Illustrative Case Study – CTA Submission with CMC Authoring for Cell Therapy

Client Profile

A hypothetical early-stage biotech company developing an autologous cell-based immunotherapy seeks to initiate a first-in-human (FIH) clinical trial in the UK. The sponsor requires support for a UK CTA submission under the Combined Review, along with expert CMC authoring for their Investigational Medicinal Product Dossier (IMPD).

Summary of Challenges

- Limited internal regulatory resources and UK regulatory experience
- Early-stage CMC data with underdeveloped Module 3 content
- Unclear GMP certification and comparability strategy
- Requirement for a UK Legal Representative and Combined Review coordination

Steps Taken by InsightReg

- Defined an overall CTA preparation plan with key milestones and roles
- Performed CMC gap assessment and authored critical Module 3 sections of the IMPD
- Provided guidance on ATMP-relevant data for identity, potency, and sterility
- Acted as UK Legal Representative and submitted through the IRAS portal
- Facilitated interactions with MHRA to align expectations for quality data

Outcome (Illustrative)

- Robust CMC dossier prepared, enabling smooth validation and review
- CTA successfully submitted and approved within standard review timelines
- Sponsor ready to initiate the UK arm of the clinical trial

This case is illustrative and designed to reflect the type of strategic and technical support InsightReg offers for ATMP clinical development.