pharmakon

GMP for Advanced Therapy Medicinal Products (ATMPs)

Strengthen your knowledge of the GMP requirements for ATMPs

Master the intricate compliance landscape governing Advanced Therapy Medicinal Products. Join this new course to learn about the GMP requirements for ATMPs used in clinical trials or for the market and elevate your expertise and shape the future of medicine with confidence.

In this course you will learn about the GMP requirements for Advanced Therapy Medicinal Products (ATMPs) used in clinical trials or for the market.

Advanced Therapy Medicinal Products (ATMPs) are a category of innovative and complex medical therapies that harness advanced technologies to manipulate or utilize living cells, tissues, or genes for therapeutic purposes. These cutting-edge therapies aim to treat, prevent, or diagnose diseases by targeting the underlying causes at the cellular and genetic levels. ATMPs include gene therapies, cell therapies, and tissue-engineered products hereby representing a paradigm shift in medical interventions.

Before we dig into the GMP requirements you will get an introduction to ATMPs from a scientific and regulatory point of view.

You will be provided with examples of ATMPs and their corresponding manufacturing processes. The similarities and differences between ATMPs and conventional biologics will be shown and discussed.

Besides an overview of global GMP guidelines for ATMPs we will have a special focus on the GMP requirements for the EU and the USA.

You will learn about the GMP requirements for both the facility, equipment, process, product, and personnel.
Furthermore, you will learn how to use Quality Risk Management to establish phase-appropriate procedures and SOPs.
Finally, you will get the chance to design your own compliant ATMP manufacturing process together with colleagues during the course. The course ends with a small test.

The course language is English.

At the course you will meet:
Erik Steffensen, Managing Partner and Principal Consultant, Spot-on Pharma Consulting

Course facts

FORMAT
2 days

RATING
4,1 out of 5

PRICE THIS YEAR
16.900 DKK excl. VAT, overnight stay included

Get a message via our newsletter when the course becomes available

Do you have questions about this course?

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Target group

• Managers working with development, manufacturing, quality control, or quality assurance of ATMPs
• Project managers working with development, manufacturing, quality control, or quality control of ATMPs

• Professionals and specialists working with development, manufacturing, quality control or quality assurance of ATMPs.

Your benefits

• you will understand what health authorities define as ATMPs and view concrete examples of such products to enhance your practical understanding
• you will determine if a new product falls under the ATMP category, ensuring precise application of the right GMP framework
• you will be able to integrate GMP requirements for ATMPs into your organization's Quality Management System (QMS). You will discern the similarities and differences from conventional biologics.

Your company's benefits

• your employee will be able to determine if a new product falls into the ATMP category hereby ensuring the right GMP framework is used
• your employee will share knowledge on GMP requirements for ATMPs with colleagues within your organisation
• your employee will be able to implement GMP requirements for ATMPs into the company’s own Quality Management System (QMS).