Agilent case study: 4150 TapeStation system with TapeStation software security module

Quality Assistance, a Belgian-Based CRO, Strengthens Pharmaceutical GxP Workflows with Compliant Nucleic Acid QC

Building compliance into nucleic acid QC

In the highly regulated landscape of pharmaceutical development, data integrity isn't just a box to check—it represents a foundation of trust. For organizations operating under GxP standards, every data point must be secure, traceable, and defensible to meet European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), and other global regulatory requirements. This level of rigor is essential to secure the safety, efficacy, and quality of therapeutic products.

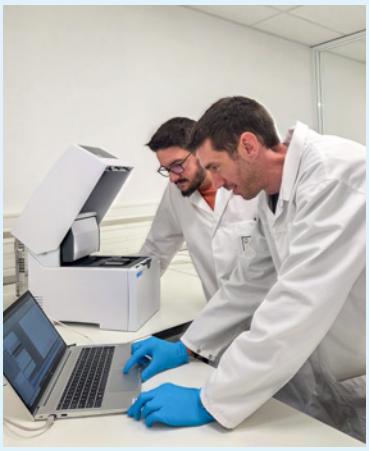
Quality Assistance, a Belgian-based contract research organization (CRO), has built its reputation over four decades, delivering analytical services across a wide range of therapeutic modalities. The company supports pharmaceutical clients throughout the drug development lifecycle—from clinical and nonclinical studies to market authorization. Their expertise spans biologics including monoclonal antibodies, vaccines, mRNA, cell and gene therapies, as well as small molecules, with a strong focus on method development and validation, characterization and stability studies, immunogenicity, and batch release testing.

To support this diverse and evolving scope of work, Quality Assistance needed a solution that could meet both scientific and regulatory expectations. The Agilent 4150 TapeStation system, paired with the Agilent TapeStation software security module, was the answer—enabling nucleic acid quality control (QC) with full confidence in data integrity, traceability, and compliance.

Closing compliance gaps with built-in security

Adopting the TapeStation system was about more than upgrading instrumentation—it was about closing compliance gaps that had previously limited the lab's ability to run certain GxP-grade experiments. When expanding into regulated pharmaceutical work, the lab recognized that technical capability alone wouldn't be enough. "We are working under 21 CFR Part 11. This means that data integrity must be proved," remarked Fabian Vandermeers, PhD, senior R&D technical leader at Quality Assistance.

So, the challenge wasn't the science—it was the compliance.



Dr. Fabian Vandermeers and Dr. Quentin De Meur from Quality Assistance using the Agilent 4150 TapeStation system and its software.

"If a lab must perform QC testing of DNA or RNA in a GxP environment, I would absolutely recommend the TapeStation system." – Dr. Vandermeers

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After evaluating the Agilent TapeStation system and participating in a demo, both the scientific and IT teams were impressed—not just by the instrument's ease of use, but by its built-in compliance-enabling features. "We needed equipment that could support DNA and RNA QC in a GxP environment," Dr. Vandermeers explained. "The TapeStation system was not only easy to use—it was fully compliant. That made all the difference."

The TapeStation software security module proved to be the missing piece, combining analytical performance with essential compliance-enabling capabilities:

- Role-based access control to restrict actions based on user responsibilities
- Comprehensive audit trails to track all modifications
- Electronic signatures that lock data once finalized

"We have full protection of the data, full traceability," emphasized Dr. Vandermeers. "In a lot of software, it's possible to sign the data, but it's not locked. That's a risk. With the TapeStation software, once everyone has signed, the data can't be changed unless authorized. That's perfect for QC testing in GxP."

Implementation began in the R&D lab, where SOPs and training documentation were developed. The IT department then led the software validation process, completing it in less than a year—faster than typical timelines for regulated systems. Once validated, the system was released for GxP use in early 2025. "We had no surprises," Dr. Vandermeers added. "Once the IT team configured the software and applied Windows rights, everything worked perfectly." The system is now routinely used for QC testing across multiple project types.

Enabling high-impact molecular biology workflows

Today, the 4150 TapeStation system is a key part of Quality Assistance's analytical toolkit for their molecular biology workflows, which include PCR, RT-PCR, and NGS. The system is used to:

- Quantify NGS libraries for mRNA and gene therapy products
- Assess concentration and RNA integrity for RT-PCR gene expression studies
- Size residual genomic DNA in cell therapy samples

These steps are critical for confirming sample identity, purity, and suitability for downstream analyses—especially in a GxP environment where precision, reproducibility, and traceability are non-negotiable.

For NGS-based projects, the team uses the Agilent D1000 ScreenTape assay to quantify their client's sequencing libraries and assess fragment size, ensuring sample purity and confirming sequence identity. "We're working mostly with mRNA vaccine and gene therapy products," said Dr. Vandermeers. "The goal is to confirm the identity of the vaccine or therapeutic by comparing the sequenced data to the theoretical sequence. The TapeStation helps us ensure that the library is clean and the fragments are the right size before sequencing."

In RT-PCR projects, RNA extracted from drug-treated cell cultures is analyzed using the Agilent RNA ScreenTape assay. The TapeStation provides both concentration and RNA integrity number equivalent (RIN^e) metrics, ensuring only high-quality RNA proceeds to reverse transcription and amplification. "If RNA concentration and quality is sufficient, we can confidently start reverse transcription followed by PCR to determine the gene expression," explained Dr. Vandermeers.

For cell therapy samples, the Agilent Genomic DNA ScreenTape assay is used to detect and size any residual DNA fragments released post-thawing, which is important for product safety and compliance.

Transforming QC with automation and accountability

Since integrating the TapeStation system and software security module, Quality Assistance has seen improvements in workflow efficiency, data integrity, and regulatory confidence. The lab now operates with a fully digital, traceable process, supported by a robust role-based access structure:

- Administrators manage accounts and system settings
- Analysts perform experiments and sign data at Level 1
- Validators review and sign at Level 2, locking the data
- Team leaders can unlock data with justification
- Suppliers are restricted to system checks and maintenance
- Read-only users can review final data without modification

This structure ensures that only authorized users can access or modify data, and that all actions are tracked in the audit trail for full accountability.

Beyond compliance, the TapeStation system has helped streamline workflows through automation that reduces human errors. ScreenTape devices are automatically identified through 2D barcodes, eliminating manual method selection. “There’s almost nothing to encode,” emphasized Dr. Vandermeers. “The ScreenTape devices are automatically identified, so it’s not possible to start with the wrong assay. Analyst intervention is limited, which is ideal for QC.”

The combination of automation and built-in compliance support has enabled Quality Assistance to operate with greater speed and confidence. “We don’t need workarounds for integrity or traceability. It’s all built in.”

Securing confidence in every data point

With the TapeStation system, Quality Assistance has closed compliance gaps, accelerated validation timelines, and strengthened their ability to deliver high-quality, defensible data to clients. The result is a more agile, diligent, and efficient lab—one that operates with full confidence in data integrity across regulated workflows.

For Quality Assistance, the Agilent TapeStation software security module isn’t just a tool—it’s a cornerstone of their commitment to data integrity. This integration of performance and protection illustrates how scientific integrity fuels discovery—and how discovery drives therapeutic advancement.

Learn more about Agilent TapeStation systems and software at:
www.agilent.com/genomics/tapestation-systems

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