Biopharma

Oxford Nanopore sequencing solutions

for quality control in biopharma

Oxford Nanopore Technologies

Compliance built in. Confidence delivered

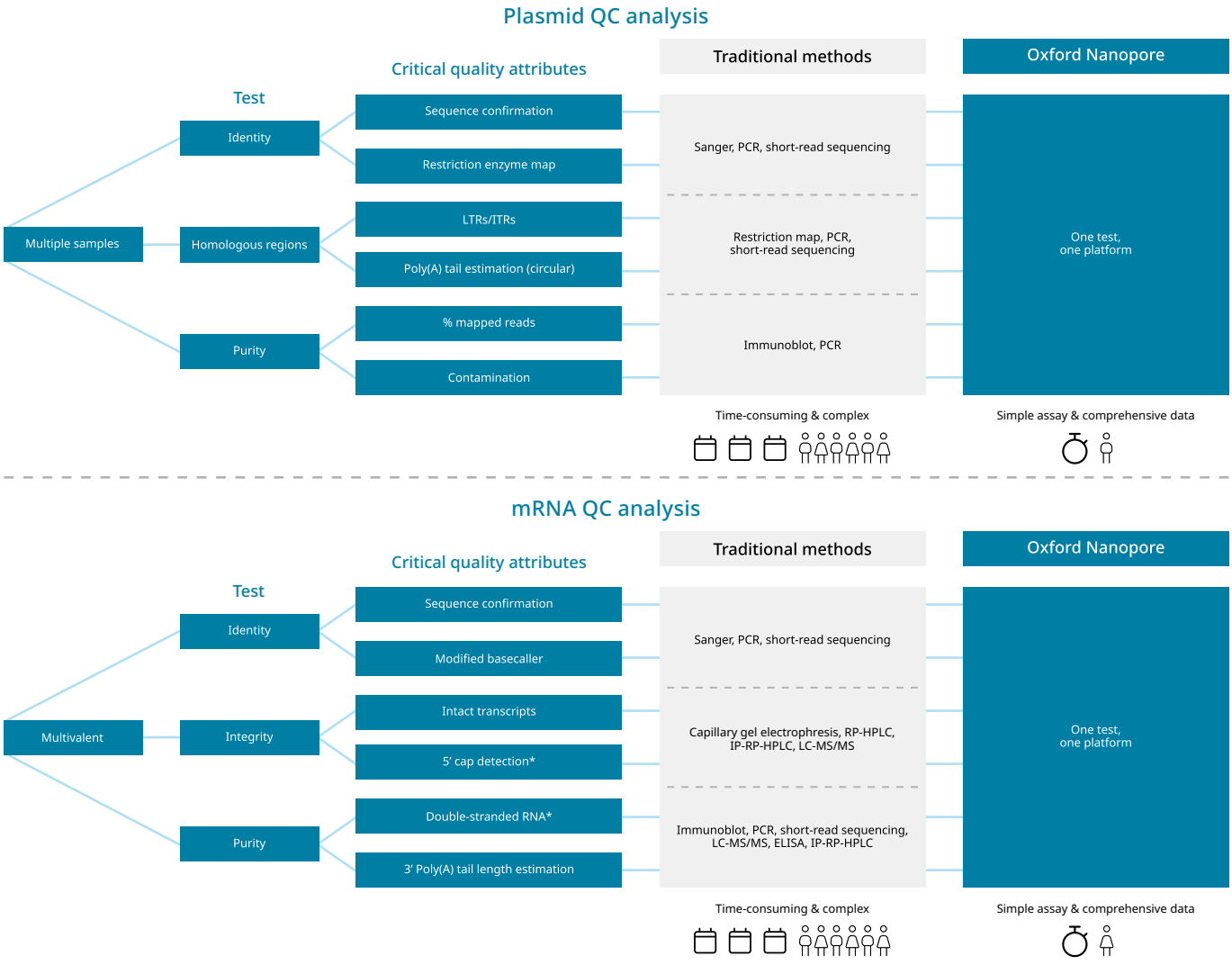
Reducing complexity, accelerating results

Oxford Nanopore Technologies offers a single-platform solution that is redefining quality control (QC) in biopharma manufacturing. Replace multiple, orthogonal methods with flexible Oxford Nanopore sequencing for fast, accurate, and comprehensive quality analysis.

Our traceable workflows and audit-ready data support good manufacturing practice (GMP)-aligned QC processes, giving your teams confidence in their results — protecting both pre-market programmes and on-market products.

