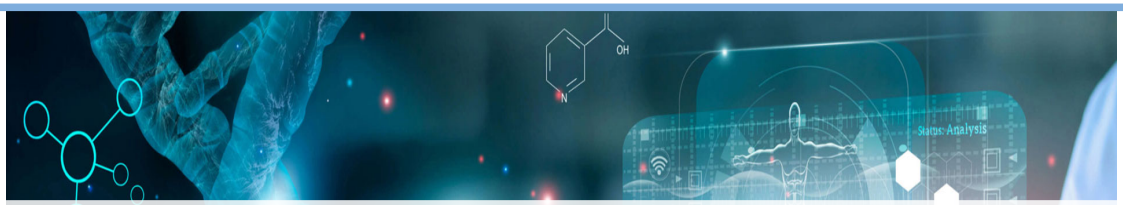
LIFE SCIENCE ACADEMY



Regulatory and Scientific Pathways for Global Advanced Therapy Medicinal Products Development (ATMPs)

A broad scientific and regulatory overview of the current status and challenges facing ATMPs development

Tipologia	Data	Lingua	Location
Online Training - Numero chiuso	16-18-22 February 2021	Inglese	Online

INTRODUZIONE

Advanced therapy medicinal products (ATMPs) are currently undergoing a boom. Several products including viral, non-viral and cell-based products have forged a path to market. In their wake, academics and clinicians continue to lead innovation and unlock the clinical potential of new approaches and technologies, whereas increased industry interest is stimulating investment and industrialization of the processes that lead to commercialization.

This online training course is designed to give a broad scientific and regulatory overview of the current state of the art and challenges facing ATMP development. It will follow the life cycle of an ATMP from concept to clinic and commercialization. and it will take into consideration global regulatory requirements and the often-challenging regulatory problems that ATMPs face.

PROGRAMMA

MODULE 1

1. Introduction to ATMPs and drug development

- Overview of small molecule drug development vs complex biological drug development
- EU regulatory framework for ATMPs
- US regulatory framework for ATMPs

2. Getting on the right track: early stage regulatory procedures for ATMP development

- ATMP classification
- Early stage regulatory procedures brief overview Orphan drug designation (ODD), Paediatric investigation plans (PIPs) and Pediatric study plans (PSPs)., Innovation meetings / scientific advice / protocol assistance / pre-IND meetings, Risk-based assessment and PRIME

MODULE 2

3. Chemistry, manufacturing and controls (CMC) for ATMPs

- Introduction to GMP and GMP guidelines
- Gene therapy manufacture main concepts
- Cell-based therapy manufacture main concepts
- QP release and import/export

4. Nonclinical issues

- Overview of nonclinical studies and timing
- Certification of CMC and/or nonclinical data for ATMPs and SMEs

MODULE 3

5. Clinical issues

- CTAs and IMPDs/IBs and INDs
- GMO licenses
- Clinical trial design considerations
- Shedding studies

6. Marketing authorization procedures

- Centralised procedure (EU) and Biologics license application (BLA) (USA)
- Accelerated assessments, expedited pathways and conditional approval
- Hospital exemption and compassionate use

- Post-marketing commitments including PSUR and Risk management plans (RMPs)

A CHI È RIVOLTO

- Regulatory Affairs Manager, Officer and Specialist
  Development Pharmacist
  Project Manager
  working for pharmaceutical company, Biotech, spin-offs and CROs.

It is also addressed to Researchers and academics in the ATMP field.

Participant experience

Participants need to have a basic understanding of regulatory procedures and/or a basic knowledge of ATMP biology.

TECNICHE DIDATTICHE

This limited enrolment online training course is intended to be a virtual class where various expert will guide you into the topics through real world case studies and examples and answering your questions.

DOCENTE/I

Christopher Mann

Scientific & Regulatory Affairs Associate Director, Asphalion S.L.

Christopher has a PhD in Biomedicine. Christopher had an academic research career in gene therapy including muscle regeneration and muscular dystrophy as well as using muscle as a platform for gene therapy applications including diabetes. He has over seven years' experience as a regulatory expert in medical writing and scientific and regulatory affairs for chemical and biologic products, including advanced therapies, biomaterials and complex new technologies. He has experience in both EU and US regulatory affairs including scientific advice/pre-IND meetings, clinical trial documentation, paediatric assessments, and commercialization procedures. As Scientific and Regulatory Affairs Associate Director at Asphalion, Christopher is involved in regulatory strategy, regulatory roadmaps and support for startups and biotechs, qualification of novel methodologies for biologicals, biomaterials, and advanced therapies. He also manages and leads regulatory Work Packages for H2020 projects.

Marta Rayo Lunar

Scientific & Regulatory Affairs Associate Director, Asphalion S.L.

Marta has a Pharmacy degree and a Specialist postgraduate degree qualification in Industrial Pharmacy and Galenic Formulation. She has over seven years' experience in drug development in the pharma Industry as R&D Project Manager on the development of drug candidates, and over five years' experience in regulatory affairs. As Scientific and Regulatory Affairs Associate Director at Asphalion, Marta is responsible of scientific and medical writing of regulatory documents working in regulatory strategy, regulatory roadmaps, ATMP designation, scientific advice and qualification of novel methodologies for biologicals, biomaterials, medical devices, and advanced therapies. She also manages regulatory Work Packages of H2020 projects.

Núria Coderch

Scientific and Regulatory Affairs Director, Asphalion S.L.

Núria has a PhD in Pharmacy. She has an academic research career and a broad scientific background in the area of microbiology and pharmacy with over ten years' experience as regulatory expert in charge of medical and scientific writing. As the director of the Scientific and Regulatory Affairs unit, Núria is a recognized expert in small molecules as well as innovative, biological and advanced therapy medicinal products (ATMPs), including gene and somatic cell therapies. She is also responsible for managing regulatory work packages of FP7 and H2020 projects and working in regulatory strategy and has vast experience in a range of global procedures including registration dossiers, IMPDs, IBs, CTAs, INDs, scientific advice, pre-INDs meetings and regulatory procedures during development.

COSA SAPRAI FARE DOPO IL CORSO

- Understand drug development pathways and pitfalls as they apply to ATMPs around the world
- Identify possible obstacles and the available resources and solutions for dealing with them

DURATA E INFORMAZIONI UTILI

Online Training – 3 modules

MODULE 1 | 16 February 2021 from 2.30 pm to 5.30 pm CET

MODULE 2 | 18 February 2021 from 2.30 pm to 5.30 pm CET

MODULE 3 | 22 February 2021 from 2.30 pm to 5.30 pm CET

After the registration, you will receive all details about the connection.

The course admits maximum 12 attendees.

The course will proceed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the

commencement of the course.

QUOTE ISCRIZIONE

Early Bird: € 1.100,00* (until 19 January 2021)

Ordinary: € 1.310,00*

Freelance – Academy – Public Administration:** € 660,00*

* for Italian companies: +22% VAT

** Early Bird discount not applicable to Freelance – Academy – Public Administration fee

The fee includes: tuition, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

SEDE DEL CORSO

Online interactive training on Zoom platform.
LS Academy will provide the access link to the virtual platform a few days before the training.