Illustrative Case Study - SOP Development for a Virtual Biotech

Background

A UK-based virtual biotech developing a novel mRNA-based immunotherapy approached InsightReg Consultancy to establish a fit-for-purpose Quality and Regulatory SOP framework in preparation for their first-in-human (FIH) clinical trial in the EU.

Client Challenge

- No in-house QA team
- Processes were loosely documented via meeting notes and emails
- No formal SOP system in place
- Imminent regulatory milestones requiring documented procedures aligned with EU GCP and GMP expectations

InsightReg Solution

InsightReg delivered a tailored SOP development package:

- Conducted a gap analysis of existing practices against EMA expectations
- Defined a core SOP framework of 12 essential SOPs, covering:
  - Document Control
  - Vendor Qualification
  - Regulatory Submissions
  - Clinical Trial Material Handling
  - Deviation and CAPA Management
- Facilitated virtual workshops with SMEs to document actual practices
- Authored SOPs using clear, scalable templates suitable for virtual operations
- Delivered training slide decks and a change control SOP for future updates

Outcome

- SOPs implemented within planned timelines
- Regulatory CTA submission received no major findings on procedural documentation
- SOPs now form the foundation for GxP inspection readiness and partner audits

Value Delivered

- Reduced compliance risk
- SOPs aligned with scalable business growth
- Supported successful CTA submission
- Improved cross-functional awareness of regulatory expectations

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