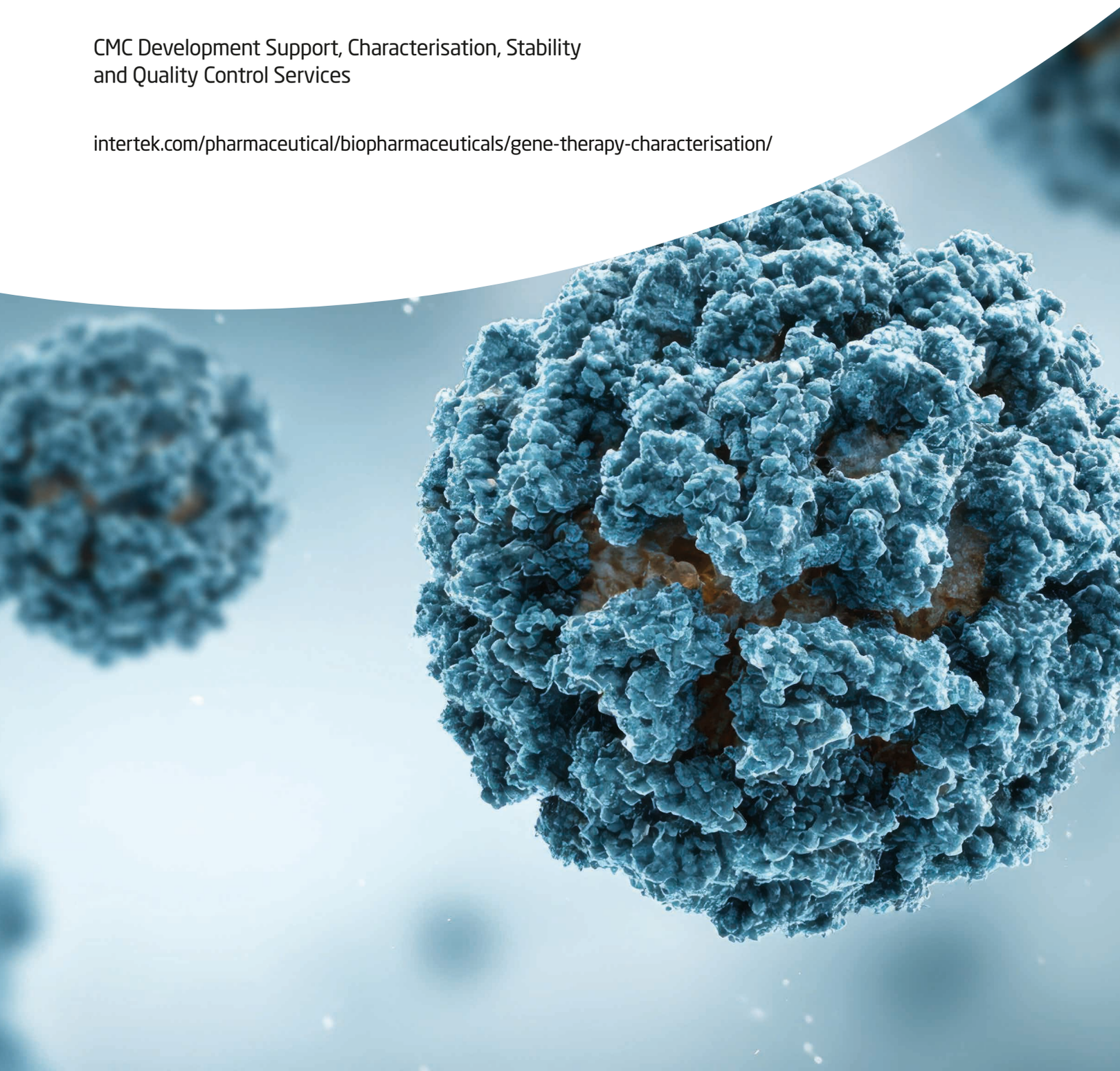
intertek
Total Quality. Assured.

GMP & CMC Laboratory Services

Cell and Gene Therapies Analytical Development Services

CMC Development Support, Characterisation, Stability and Quality Control Services

intertek.com/pharmaceutical/biopharmaceuticals/gene-therapy-characterisation/



Analytical & Characterisation Technologies

- PCR [qPCR, ddPCR]
- NGS
- Flow Cytometry
- AUC
- Morphology [cryoTEM/SEM]
- DLS

Analytical Development and Chemistry, Manufacturing and Control (CMC) Support

From breakthrough science to real-world treatment, cell and gene therapies are transforming medicine - while redefining the challenges of development, manufacturing, and regulation.