Our single-platform solution supports you in meeting your regulatory requirements for clinical trials and subsequent commercial products. As you transition from R&D to analytical development, and finally, to GMP-validated QC assays, we can equip you with the devices, reagents, and documentation needed for smooth method transfer and regulatory compliance.

Oxford Nanopore technology delivers fast, accurate sequencing on a single platform



ELISA: enzyme-linked immunosorbent assay; IP-RP-HPLC: ion-pair reversed-phase high-performance liquid chromatography; LC-MS/MS: liquid chromatography tandem-mass spectroscopy; LTRs/ITRs: long terminal repeats/inverted terminal repeats; RP-HPLC: reversed-phase high-performance liquid chromatography.
*Capability to measure critical quality attribute is in development.

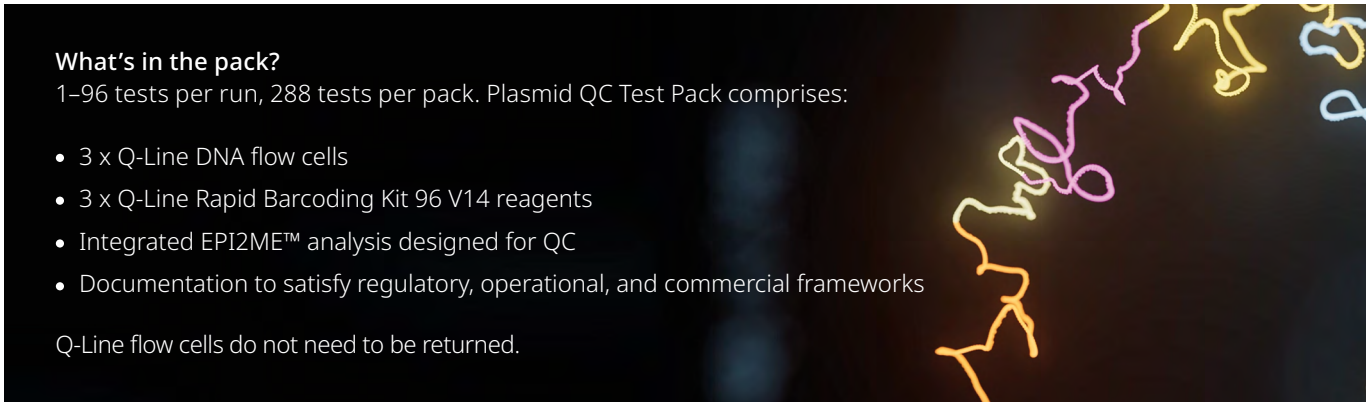
Oxford Nanopore QC Test Packs: mRNA and plasmid

More than just a device or a kit, the Oxford Nanopore QC products offer a ready-to-use solution for quality control in regulated environments. Our QC-ready offering brings together the Q-Line GridION sequencing device and the QC Test Packs into one integrated system, with verified analysis workflows, Q-Line consumables, and a robust suite of documentation, technical support, and commercial assurances. This combination is designed to reduce validation effort, simplify procurement, and give you everything you need for successful deployment in GMP environments. It also supports long-term stability and compliance for mRNA and plasmid QC across regulated biopharma manufacturing.

1. Plasmid QC Test Pack

High-quality, whole-plasmid sequencing without primers

Plasmids are an essential starting material in drug development and manufacturing, so accurate sequence verification is critical. Using rapid barcoding, you can prepare up to 96 plasmid samples for full-length sequencing. Long nanopore reads deliver complete coverage of plasmid DNA inputs, enabling the following critical quality attributes (CQAs) to be measured: construct identity, long terminal repeats (LTRs), inverted terminal repeats (ITRs), linearisation efficiency[†], poly(A) tail length estimation (circular plasmids), restriction enzyme mapping, and residual host DNA.



What's in the pack?
1–96 tests per run, 288 tests per pack. Plasmid QC Test Pack comprises:

- 3 x Q-Line DNA flow cells
- 3 x Q-Line Rapid Barcoding Kit 96 V14 reagents
- Integrated EPI2ME™ analysis designed for QC
- Documentation to satisfy regulatory, operational, and commercial frameworks

Q-Line flow cells do not need to be returned.

2. mRNA Identity QC Test Pack

Direct sequencing of mRNA intermediates, drug substances, and drug products without amplification

Traditional mRNA analysis relies on complementary DNA (cDNA) conversion, erasing modified bases and introducing amplification bias. Using the Direct RNA Sequencing Kit, you can prepare native mRNA, allowing you to measure multiple CQAs in one assay, including identity, integrity[‡], and poly(A) tail length estimation. Our bespoke basecallers are trained to report on mRNA with N^1-methylpseudouridine base modifications.

