Sunday 23 June 2024
15:00 – 16:30
Room - Kilsyth

Transitioning Advanced Therapies from Research to Development and Manufacturing - What Have We Learned About Developability?

Organiser: Dr Till Wenger, Boehringer Ingelheim Pharma and Dr Simon Fischer, Boehringer Ingelheim Pharma

Advanced therapeutic medicinal products (ATMPs) used for cell and gene therapy applications are an emerging class of biopharmaceuticals with the potential to become curative treatments for diseases that were considered untreatable so far. These novel modalities are amongst the most complex biological formats found under clinical development and rely on animal cell technology. In contrast to the more established protein-based therapeutics, prior knowledge about development and manufacturing is still scarce, making the transition from research to development and manufacturing more cumbersome. In this workshop, we propose to bring together experts from research and development working on these novel modalities to discuss about how ATMP products can be designed to function as efficient and safe drugs, and how advancements and challenges in the development of these novel products can be overcome in the future.

ATMPs represent a fast-growing novel class of biopharmaceuticals and their manufacturing is highly dependent on animal cell derived expression systems. While ATMP research at academic institutions has been carried out for many years, an increasing number of small and large biopharmaceutical companies have only recently stepped in to the development of ATMP products. Consequently, regarding clinical development and manufacturing this field is still in its infancy. In recent years, also the ESACT community has faced a growing interest in topics related to ATMPs and therefore this workshop is intended to bring together experts and interested scientists from academia and industry to streamline the development of innovative ATMP products in the future.

Format of the workshop:

1. Introductory comments by the session chairs Till Wenger and Simon Fischer
2. Overview presentations on various topics on ATMP developability

    - Dr Markus Hoerer, Ascend Gene & Cell Therapies, Germany
      CMC stumbling blocks that need to be removed at an early stage in the development of AAV gene therapeutics

    - Dr Marie Clincke, UCB Pharma, Belgium
      Efficient development of rAAV manufacturing process through integrated CMC development with the end in mind

    - Dr Raphael Drerup, Boehringer Ingelheim Viral Therapeutics Center, Germany
      The power of a platform: accelerating the development of an oncolytic virus

    - Dr Oliver Kraemer, Flagship Pioneering, USA
      Navigating the shift from research to development in advanced therapies: Understanding the critical impact of early product decisions on the success of ATMPs

3. Interactive speaker panel and audience discussion moderated by the session chairs