Our experts provide integrated analytical development and testing services to support robust product characterisation, safety, potency, and regulatory compliance across the full development lifecycle.

Cell and gene therapies span a rapidly evolving range of modalities—from viral and non-viral gene delivery to mRNA and engineered cell therapies. Their inherent complexity and sensitivity demand specialised, phase-appropriate analytical strategies.

Ensuring identity, purity, potency, and safety demands tailored, orthogonal analytical methods capable of meeting the challenges of limited samples, product heterogeneity, and GMP release.

Regulatory expectations from agencies such as the EMA and FDA continue to evolve, placing greater emphasis on well-characterised potency assays, impurity profiling, comparability, and lifecycle management of analytical methods. Early, risk-based control strategies grounded in sound science are critical to enabling accelerated development and commercial readiness.

Our expertise

With over 20 years of experience, our GLP, GCP, and GMP-compliant laboratories support developers and manufacturers through advanced analytical characterisation, method development, validation, and routine QC testing.

Our services are built on deep technical expertise and active engagement with industry groups, ensuring alignment with current regulatory and scientific expectations.

We have extensive experience working with a range of viral vector systems, including AAV, adenovirus, and lentivirus, as well as plasmid DNA and mRNA-based products.

Analytical Capabilities

Impurity & Compendial Testing

- Host cell DNA and residual DNA analysis
- Host cell protein quantification
- Residual plasmid and process-related impurities (e.g. PEI, solvents)
- Particulate matter assessment
- General compendial testing (e.g. pH, osmolality, appearance)

Bioanalytical Services

- Pharmacokinetics (PK) and biodistribution studies
- Biomarker and pharmacodynamic (PD) analysis
- Immunogenicity (ADA/NAb)
- Target gene engagement

Viral Vector Characterisation

- Empty vs full capsid analysis
- Aggregation assessment
- Charge heterogeneity (icIEF)
- Capsid protein purity (CE-SDS)
- Protein quantification (BCA)

Cell & Molecular Analytics

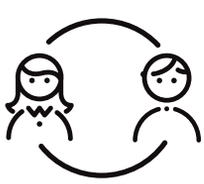
- Transgene expression analysis
- Flow cytometry-based assays
- Potency testing (vector genome titre and functional assays)
- Infectivity and functional titre (e.g. TCID50)
- Identity testing, including genome sequencing

Stability & Batch Release

- Stability programs, including forced degradation studies
- Phase-appropriate statistical design
- Batch release testing programs to support clinical and commercial supply

Specialist Facilities

Our purpose-built laboratories are designed to handle Class I and Class II biological agents and recombinant genetic materials for research and compliant testing. We also support encapsulated and lipid-based delivery systems, including liposomal formulations.



Partnering with You

We support clients from early development through to commercialisation, delivering flexible, science-driven solutions tailored to the specific challenges of each product. Our integrated approach ensures reliable data generation, regulatory alignment, and accelerated development timelines.

~46 FDA-approved cell and gene therapies

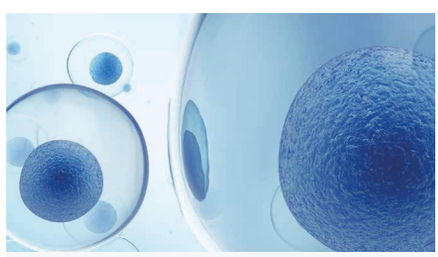
This includes: CAR-T therapies, *in vivo* gene therapies and autologous cell-based gene therapies

~100 – 200 INDs submitted annually

~3-8 approvals approvals expected per year

Source: U.S. Food and Drug Administration, 2025-2026

Approved Cellular and Gene Therapy Products | FDA



Ask the Expert: Implementing effective E&L programs for Advanced Therapeutic Medicinal Products (ATMPs)

Cell and gene therapies present a higher risk of leachables due to the use of single-use systems and limited purification steps.

Unlike traditional biologics, contaminants are harder to remove and may remain in the final product.

These leachables can directly impact cell viability, product quality, and therapeutic performance.

Understanding and controlling these risks is critical to ensuring safety and regulatory success.

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