EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Translational Centre for Regenerative Medicine
TRM Leipzig

PROGRAMM DETAILS

8:00 **Registration**

8:45 - 9:00 **Welcome and Opening**

Frank Emmrich
Congress President / TRM Leipzig – Director

Christian K Schneider
Workshop Co-Chair / European Medicines Agency – CAT Chair

Ulrich Sack
Workshop Co-Chair / TRM Leipzig – Associate Director Research

9:00 - 10:30 **Session 1** **Regulatory environment landscape**

Chairs Patrick Celis (CAT) – Timo Faltus (TRM Leipzig)

Role of European and national regulatory authorities: who advises on what?
Lucia D'Apote
CAT Scientific Secretariat
Martina Schuessler-Lenz
CAT alternate member – Germany – PEI

Overview of the bench to bedside process
Timo Faltus
TRM Leipzig – Germany

Reimbursement for ATMPs in Germany – perspective for Europe
Matthias Perleth
Gemeinsamer Bundesausschuss (G-BA) – Germany

ATMP post-authorisation and pharmacovigilance
Caroline Voltz-Girolt
European Medicines Agency ² UK

10:30 - 11:00 **Coffee break**

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11:00 - 12:30 **Session 2** **Cell-based medicinal products**

Chairs Paula Salmikangas (CAT) – Bastian Marquaß (TRM Leipzig)

Manufacturing of cell-based medicinal products: common issues & advice
Jean-Hugues Trouvin
Paris Descartes University; Biologicals Working Party (BWP)* Chair – France – ANSM

Tumorigenicity and genome stability in potential stem cell based medicinal products – relevance of cytogenetic analysis
Heidrun Holland
TRM Leipzig – Germany

Non-clinical development of cell-based medicinal products
Egbert Flory
CAT Member – Germany – PEI

Practical experiences of non-clinical studies for ATMPs (focus on TEPs)
Ronny Schulz
TRM Leipzig – Germany

Progressing cell-based medicinal products to market authorisation and into the clinic
Gopalan Narayanan
NDA Group – UK – former CAT Member

Questions and answers
All session speakers/chairs

12:30 - 14:00 **Lunch & Learn Session** **Meet the regulators**
for pre-registered participants (room 6 and 7, floor +2)

12:30 - 14:00 **Lunch**

14:00 - 15:30 **Session 3** **Combined ATMPs: Tissue engineered products containing medical devices**

Chairs Egbert Flory (CAT) – Hans Jörg Meisel (TRM Leipzig)

Combined ATMPs: case study product
Paula Salmikangas
CAT Vice-Chair – Finland – Fimea

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Progressing TEP combined ATMPs into the clinic
Vuk Savkovic
TRM Leipzig – Germany

Combined ATMPs: development of the medical device part of the product
Zaklina Buljovcic
PharmaLex GmbH ² Germany

Panel discussion
CAT and TRM Experts

15:30 - 16:00 **Coffee break**

16:00 - 17:30 **Session 4** **EU and international environment**

Chairs: Lucia D'Apote (CAT) – Timo Faltus (TRM Leipzig)

The regulatory pathways for cell-based therapies in the USA
Kenneth K Kleinhenz
Cytori Therapeutics, Inc. ² USA

Transition from an academic concept to a clinical stage – what is the regulatory path to accelerate product development?
Christian K Schneider
CAT Chair

ATMP development challenges – industrial view/perspective
Kai Pinkernell
Miltenyi Biotec GmbH – Germany

Questions and answers
All session speakers/chairs

17:30 **Closing Remarks**

Frank Emmrich
Congress President / TRM Leipzig – Director

Christian K Schneider
Workshop Co-Chair / European Medicines Agency – CAT Chair

Ulrich Sack
Workshop Co-Chair / TRM Leipzig – Associate Director Research

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PROGRAMME SCIENTIFIC COMMITTEE

Prof. Dr. Frank Emmrich	Congress President / TRM Leipzig – Director
Prof. Dr. Ulrich Sack	Workshop Co-Chair / European Medicines Agency – CAT Chair
Dr. Christian K Schneider	Workshop Co-Chair / TRM Leipzig – Associate Director Research
Patrick Celis	European Medicines Agency – CAT Scientific Secretariat
Dr. Lucia D'Apote	European Medicines Agency – CAT Scientific Secretariat
Timo Faltus	TRM Leipzig – Germany – Investigator
Dr. Egbert Flory	CAT Member – Germany – PEI
Dr. Bastian Marquaß	TRM Leipzig – Germany – Investigator
Prof. Dr. Hans Jörg Meisel	TRM Leipzig – Germany – Executive Board
Dr. Susanne Müller	TRM Leipzig – Germany – WRM Organizing Committee
Dr. Gopalan Narayanan	NDA Group – UK – former CAT Member
Dr. Paula Salmikangas	CAT Vice-Chair – Finland – Fimea
Prof. Jean-Hugues Trouvin	Paris Descartes University, BWP Chair – France – ANSM

National Authorities of CAT members
ANSM – Agence nationale de sécurité du médicament et des produits de santé, Saint-Denis Cedex, France
Fimea – Lääkealan turvallisuus- ja kehittämiskeskus, Helsinki, Finland
MHRA – Medicines and Healthcare products Regulatory Agency, London, United Kingdom
PEI – Paul-Ehrlich-Institut, Langen, Germany

* European Medicines Agency – Committee for Medicinal Products for Human Use (CHMP) – Biologics Working Party