
PIER
Pharmacists in Industry, Education and Regulatory
IRELAND
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EIPG
Advanced Therapy Medicinal Products
Robert Smith
Webinar for members of EIPG
in conjunction with
PIER and University College Cork
Tuesday 24th November 2020
at 17.00 CET (16.00 GMT)
Click here to register

About the Speaker

Robert Smith BSc (Hons), MSc, PgDip, FRPharmS is pharmacist and qualified person whose areas of expertise include quality systems, auditing, validation and training as well as clinical trials and advanced therapy medicinal products. He has been working with ATMPs since 2006, and has practical experience certifying ATMP products both in the UK and in the EU. He is also experienced in assisting in the design of ATMP facilities for his clients and was involved in the design of the UK Cell and Gene Catapult Manufacturing Centre, as well working on the design of the Pharmaceutical Quality System for this facility. Robert is the Vice-chair of the Royal Pharmaceutical Society's Panel of Assessors for Qualified Persons and is a Committee member of the Industrial Group. Previously, he has been Chair of both the ISPE Investigational Product Community of Practice and the European Regional Steering Committee Investigational Product Community of Practice. He co-authored the Supply Chain Management Chapter of the ISPE Good Practice Guide on the Development of Investigational Biological Products and was author of the validation and standards chapter of the ISPE Good Practice Guide for Interactive Response Technology. He is a member of Phacilitate, a group that aims to promote advanced therapies globally, and was formerly Global Head of Quality for the Clinical Pharmacy Research Services group at Genzyme.

Overview of Webinar

Advanced therapy medicinal products (ATMPs) include gene therapy products, somatic cell therapy and products produced from tissue engineering. They offer ground-breaking new opportunities for the treatment of disease and injury. During this webinar the main types of ATMPs will be described and an outline provided of their manufacture and testing. In Europe, the Committee for Advanced Therapies (CAT) plays a central role in the scientific assessment of advanced therapy medicines for humans and the speaker will review the regulations and guidelines applicable to these products.

Leaning Outcomes

By the end of this presentation, you will be able to:

1. Understand the definition of an Advanced Therapy Medicinal Product (ATMP)
2. Identify the regulations and specific guidelines applicable to ATMPs
3. Outline the manufacturing process and testing procedures for ATMPs
4. Recognise the challenges of advanced therapy investigational products and ATMPs

To Join the Webinar

Please register for the event by filling out the Webinar Registration Form. The instructions will be shown on the screen when you submit the form, for you to keep a record of them.

Continuing Education:

A certificate of attendance will be issued after the webinar. The session will be an hour of Continuing Education.