What's in the pack?
1 test per run, 6 tests per pack. mRNA QC Test Pack comprises:

- 6 x Q-Line RNA flow cells
- 1 x Q-Line Direct RNA Sequencing Kit reagents
- 1 x Q-Line RNA Integrity Expansion Kit reagents
- Integrated EPI2ME analysis designed for QC
- Documentation to satisfy regulatory, operational, and commercial frameworks

Q-Line flow cells do not need to be returned.

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

[†]Linearisation efficiency can only be measured for plasmids with one cut site per restriction enzyme.

[‡]Integrity measurement currently only supports polyadenylated mRNA. Integrity measurement for non-polyadenylated mRNA is in development.

Q-Line: sequencing in regulated environments

Q-Line is a range of sequencing products designed to support regulated GMP environments. It delivers real-time nanopore sequencing in a standardised, tightly controlled format, supporting seamless and scalable transfer of analytical methods from discovery to commercialisation.

The Q-Line GridION combines five independent MinION™ Flow Cells with integrated high-performance compute, industry-specific software, simplified user interface, and configurations supporting 21 CFR Part 11[1] and EU GMP Annex 11[2]. Q-Line also provides long-term support for released configurations that are compatible with computer system validation (CSV) processes.

Key features:

- Simple workflows with minimal user interaction
- Closed system with human-readable audit trails
- Secure, whole-device at-rest encryption
- Permission-based access with authentication system integration
- REST API for LIMS connectivity
- Preconfigured run settings for QC assays
- Onboard data analysis

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

Five MinION 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

API: application programming interface; LIMS: laboratory information management system; REST: representational state transfer.

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Comprehensive support packages for Q-Line

All Q-Line GridION purchases include one year of the Standard Plan, offering comprehensive, responsive support. Upgrade to the Enhanced Plan for 24-hour support (five days a week), priority responses, and additional training for extra reassurance. Pricing available on request.

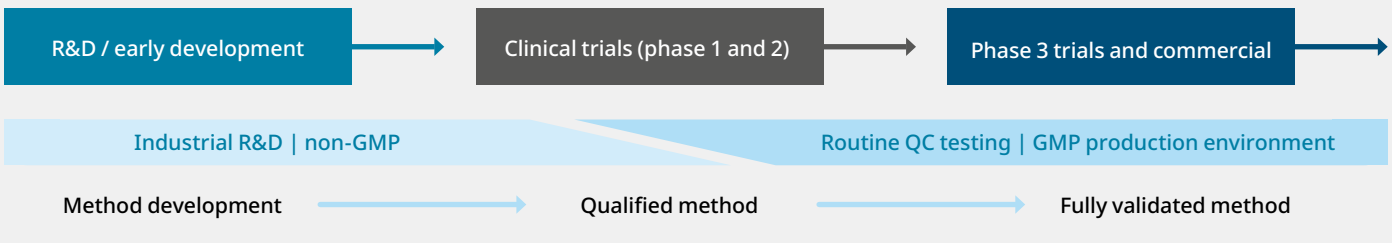
	Enhanced Plan**
Online installation onboarding	✓
Training	Two-day on-site training
Email / chat support	Mon–Fri, 24 hours (prioritised)††
Phone support	✓
On-site repairs	✓
Replacement	✓
Loan device (during prolonged downtime)	✓
Preventative maintenance visit	✓
Documentation support	✓
Service-level agreement response time	✓††

**Enhanced Plans available in selected countries only — contact your local representative for more information.
††Visit nanoporetech.com/support-plans for full details.

Stage-appropriate sequencing devices

Beyond Q-Line, Oxford Nanopore offers flexible sequencing devices suitable for use in research labs and analytical development or production sites, either on-site or with a contract research organisation (CRO) or contract development and manufacturing organisation (CDMO) partner.

MinION, GridION, and PromethION™ deliver scalability across biopharmaceutical R&D and early development explorations — from early target identification and biomarker discovery to cell line and viral vector engineering, all the way through to cell, gene, and RNA therapy drug development, including phase 1 and 2 clinical trials. At Oxford Nanopore, we offer you a clear pathway for the seamless transfer of nanopore-based analytical tests across the full drug development process.



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

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 cited in over 20,000 peer-reviewed publications

Register your interest to find out more about our biopharma QC products: nanoporetech.com/ryi-q-line.

References

1. US Food and Drug Administration. Part 11, Electronic records; electronic signatures — scope and application (2003). Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application [Accessed 17 March 2026]

2. European Commission. Good manufacturing practice (GMP) guidelines; annex 11: computerised systems (2011). Available at: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en [Accessed 17 March 2026]

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