15:50	Transition from clinical trials to marketing authorization application. Experience of an academic developer	M. Juan, Barcelona
15:50-16:10	PEI support for ATMP developers - scientific advice and regulatory guidance	A.Berger, PEI
16:10-16:30	Challenges of the GMO/CTR interface	B. Anliker, PEI
16:30-16:55	Q&A	ALL
16:55-17:00	Closing remarks	