Biopharma

Nanopore sequencing solutions

for quality control in biopharma

Oxford Nanopore Technologies

WHAT YOU'RE MISSING MATTERS

Reducing complexity, accelerating results

Throughout the drug development pathway, numerous analytical methods are developed to measure critical quality attributes (CQAs) to support the robust characterisation of drugs used within clinical trials and subsequent commercial products. Oxford Nanopore Technologies offers a unique sequencing technology that is redefining the landscape of genetic analysis, enabling the delivery of rapid and comprehensive, single-assay quality control (QC) tests that can replace multiple legacy assays for faster access to robust results.

Oxford Nanopore is committed to supporting the seamless transfer of nanopore sequencing-based analytical methods across the full drug development pathway, from discovery to commercial. Our secure supply chain solution enables biopharma companies to meet global regulatory requirements through:

- Biopharma QC-specific test packs, including consumables, analysis pipelines, and documentation
- Locked-down consumables and analysis pipelines
- Stage-appropriate sequencing devices
- Comprehensive support packages

Test packs for GMP-grade biopharma QC

1 Test Packs: mRNA Identity, Integrity & Purity | Plasmid Identity

Multiple orthogonal techniques are currently used to define the CQAs for messenger RNA (mRNA)-based drugs, covering identity, integrity, and purity testing. These testing methods are typically slow, complex, and require large investments of capital expenditure and labour. The mRNA Identity & Integrity Test Pack from Oxford Nanopore can reduce the complexity and testing time by measuring multiple CQAs in a single assay. In addition, the Plasmid Identity Test Pack enables verification of starting material prior to *in vitro* transcription and the identification of plasmid-derived impurities in the mRNA drug substance.

Why Oxford Nanopore?

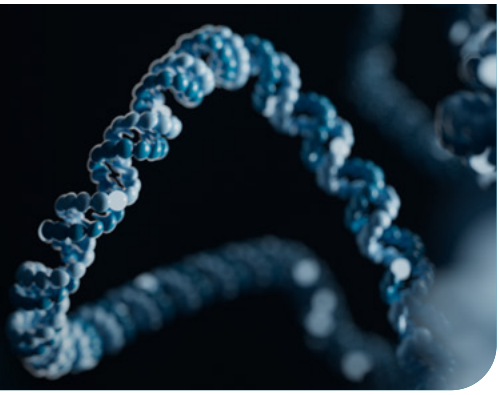
- Direct mRNA profiling overcomes the limitations and biases of traditional cDNA sequencing approaches
- Multiple CQAs can be measured in a single assay, including poly-A tail length, fragmentation, sequence identity match to reference, and N1-methylpseudouridine base modifications
- Long sequencing reads deliver complete coverage and analysis of plasmid or DNA input materials

2 Test Pack: Integration Site Analysis (ISA)

Antibodies and therapeutic proteins have transformed how we treat a variety of diseases — from complex diseases, such as cancers and autoimmune conditions, to infectious diseases. Genetically engineered mammalian cells are commonly used to produce large volumes of these high-value drugs; however, accurate genetic integrity verification of these cells, and in particular Chinese hamster ovary (CHO) cells, is notoriously difficult. The identification of transgene truncations, rearrangements, duplications, and integration into undesirable locations is currently hindered by the use of slow and inaccurate methods.

Why Oxford Nanopore?

- Long sequencing reads provide an enhanced ISA approach
- Comprehensive identification of transgene copy numbers, orientation, concatemers, truncations, and inverted repeats — replacing legacy methods
- Rapid test option available



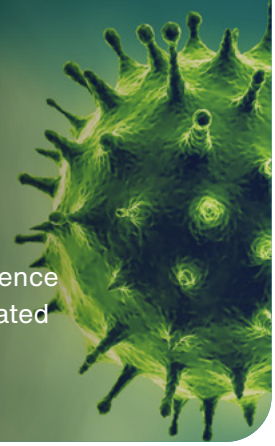
3 Test Pack: Adventitious Viral Agents (AVA)

AVA testing currently comprises a complex list of compendial methods that require significant investment in infrastructure, large capital equipment, and labour. Additionally, testing methods can be time consuming and error prone, leading many companies to outsource AVA testing.

International regulatory bodies now encourage the use of high-throughput sequencing for AVA testing within GMP environments, replacing the use of some compendial methods (e.g. *in vivo* testing)*. Nanopore sequencing, which can deliver long reads of native DNA and RNA, is ideally suited to the detection of viral contamination within complex samples, such as cell banks, seeds, and in-process or bulk harvests of drug substances.

