

Strengthening Quality Operations for an Allogeneic T-Cell Therapy Developer

THE CHALLENGE

A clinical-stage allogeneic gamma-delta T-cell therapy developer had built its Pharmaceutical Quality System and quality procedures to be resourced by a larger team. Following organisational restructuring, the remaining team could no longer manage those procedures in the same way, contributing to **overdue quality actions and mounting pressure on supplier oversight**.

OUR APPROACH

One of eXmoor Pharma's Qualified Persons, **Drew Hope**, was named on the client's manufacturing authorisation following a focused onboarding process. Drawing on experience supporting multiple CGT manufacturers, he identified where quality processes could be made **more proportionate to the resources available**.

Alongside routine QP duties, Drew worked directly with the client to ease operational bottlenecks and help the team regain control of priority quality activities without compromising compliance or product quality.

As revised Annex 1 requirements came into effect, Drew also developed the facility's **first written Contamination Control Strategy**, bringing the existing approach into a single documented framework.

DELIVERABLES

- **Routine QP oversight and batch certification**
- Revised raw material categorisation, focusing quality oversight according to **risk and criticality**
- Introduction of **remote vendor assessment methods** to reduce the supplier management burden
- Hands-on support as part of the client's audit team
- Development of the facility's **first written Contamination Control Strategy**

IMPACT

A more risk-based approach to supplier oversight, combined with hands-on audit support, helped the client **bring its supplier audit schedule back under control**. This freed quality resources to **close compliance gaps and strengthen the wider Pharmaceutical Quality System**.

EXMOOR PHARMA AT A GLANCE



Philosophy: With a focus on the entire journey from bench to market, we streamline and de-risk projects to maximise product success.



Capability: A full-service partner delivering high-value solutions for better, faster and cost-effective outcomes.



Trust: Building lasting relationships through trust, transparency, and respect.



Collaboration: An open partnership that complements and enhances your capabilities.



Experience: Over 20 years of expertise, supporting 190+ clients from discovery to patient delivery across diverse programmes.



"Drew brought experienced, practical QP support exactly when we needed it. He worked closely with our team to simplify key processes, strengthen supplier oversight and restore control of priority quality activities, while maintaining the compliance standards required for clinical manufacturing."

Former Head of Operations & Supply Chain

