About

There are numerous developments in the field of Advanced Therapy Medicinal Products (ATMPs), which include products for tissue engineering, gene and somatic cell therapy. Despite their great potential, only relatively few ATMPs have as yet received a marketing authorisation. However, expectations of the ATMPs field have been boosted by the recent success with CAR-T cells in immunotherapy for cancer. The patient’s own immune cells are treated outside the body and programmed to fight the cancer cells. The expectations are high, because the first two registered medicinal products are considered game changers in the treatment of certain types of blood cancer. Also the field of gene therapy treatment of gene defects has clearly matured. Some products have recently been approved. Several others show very promising clinical results and are coming close to applying for marketing authorisation.

What can we learn from the successful developments? Also why has for some ATMPs marketing authorisation been withdrawn and what can we learn from the CAR-T cells? How can you ensure that ATMPs become successful and available to patients? Which (scientific/regulatory/financial) hurdles have been encountered, and what can we learn from the solutions? These are the questions that will be addressed during the MEB Regulatory Science Day.

Registration

Please use the link below to register:
https://www.mebscienceday.nl/

After registering, you will receive a mail confirmation in your inbox.

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Programme

Chair Dr Marjon Pasmooij, Science Programme Manager MEB

12.00 - 13.00  Registration and lunch
13.00 - 13.05  Opening and welcome
Hugo Hurts, director MEB
13.05 - 13.20  Current trends in ATMPs as seen by CAT
Dr Carla Herberts, senior clinical assessor MEB and alternate
CAT member
13.20 - 14.05  Designing ATMPs with the end in mind
Prof. Marc Turner, Professor of Cellular Therapy at the University
of Edinburgh and Medical Director at the Scottish National Blood
Transfusion Service
14.05 - 14.35  Lessons learned from Yescarta
Dr Bethany Dudek, Kite Pharma
14.35 - 14.50  Regulatory science poster pitches of PhD candidates and students
Renske ten Ham, PhD candidate, Challenges in development
and marketing authorisation of Advanced Therapy Medicinal
Products in Europe
Delphi Coppens, PhD candidate, A decade of marketing approval
of gene and cell based therapies in the United States, European
Union, and Japan: A regulatory decision-making evaluation
Tahira Nakchedi, Master student, Regulatory experience with
non-clinical studies of cell-based therapies: An analysis of studies
on the biodistribution and tumorigenicity
14.50 - 15.20  Break and poster session
15.20 - 15.50  Experiences of the Dutch Health and Youth Care Inspectorate
regarding ATMP GMP inspections and Hospital Exemptions
Dr Christianne Reijnders, Senior inspector IGJ
15.50 - 16.20  Panel discussion led by Dr Hans Ovelgönne, CAT member
Panel: Dr Carla Herberts, Prof. Marc Turner, Dr Bethany Dudek,
Dr Christianne Reijnders, Dr Yolanda van Kooij
16.20 - 16.30  Reflection on the day
Hugo Hurts, director MEB
16.30 - 18.00  Drinks and networking
Anyone who uses medicines should be able to trust them. The MEB is dedicated to fulfilling this mission every single day, in the Netherlands and in Europe. Good medicines used better.

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