CASE STUDY

Optimising AAV8 Manufacturing for Preclinical Success

THE CHALLENGE: SCALABLE, HIGH-QUALITY MANUFACTURING

AAV8 gene therapy developers often face significant hurdles in **scaling academic processes** for clinical readiness. Challenges include low process yields and a complex impurity profiles that without significant optimisation in process development can impact the delivery of suitable material for preclinical and toxicology studies resulting in delays to clinical programs.

OUR APPROACH

Over the past decade, eXmoor has partnered with multiple clients to deliver **AAV8 material generation projects** alongside **full process and analytical development** packages. By maintaining **close collaboration** throughout, from **technology transfer to final deliverables**, eXmoor applied its deep expertise in AAV manufacturing process design to optimise performance and ensure scalability.

DELIVERABLES

- **Technology Transfer:** Reviewed existing documentation, conducted reciprocal site visits, and executed baseline processes for sign-off.
- **Process Development:**
  - Investigated the impact of **seeding density** on AAV8 upstream yield.
  - Evaluated alternative **lysis reagents** to replace Triton X-100.
  - Designed scalable **clarification filter trains** and eliminated non-scalable steps from academic processes.
  - Optimised **polishing steps** to remove contaminants and empty capsids.
  - Developed scalable **ultrafiltration-diafiltration (UFDF)** unit operations.
- **Material Generation:** Supplied **low endotoxin AAV8 material** (adherent and suspension-based) for R&D and preclinical studies, including toxicology.
- **Analytical Development:**
  - Developed rapid **AEX-HPLC methods** to measure full-to-empty capsid ratios.
  - Optimised **qPCR assays** for viral titre measurement.
  - Conducted residual analysis of **HCP** and **HCDNA**.

IMPACT

eXmoor delivered an **improved, scalable manufacturing process** for AAV8, alongside high-quality materials required for **preclinical development**. This enabled clients to progress confidently towards clinical trials with a robust and compliant process.

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

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