pharmakon

Development and Manufacturing of ATMPs

Learn how to develop and manufacture cell and gene therapies that meet regulatory requirements

Learn how to develop and manufacture your cell or gene therapy product in a way that enables fast approval by the health authorities.

Advanced Therapy Medicinal Products (ATMPs) — also known as cell and gene therapies — represent a new generation of medicines designed to repair, replace, or modify cells or genes to treat or even cure diseases. These innovative products are transforming modern medicine, but their development and manufacturing are governed by complex regulatory requirements.

To bring these advanced therapies safely and efficiently to patients, companies must ensure that products are developed and manufactured in accordance with health authority requirements. This includes understanding how ATMPs are defined and classified, how the product and process must be developed, and how Good Manufacturing Practice (GMP) principles apply from early development through to market approval.

This course gives you a clear roadmap for how to develop and manufacture your ATMP in a way that meets regulatory CMC (Chemistry, Manufacturing and Control) and GMP requirements from early development to market approval. You will learn how to use the Quality by Design framework to define critical quality attributes, establish control strategies, and build scientific justification for your regulatory submissions.

Through interactive lectures and case discussions, you will gain insight into navigating the regulatory landscape and learn how to develop and manufacture your ATMP in a way that fulfills health authority expectations — thereby supporting a smooth approval of your clinical trial or marketing authorisation application.

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
1 day

PRICE THIS YEAR
5.900 DKK excl. VAT

Sign-up dates

Hillerød
1. jun.
2026

Do you have questions about this course?

Kontakt
Kursuskoordinator
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Target group

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

Your benefits

- You will understand the regulatory CMC (Chemistry, Manufacturing, and Control) and GMP (Good Manufacturing Practice) requirements for developing and manufacturing ATMPs
- You will know how to apply the Quality by Design framework to define critical quality attributes and establish control strategies for your product
- You will be able to develop and manufacture your ATMP in a way that meets regulatory requirements hereby supporting a fast approval of your clinical trial or marketing authorization application.

Your company's benefits

- Your employee will strengthen competences within regulatory requirements for development and manufacturing of ATMPs
- Your employee will learn how to apply the Quality by Design framework to define critical quality attributes and establish control strategies for your ATMP
- Your employee will be able to ensure ATMPs are developed and manufactured in accordance with the regulatory CMC and GMP requirements hereby ensuring a fast approval of your clinical trial or marketing authorisation application.

Course agenda

09.00 - 16.30

- Definition of ATMPs
- Examples of ATMPs and their manufacturing processes
- Overview of regulatory requirements within Chemistry, Manufacturing and Control (CMC), and Good Manufacturing Practice (GMP) for ATMPs
- Use of Quality by Design framework for development and manufacturing of ATMPs

The course will be a combination of interactive lectures and group work.
The course language is English.

The tutor are Danish i.e. questions can be asked both in Danish and in English.

Sign up online at

www.pharmakon.dk