

Oxford Nanopore sequencing solutions

for cell and gene therapies

Oxford Nanopore Technologies

What you're missing matters

Comprehensive sequencing: a critical checkpoint at every stage in cell and gene therapy development

Cell and gene therapy development is inherently complex. As these medicines are biologically derived, variability and error can emerge at multiple points during the process. That is why comprehensive sequencing is essential: it serves as a critical quality control (QC) checkpoint throughout development, helping ensure product consistency, efficacy, and safety.

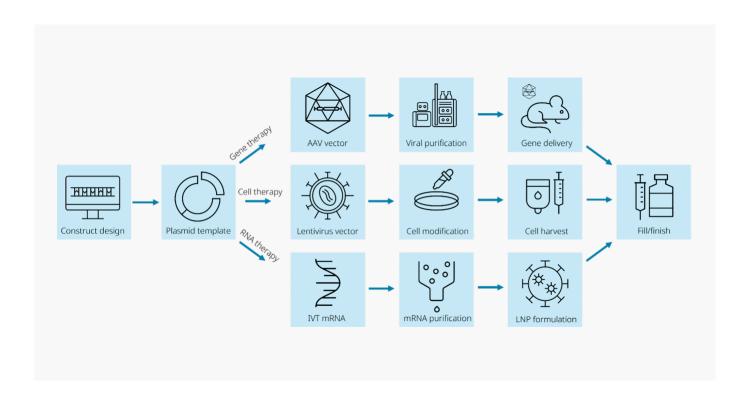
However, many of the analytical techniques still in use today were not designed for the unique demands of advanced biologics. Legacy next-generation sequencing (NGS) methods depend on nucleic acid fragmentation, amplification, and short-read assembly — processes that can erase crucial sample information and distort the biological picture.

Oxford Nanopore sequencing overcomes these limitations by reading DNA and RNA molecules directly, revealing the true biology of your samples and uncovering what you've been missing.

Nanopore sequencing delivers:

- Ultra-rich, multiomic data for comprehensive insights
- Any read length from short to ultra long, spanning several million bases
- PCR-free data no amplification bias
- Built-in methylation detection no additional bisulfite or enzymatic conversion
- Real-time analysis immediate access to data for fast decision-making

From early construct design through to final product characterisation, our industry-leading solutions for the development of cell, gene, and RNA therapy drug modalities provide the data you need to develop better and safer drugs, while reducing risk.



Plasmid sequencing — start with confidence

Plasmids are an essential starting material for cell, gene, and RNA therapies, serving as templates for vector and mRNA production. Even small sequence errors can propagate downstream and impact desired yield and fidelity, leading to wasted effort and costly process failures. Legacy assays such as Sanger sequencing are often limited to partial plasmid coverage, rely on vector-specific primers, and cannot resolve structural rearrangements or repetitive regions, leaving blind spots in plasmid verification.

Oxford Nanopore sequencing enables whole-plasmid characterisation in a single run, providing full-length, amplification-free reads that reveal every base of your input plasmid construct to deliver complete confidence in your production processes.

Sanger sequencing

Gene insert

No mutations

Partial plasmid sequence

Oxford Nanopore sequencing

Promoters

 Compatible with host organism

Gene insert

- Correct orientation
- No mutations

Complete plasmid sequence

Resistance genes

- Correct sequence
- Not already present in host organism

Backbone

- No mutations
- Suitable for storage and future use

Why Oxford Nanopore sequencing?

- Whole-plasmid sequence verification, including insert orientation, resistance genes, promoters, and backbone — without primers or complicated primer walking
- Resolve repetitive regions, dimers, and deletions
- Simple end-to-end workflow with rapid, same-day turnaround time up to 96 samples per run
- In-house process less downtime plus increased data and intellectual property security



Gene therapy — ensure vector genome integrity

Accurate QC of adeno-associated virus (AAV) vectors is crucial to ensure that the correct, error-free genomes are packaged into capsids and delivered to cells. However, legacy short-read sequencing often struggles to capture the full picture, missing complex structured regions like inverted terminal repeats (ITRs), failing to detect truncations, and requiring multiple assays to identify impurities.

Oxford Nanopore offers a streamlined, end-to-end workflow for the rigorous QC of AAV genomes. Nanopore reads are not restricted in length and can span entire AAV genomes, from ITR to ITR, enabling complete characterisation and easy identification of truncated genomes, production contaminants, and mutations in a single assay.

Short-read Full-length AAV genome? ITR 2 ITR 1 sequencing ITR₁ Truncated AAV genome? Ambiguous data caused by incomplete AAV coverage Oxford Nanopore ITR 1 Full-length AAV genome < ITR 2 sequencing ITR 1 Truncated AAV genome ~ Long sequencing reads deliver complete AAV coverage



Cell therapy — confirm edits and integration accuracy

In engineered cell therapies such as chimeric antigen receptor T (CAR T) cell therapy, verifying the accuracy of gene edits and integration sites is vital to ensure both therapeutic efficacy and patient safety. Legacy approaches, typically based on short-read sequencing or PCR, are prone to missing insertional events in repetitive or complex regions of the genome and provide limited genomic context of the insertion site.

Nanopore sequencing overcomes these limitations by delivering long reads that fully resolve gene insertions, their orientation, and surrounding genomic architecture. Using either whole-genome or targeted sequencing approaches, Oxford Nanopore technology confirms both on- and off-target edits in modified cells, ensures consistency across batches, and can detect microbial contamination.



RNA therapy — verify molecular attributes

RNA-based therapeutics are revolutionising treatment for infectious diseases, cancer, and genetic disorders. However, sequencing methods that rely on reverse transcription and amplification can introduce bias and erase vital information about native RNA modifications and poly(A) tail structures, which are both known to play a role in transcript stability and translational efficiency.

Oxford Nanopore offers the only technology that directly sequences native RNA molecules, without conversion to cDNA or amplification. This delivers unbiased analysis of RNA molecules, including base modifications, providing unmatched visibility into RNA identity and integrity in a single assay.



About Oxford Nanopore Technologies

Founded in 2005, Oxford Nanopore has developed a new generation of DNA/RNA sequencing technology. It is the only sequencing technology that offers real-time analysis, in fully scalable formats from pocket to population scale, that can analyse full-length native DNA or RNA. The technology is used in over 120 countries worldwide to deliver rapid, comprehensive genomic insights to users across academic, healthcare, environmental, and industrial settings. The company is headquartered in Oxford, UK, with satellite offices around the world.



Your trusted partner for cell and gene therapy solutions

- Easy, robust, and scalable protocols and end-to-end workflows
- Rapid, local, field-based support
- Global presence with offices across North America, Europe, and Asia
- Proven technology backed up by over 18,000 peer-reviewed publications



Contact us today to discuss your drug development requirements or visit **nanoporetech.com/biopharma** for more information.



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