

# The MODA<sup>®</sup> Platform

Digitalize Quality and Manufacturing





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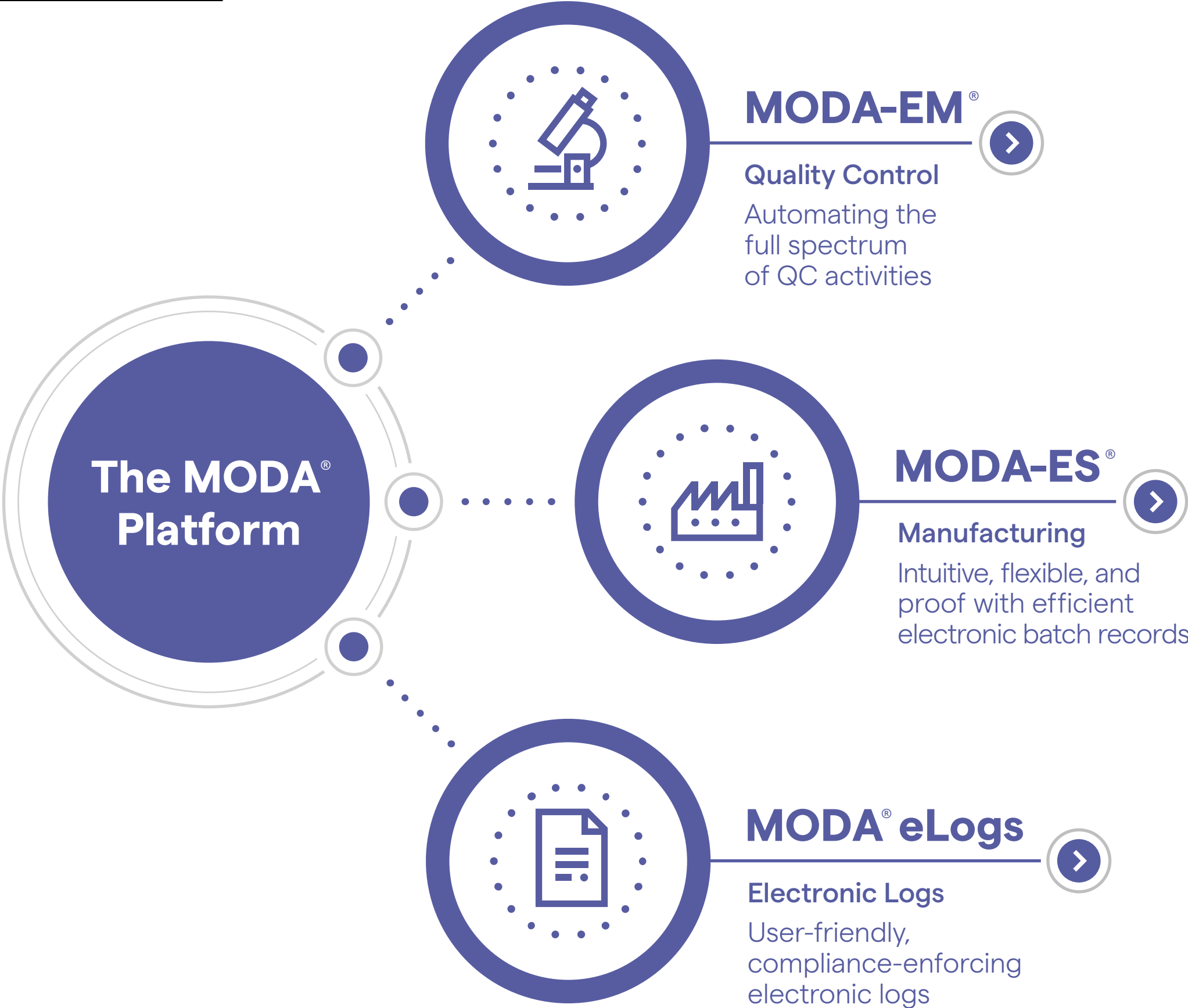


# The MODA® Platform: Digitalizing Quality and Manufacturing

The MODA® Platform combines manufacturing and laboratory data into a single comprehensive source to expedite pharmaceutical product release.

- User Centric
- Modular
- Scalable

The MODA® Platform is comprised of 3 modules. Choose the module that’s right for you now and easily scale to suit your requirements by adding additional modules when needed.

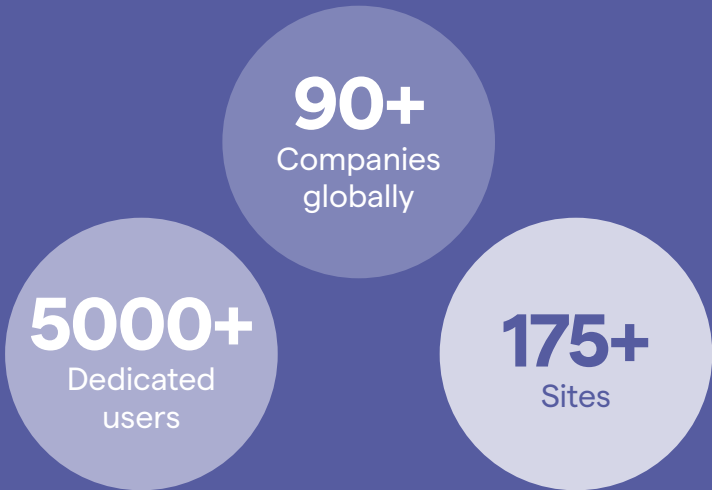


# Why Choose the MODA® Platform

The MODA® Platform is designed specifically for the pharmaceutical industry to enable organizations to digitalize their operations.

