

# Accelerating **Advanced Therapies** from Strategy to Patient

*Your Integrated Regulatory & GMP Clinical Supply Partner for ATMPs and Innovative Medicines.*



## Why Leading Biotech & Pharma Choose Advanthera

- End-to-end execution: From early regulatory strategy to patient-ready clinical supply
- Integrated regulatory + GMP depot model — eliminate fragmentation and reduce risk
- Deep ATMP expertise across gene therapy, cell therapy & innovative biologics
- Direct interaction with AEMPS & EMA
- Fully GDP/GMP-compliant infrastructure with QP oversight
- Sponsor-centered project management with strict timeline & budget control



## Regulatory Acceleration & Development Strategy

- Global regulatory roadmap design for ATMPs & innovative medicines
- Scientific Advice meetings (AEMPS / EMA)
- IMPD / CTD preparation & optimization
- Clinical Trial Applications (CTA) management
- Hospital Exemption pathways
- Marketing Authorization support
- Regulatory representation & authority interactions



## GMP, Quality & Tech Transfer Excellence

- Full GMP Quality System implementation & optimization
- Custom SOP development & risk management frameworks
- Internal audits & CAPA management
- Tech transfer to CMOs
- Certification readiness & inspection support
- Electronic Quality Management System (eQMS)



## Clinical Supply & Global Logistics Mastery

- GMP-certified depot for ATMPs & innovative medicines
- Qualified Person (QP) batch certification & release
- Patient kit assembly & clinical labeling
- Multi-temperature cold chain management (-100°C to 25°C)
- GDP-compliant global warehousing & distribution
- Comparator sourcing & BioRepository services
- Full chain-of-custody & end-to-end traceability



## Operational Infrastructure Built for Scale

- 1,100+ m<sup>2</sup> GMP operational facilities
- 4 clean rooms with simultaneous batch processing capability
- Advanced temperature-controlled storage (15–25°C | 2–8°C | -20°C | -80°C | -100°C)
- Fully paperless facility (ERP, WMS, IMS, TMS, eBR, eQMS)
- Complete traceability of IMPs, non-IMP & biological samples



## Proven Track Record

- 23+ IMPDs / CTDs delivered
- 60+ Scientific Advice meetings
- 10+ GMP implementation projects
- 70+ Quality & GMP audits
- 150+ specialized training programs delivered
- 23+ Advanced Therapy success stories