GOOD CLINICAL PRACTICE FOR ATMPs

Delivery: Online, Inhouse **Duration:** 1 days **Cost:** £780 (+ VAT)

Course overview

This interactive course provides an advanced, practical detailed interactive review of the organizational fundamentals of Good Clinical Practice (GCP) specific to ATMPs. This course also covers the EMA's and FDA's requirements for the conduct of clinical trials with Advanced Therapy Medicinal Products.

During this interactive workshop, we will discuss in what way clinical research team members can apply and comply with the expected requirements of GCP specific to ATMPs. Specific attention will be given to how quality systems effect overall data integrity, patient clinical risk, and respective regulatory risk for clinical trials conducted on ATMPs.

ATMPs are complex and inventive products that may pose specific challenges to the design and conduct of clinical trials. The challenges stem from various aspects of ATMPs such as (but not limited to) :

- Manufacturing constraints and the short shelf-life of the product may necessitate the application of rigid controls on logistical procedures to administer the product.
- Likewise, the mode of application may render very difficult the use of placebo controls and/or may require specific training.
- Furthermore, the long-term effects of the product may involve specific arrangements for long-term follow-up of trial subjects.
- Additionally, it is acknowledged that it may not always be feasible to generate related non-clinical data before the product is tested in humans.

Albeit the broad tenets of GCP set out in ICH Guidelines which are applicable to clinical trials with ATMPs, in some cases, it may be necessary to adapt those to the specific characteristics of ATMPs (e.g. regarding retention of samples). The application of extra procedures may also be needed (e.g. traceability requirements for ATMPs that contain cells or tissues of human origin, follow-up of patients after the end of the clinical trial, training on the upstream intervention of subjects and/or administration procedures

Who should attend?

This course is recommended for all organisations and professionals, Clinical Research Organizations (CROs), and academic institutions conducting clinical trials on ATMPs. Professionals who wish to consolidate their learning to date with experiences gained from experts, advance their practical knowledge in this area. Including professionals from pharmaceutical, biotech, and medical device companies as well as CROs and eTMF/TMF service providers having or seeking responsibilities in the following areas, w.r.t planning and conduct of clinical trials with ATMPs, for example; Clinical Operations, Clinical Project Managers, CRAs, CTAs, Investigators, Research Nurses, Study Site Coordinators, and managers.

Course programme

This covers the following topics :

- Clinical Trial Design
- Non-clinical studies
- Quality of the investigational ATMPs
- General considerations, including Tissues and cells of human origin, Medical devices, and Reconstitution
- Traceability
- Retention of samples
- Safe conduct of the clinical trial, including Information on the product, Handling of the investigational ATMP, and Risk-minimisation measures
- Upstream interventions on subjects and administration procedures, including Upstream interventions on subjects, and Administration procedures
- Protection of clinical trial subjects, including Informed consent, Long-term follow-up, and Administration of out of specification products
- Safety Reporting
- Monitoring

Learning outcomes

By the end of the course, you will have learned :

- Special legislation and guidance relating to the conduct of clinical trials with ATIMPs
- Specific regulatory requirements
- Pragmatic implications for clinical trials