INFO SHEET

CMC Strategy: De-risking Development and Supporting Investment

Early-stage CGT developers face a unique challenge: securing **investment** and **regulatory buy-in** while translating **promising science** into **commercially viable therapies**. Developers must also carefully balance **what to prioritise for First-in-Human studies** versus what to defer until **clinical efficacy is proven,** and **further funding is secured**.

Our CMC Strategy service provides the technical, regulatory and cost foundations to support confident decision-making and investor engagement.

OUR APPROACH

We work collaboratively with clients to **pressure-test development scenarios**, define a **credible roadmap,** and **model costs aligned to commercial viability**.

Starting with a structured assessment of current assets and data, we apply our proven **Health Check framework** and **CMC Building Blocks** to map the path to First-in-Human or commercial milestones. This includes evaluating **dose requirements, product expansion potential, quality attributes, potency strategy and CoGs assumptions** — all in the context of scale-up and regulatory expectations.

In parallel, we help clients define what is appropriate to invest in now versus what can be phased in later, aligning development with both **risk appetite** and **funding stage**. Our methodology is **modular**, allowing us to tailor delivery to the client's needs, investment stage and clinical objectives.

DELIVERABLES

- **Development Roadmap:** Key gaps and staged steps to clinical or commercial readiness
- **Manufacturing Strategy:** Scale and quality approach tailored to product maturity
- **Regulatory & Quality Alignment:** High-level plan across analytics, territory and control strategy
- **Cost Modelling & Summary:** Treatment cost estimates and actionable programme plan

IMPACT

Our CMC Strategy work gives developers **clarity, credibility** and **commercial** perspective. By aligning **scientific, regulatory** and **economic considerations**, we help clients demonstrate a **realistic, investor-ready plan**. We reduce risk by defining a phase-appropriate **process for First-in-Human studies**, with improvements built in **post-FIH as funding allows**. For many, it's the **bridge between proof of concept and a fundable development pathway**.

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."

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