Why Oxford Nanopore?

- Long sequencing reads can span entire viral genomes — delivering more comprehensive viral contamination detection
- Identify replicating DNA or RNA viruses by direct sequencing of native mRNA — no cDNA conversion required
- Easily generate accurate host reference genomes, enabling removal of host sequence from AVA data prior to contamination detection — reducing false positives associated with legacy sequencing techniques



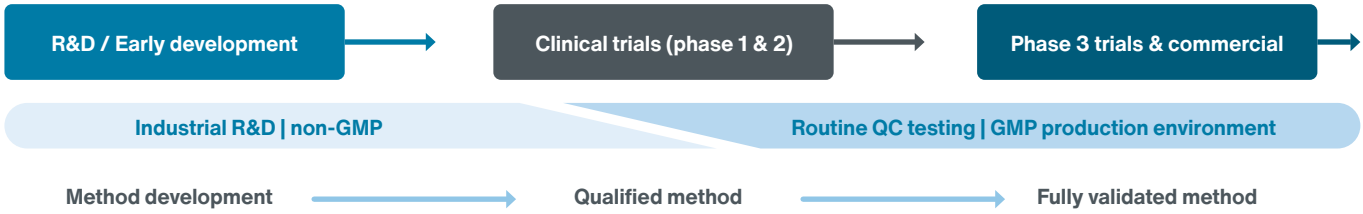
* For example, the European Pharmacopeia (EuPh)[1] and the International Council for Harmonisation (ICH) Q5a (R2).[2]

Test Packs for other applications, including customisation options, are currently in development. Contact us to find out more: nanoporetech.com/biopharma.

Stage-appropriate sequencing devices: from research to Q-Line

Oxford Nanopore's compact and versatile sequencing devices are suitable for deployment within research laboratories and analytical development or production facilities, either on-site or with a CRO/CDMO partner.

From R&D/Early development explorations with MinION™, GridION™, or PromethION™ devices to GMP QC release testing with the Q-Line GridION device, nanopore sequencing offers a clear pathway for the seamless transfer of nanopore-based analytical tests across the full drug development pathway.



Compact and versatile sequencing devices suitable for any lab and sample throughput.
View all devices at nanoporetech.com/products.

Discover more about Oxford Nanopore's biopharma research solutions at nanoporetech.com/biopharma.

Q-Line

Oxford Nanopore's Q-Line products deliver all of the benefits of real-time, on-demand nanopore sequencing in a locked-down, standardised format — ideally suited for use in regulated environments. Q-Line products provide the critical infrastructure necessary to ensure the seamless and scalable transfer of analytical methods from discovery to commercialisation.

GridION Q combines the capacity to run five independent flow cells with integrated high-performance compute and industry-specific software — offering a simplified user interface and 21 CFR Part 11[3] and EU GMP Annex 11[4] configuration. The GridION Q has been designed to facilitate your computer system validation (CSV).

Key features:

- Simple workflows requiring minimal user interaction
- Closed system with comprehensive audit trails
- Secure, whole-device at-rest encryption
- Permission-based access with authentication system integration

Discover more about Q-Line at nanoporetech.com/q-line.

Five flow cells can be operated individually or together

Industry-specific software supporting 21 CFR Part 11 and EU GMP Annex 11 configuration

Onboard data analysis

Preconfigured run settings for specific QC assays

Specification	
Weight	14.4 kg
Size	W 370 mm | H 220 mm | D 365 mm

FS 686041

Comprehensive support packages

Enhanced support packages are available to meet your installation, validation, and routine operational needs.

Device Configuration Package	Includes defined installation and operational qualification (IQ/OQ) package performed on-site by our expert team
Performance Qualification Package	On-site support to verify sequencing system performance in your laboratory
GMP Validation Support Package	Additional materials and access to Oxford Nanopore expertise to support your internal validation requirements
Advanced Nanopore Training Package	A comprehensive, personalised training programme tailored to your specific requirements
Support Package	Includes service visits and preventative maintenance

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 biopharma QC

- Rapid, local, field-based support
- Global presence with offices across North America, Europe, and Asia
- Proven technology, backed up by over 11,000 peer-reviewed publications

Contact us today to discuss your biomanufacturing QC assay requirements or visit **nanoporetech.com/biopharma** for more information.

References

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3. US Food and Drug Administration. Part 11, Electronic records; electronic signatures — scope and application. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application (2003) [Accessed: 29 April 2024]
4. European Union. Annex 11: Computerised Systems. https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en (2011) [Accessed: 29 April 2024]

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