Revio
Regulatory Vision

Training course on Advanced Therapy Medicinal Products (ATMPs)

A course to have a good command of ATMPs and its regulation

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Introduction

Pharmaceutical regulatory landscape is always changing, evolving, and become more complex every year. Understanding the regulatory environment is vital for the pharmaceutical development of a product, especially for advanced and innovative medicinal products that may lack new guidelines and expertise from the Regulatory Authorities.

This course will review the role and evolution of the most relevant Regulatory Agencies, the different procedures and guideline that support the development of Advanced Therapy Medicinal Products (ATMPs) and the specification to consider when building the common technical document and marketing authorisation procedures of ATMPs.

This course will go through all the procedures that Regulatory Agencies make available to the manufacturers to help and support the development of their products, with special attention to these critical points that can be more problematic when brining and advanced therapy medicinal product to the patients.

Who Should Attend?

This course will provide relevant advice to professionals who want to begin or progress in the field of Regulatory Affairs, or for those working in Scientific areas related to Advanced Therapy Medicinal Products that want to know more or get involved in the development process of these products. Such as:

- ATMP Manufacturers
- CMC Development
- Process Development
- Clinical Research specialist
- QC and Stability
- Laboratory Managers
- Regulatory Affairs Department

Main aims of ATMPs Course

Objective 1.
Understanding the European Regulatory Framework for an ATMP.

Objective 2.
Understanding the possible interactions with Regulatory Agencies, such as Classification of ATMPs and Scientific Advice procedures.

Objective 3.
Addressing drossier's specifications for ATMPs on the different Modules for CTA and IMPD and most common issues.

Objective 4.
Addressing Quality/CMC Challenges in the development of ATMPs.

If you have any questions, please contact us:

regaffairs@reviopharma.com

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Agenda

Legal and Regulatory Framework for ATMPs - 1 hour

- EU ATMPs legislation.
- EU Marketing Authorization procedure.
- Compassionate Use and Hospital Exemption.

Clinical Trial Application and Investigational Dossier - 1 hour

- Clinical Trial Application (CTA).
- Investigational Medicinal Product Dossier (IMPD).
- Amendments.

Concepts on Advanced Therapies - 1 hour

- Types of Advanced Therapies.
- Authorised ATMPs.
- Case Studies on Types of ATMPs.

Good Manufacturing Practices for ATMPs - 1 hour

- GMP Guidelines: EudraLex.
- Part IV: GMPs for ATMPs

Interactions with EMA during ATMPs Development - 1 hour

- ATMP Classification Procedure.
- PRIME Squeme.
- Orphan Designation.
- Scientific Advice.

CMC Quality Challenges for ATMPs - 1 hour

- Starting Materials.
- Characterisation.
- Comparability.
- Potency.
- Viral Safety.

Course information

Date: 18-19 April 2024. Time: 10:00-13:00h

Cost: 450,00 EUR.

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Trainers

Maria Reviriego

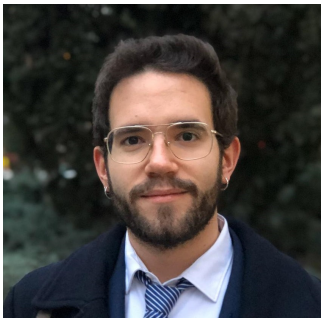
- Ex-regulator at the **Medicine and Healthcare products Regulatory Agency (MHRA)** in the UK as a Pharmaceutical Assessor of registration dossiers where it was nomi-nated as **EMA expert**.

- More than **20 years' professional experience** across Europe mainly in Regulatory Affairs and Product Lifecycle Management of Human Medicinal Products.

- She worked as **Regulatory Affairs Head in TiGenix (currently Takeda)** where among other projects with ATMP, she was actively involved in the successfully approval of the European Marketing Authorization of Alofisel (first authorization for an allogeneic cell therapy product in Europe).

- **Since April 2019**, she established herself as an **independent consultant** and collaborated with Biopharmaceutical Companies and Public institutions in the **field of ATMPs**.

- Lecturer in Pharmaceutical Industry Masters.



Jose Manuel Díaz

- Graduated in **Biology**, with a Master's in **Virology** and a Master's in **Biosciences Enterprises**.

- With professional experience as a researcher in a Microbiology Laboratory and as a **Pharmaceutical Regulatory Consultant** from Alladvice Regulatory Consultants and Revio Pharmaceutical Consultants.

- He has worked in different national and international regulatory processes such as **Scientific Advice, PRIME, Innovation Task Force Meeting, National Authorizations, Orphan Designation**. etc.

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