1 Global CDMO Selection & Oversight Program

Challenge

A biotechnology company required a global CDMO network across the USA, Europe, India, and China to support development and GMP manufacturing of small molecules, biologics, viral vectors, and cell therapies.

Key Pharma Role

- Developed outsourcing strategy
- Defined CDMO selection criteria
- Led technical and GMP due diligence
- Established quality governance
- Managed global CDMO partnerships

Business Impact

Established a scalable global outsourcing network supporting multiple development programs across diverse technologies and regions.

2 Development of Corporate Quality Management System

Challenge

An emerging biotechnology company required a scalable Quality Management System to support GMP manufacturing and regulatory submissions.

Key Pharma Role

- Designed phase-appropriate QMS
- Developed SOPs, templates, and Quality Manual
- Implemented Change Control, CAPA, and Deviations
- Established Vendor Qualification
- Built document control and training systems

Business Impact

Implemented a complete QMS supporting GMP operations, IND readiness, and future organizational growth.

3 EU IMPD Submission Support

Challenge

A biotechnology sponsor required CMC leadership to prepare an IMPD for the Phase II clinical trial in Europe after completion Phase I in Australia.

Key Pharma Role

- Developed regulatory CMC strategy
- Authored Module 3 (CMC)
- Coordinated global development partners
- Supported EU regulatory interactions
- Managed submission readiness

Business Impact

Successfully enabled Phase II clinical trial authorization in the European Union.