

METIS

Cell Therapy Quality Assurance Case Study



Client Background: Our client is developing CAR-T and NK therapies targeting oncologic indications. They are VC funded and in multiple clinical trials. Metis has supported this client for five years and aided them to improve their quality management systems and management of their service vendors located in the USA and Europe.

Problems Identified

Metis worked with the client to identify appropriate vendors while in the discovery and pre-clinical stages of development. They have since moved to Phase 1 and 2 clinical trials, in the US and the Europe. Metis continues to support the development of both CAR-T and NK therapies.

Metis has worked in collaboration with the client to develop the internal Quality Assurance Department, and to ensure that milestones were met in consensus with all necessary parties.

Metis identified significant quality issues with some vendors that client was considering, including issues that would result in a Form 483 if inspected by FDA and could result in a CRL if inspected during client's BLA filing.

Services for Client & Vendors:

- Gap Analysis
- Audit
- Quality Assurance Support

Client is utilizing vendors for collection of donor cells, transferred by cryopak, prepared for cell isolation, and manufacturing of APIs for use in research setting and clinical trials.

Results:

Metis successfully improved client's Quality Management System and guided them to select vendors who would successfully support their clinical programs, BLA filing and commercialization plans.

WHO IS METIS?

Metis Consulting Services was founded to provide trusted advisory services to organizations within the Life Sciences Industry. Our experience spans from bench to post-approval services in GXP space. We help clients leverage cross-functional expertise to efficiently develop their assets while anticipating and addressing potential pain points along the way.

At METIS, our mission is to ensure quality, drug safety, pharmacovigilance, clinical, and data management have the tools to support innovation pathways, with a balance of humanity and lightheartedness along the way.



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AUDITS | DATA MANAGEMENT | PHARMACOVIGILANCE | QUALITY MANAGEMENT | REMS