9:00 - 17:00 H • Postillion Hotel Bunnik • max 30 participants

Course Advanced Therapy Medicinal Products

28 oktober 2021

NVFG member: € 250,-
Non-member: € 375,-
(Prices are excl.. BTW)

Want to know all about the regulatory landscape of Advanced Therapy Medicinal Products? Join the RegNed course to learn about the regulator's as well as industry perspective on gene, cell and tissue therapy. In this interactive course the science, classification, regulations, procedures and quality aspects behind ATMP regulatory approvals will be addressed.

This course is organised by RegNed, a division of NVFG.

Course content
The aim of the course is to introduce participants to ATMPs and the way these are assessed and approved in the EU.
The following topics are addressed:

- Science behind cell therapy, gene therapy, tissue-engineering
- Classification, regulations, procedures
- Environmental Risk Assessment
- Quality assurance aspects
- Industry interactions with regulatory authorities

The unique features of ATMPs versus "regular" medicinal product in this respect will be taken into account.

Participants profile
RA professionals interested in ATMPs are much welcomed to this course. General RA experience (not specific to ATMPs) is expected.

Course output
The course will provide participants with ATMP specific:

- Basic scientific knowledge
- Views of different stakeholders
- Understanding of key challenges
- Real-life examples
- A network of co-RA-professionals and NVFG
- The course will enable participants to put ATMP specifics in perspective and, when needed apply them in their daily regulatory activities.

Practical

- Date: 28 oktober 2021, 9:00h to 17:00h
- Location: Postillion Hotel, Bunnik
- Lunch included
- Format: 1 day meeting, presentations and interactive sessions
- Depending on the preference of the majority of participants, the presentations will be in Dutch or English
- Course materials, in English, will be provided, if possible

If Corona rules do not allow this approach to the course, an alternative will be sought.

NVFG-secretariaat
Leidsestraatweg 41D
3443 BP Woerden

085 - 00 43 084
info@nvfg.nl
www.nvfg.nl

NVFG

9:00 - 17:00 H ● Postillion Hotel Bunnik ● max 30 participants

Course Advanced Therapy Medicinal Products

28 oktober 2021

Registration

- Register via: https://www.nvfg.nl/activiteiten/
- Maximally 30 participants: register now!
- Fee: € 250,- (excl. BTW) for NVFG members, € 375,- (excl. BTW) for non-members
- Note: the fee to become a member of NVFG is €100,- in the first year and €175,- annually thereafter

Programm

Welcome
Brief introduction to NVFG and RegNed and explanation of course set up.

The Science behind ATMPs

`What is cell therapy, gene therapy and tissue-engineering? Participants will get an understanding of the essentials on the technology (eg. gene therapy/editing platforms), terminology (such as vector, plasmid, transgene, transduction) and principles involved in the science and application of ATMPs.

ATMPs from a regulators perspective

The Committee for Advanced Therapies (CAT) is the European Medicines Agency's (EMA) committee responsible for assessing the quality, safety and efficacy of ATMPs. In addition to the role of CAT, an insight view will be given on applicable guidelines, ATMP classification/certification and applicable procedures (and challenges encountered!).

Environmental risk assessment

Especially for ATMPs, ERAs are of key importance. Since regulations are local, hurdles need to be taken for commencing global clinical trials. The Dutch approach will be taken as an example to explain regulations, dossier content, submission procedures and involvement of agencies like the Gene Therapy Office.

Bringing a product on the market - QA perspective from industry and hospital

Which local supply arrangements need to be made? How to set up QA agreements with hospitals? What are the challenges for release of an ATMP product? Looking at real-life examples, these questions will be answered.

Regulatory from an industry perspective

Working with ATMPs comes with challenges and hurdles and requires a different approach than for “regular” medicinal products. Therefore, interaction with the authorities is key. In this session, an industry professional will share experience on dealing with local authorities and EMA with respect to scientific advice, classification, procedures and clinical trial set up.

NVFG-secretariaat
Leidsestraatweg 41D
3443 BP Woerden

085 - 00 43 084
info@nvfg.nl
www.nvfg.nl

NVFG

9:00 - 17:00 H ● Postillion Hotel Bunnik ● max 30 participants

Course Advanced Therapy Medicinal Products

28 oktober 2021

Speakers

Merel Stok (uniQure)
Merel works as a senior manager regulatory affairs at uniQure, and is involved across the entire gene therapy product lifecycle; from R&D to clinical trial applications. She has a scientific background in gene therapy and tissue engineering in academia and worked as a consultant with a focus on ATMPs and Biologicals prior to joining uniQure.

Babs Fabriek (Medicines Evaluation Board)
Babs works as a clinical assessor at the Dutch Medicines Evaluation Board. As alternate CAT member, she is highly involved in the evaluation of the safety, efficacy and quality of ATMPs and up to date with the scientific development in the field.

Erik Schagen (ProPharma Group)
After his scientific endeavors at different academic institutes, Erik was appointed as scientific secretary of the Subcommittee Medical and Veterinary Aspects of COGEM for almost 10 years. In this role he has been involved in the environmental risk assessment of many clinical trials and market authorization applications that included ATMPs. Currently, Erik is employed as senior consultant regulatory affairs at ProPharma Group, focusing on regulatory CMC and ERA aspects of clinical trial applications, marketing applications and product lifecycle management of Biologicals and ATMPs.

Anton Terwisscha van Scheltinga (Bristol Myers Squibb BV)
Anton is Qualified Person at Bristol Myers Squibb where he leads the EU team that is responsible for quality oversight and batch certification of clinical and commercial ATMPs. He obtained a PhD in translational research in medical oncology and was as hospital pharmacist responsible for a manufacturing facility for cell and gene therapy products for investigational use. His ATMP knowledge is based on experience in academic hospitals and industry and is focused on translational research and development, manufacturing and quality assurance.

Els Caenen& Hanneke Popma (Janssen Pharmaceutical Companies of Johnson & Johnson)
Els and Hanneke both have an extensive experience within the pharmaceutical industry and regulatory affairs. Els is Director EMEA Regulatory Affairs Team Lead and Hanneke is Regulatory Affairs Manager in the Netherlands, both responsible for a portfolio of Janssen products, including ATMPs.

NVFG and RegNed
NVFG is the abbreviation for “Nederlandse Vereniging voor Farmaceutische Geneeskunde” (Dutch association for Pharmaceutical Medicine) and supports its members to perform their roles in this particular working field. RegNed, a division of NVGF, is a network of professionals in Regulatory Affairs and platform for knowledge sharing focused on daily practice and future perspectives of Regulatory Affairs.

NVFG-secretariaat
Leidsestraatweg 41D
3443 BP Woerden

085 - 00 43 084
info@nvfg.nl
www.nvfg.nl

NVFG