

Building a CMC Roadmap for an AAV-targeting Platform

DEFINING PROCESS, QUALITY AND REGULATORY PRIORITIES FOR FIH

THE CHALLENGE

Tavira Tx, a biotech developing an **AAV-targeting platform**, needed to define a **clear CMC strategy** to progress towards **clinical asset development**. The company sought expert support to assess **manufacturability and reproducibility**, establish **quality considerations** across its portfolio, and understand the **regulatory requirements** at this stage.

OUR APPROACH

eXmoor Pharma structured a three-phase consulting project. We began with workshops to assess **Tavira's platform**, **manufacturing processes** and **portfolio priorities**. Findings were consolidated into a **detailed CMC strategy report**, which was reviewed and refined with the client team. A final alignment session set out **next steps for development and regulatory preparation**.

DELIVERABLES

- A **high-level CMC roadmap** tailored to Tavira's stage of development, outlining critical technical, quality and regulatory priorities
- A **manufacturability and reproducibility review** to assess the technical feasibility of the platform
- Guidance on defining **suitable quality attributes and controls** across the product portfolio
- An outline of **regulatory considerations** for moving toward clinical development
- Strategic recommendations on **sequencing of activities** to align science, CMC and business needs

IMPACT

The engagement gave Tavira **clarity on its development path**, providing an **actionable roadmap** that aligned its **leadership team and investors** around key priorities. By combining **scientific insight** with **regulatory and quality foresight**, eXmoor created a practical plan that enables Tavira to progress its platform toward **clinical asset development with confidence**.

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 170+ clients from discovery to patient delivery across diverse programs.



eXmoor Pharma helped us translate our scientific platform into a clear, phase-appropriate CMC plan. Their structured approach identified the critical challenges and set out practical next steps toward first-in-human studies, giving our team and investors confidence in the path ahead."

Els Henckaerts

Co-founder, Director & Scientific Advisor, Tavira Tx