## A track record of success

We have extensive experience in pharmaceutical manufacturing and informatics, having worked with customers around the world, across all therapeutic modalities. Partnering with us gives you the expertise needed for timely implementation and long-term digitalization success.



## Industry experience

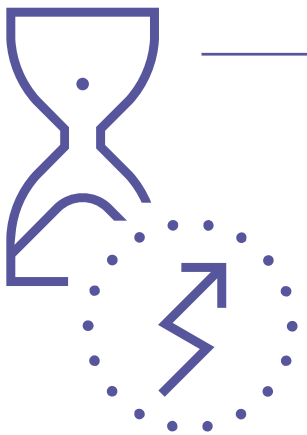
The MODA® Platform addresses the issue of paper records associated with batch records, QC forms and logbooks, long cycle times for review/approval activities, deviations for missing entries, incorrect entries, calculation errors and incorrect workflow decisions.

Lonza looked externally for a solution, but found the marketplace was too expensive and not flexible enough to meet our needs for clinical phase CMO customers that had changes more frequently than commercial operations.

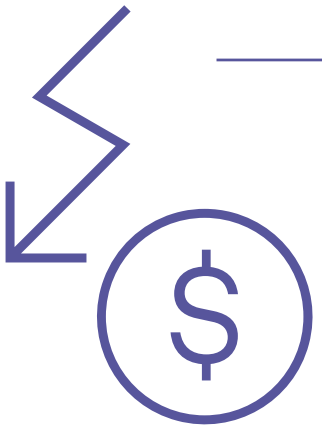
The Lonza Informatics Team stepped in to help solve that issue. The combination of the subject matter expertise from multiple Lonza Manufacturing Groups and Lonza Informatics understanding of paperless solutions in a regulated space allowed for a product that solves the needs of the mid-sized CMO/Pharma plant. Lonza Informatics know-how and Lonza manufacturing’s experience allowed for a more flexible, cost effective solution to replace paper records than other solutions in the market.



**Quality**  
Enforce compliance to SOP's



**Efficiency**  
Real time access to data



**Cost**  
Reduced time to collect and analyze data



# MODA-EM® Paperless Quality Control

## More Science. Less Paper.®

The MODA-EM® Module is a regulatory-compliant paperless solution that automates QC processes. Users can easily manage and report on the full spectrum of EM and QC information — including surface, air, personnel, compressed gas, and product testing.

Out of the box, the MODA-EM® Module seamlessly integrates with commonly used instrumentation automation technologies and media found in manufacturing facilities, as well as with laboratory information management systems (LIMS).

With the MODA-EM® Module, organizations get timely, accurate QC monitoring through location-based scheduling, mobile data collection, and paperless lab processing. Real-time access to data enables on-demand reporting, trending, and visualization capabilities for in-depth process analysis and ad hoc queries.







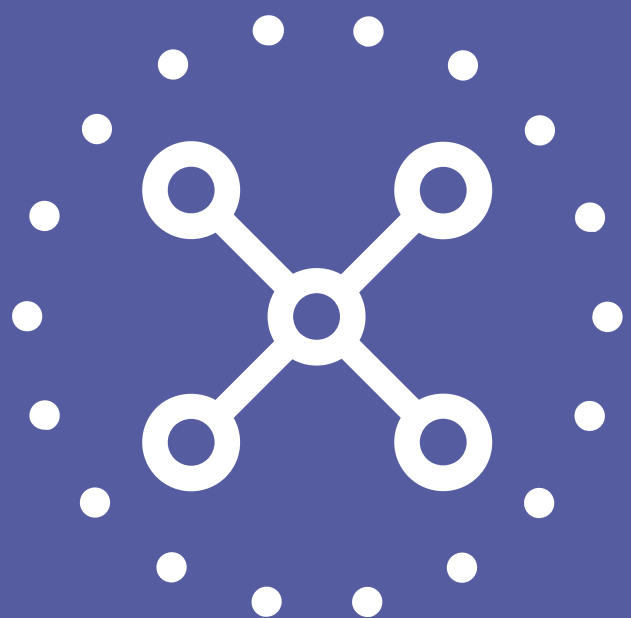
### A dedicated QC solution

Built by QC personnel, for QC personnel. Delivers the efficiency, quality, and compliance that QC labs need



### Powerful analytics

Easily collate, trend, and visualize data with robust reporting and trending packages. Real time access to your data at the click of a button



### Seamless integrations

Extensive library of interfaces to devices, automation and IT systems to support connected operations

# MODA-ES® - Digitalize Manufacturing

Manufacturing Execution Systems (MES) have been unattainable for most companies due to cost and flexibility concerns. But the MODA-ES® Module provides a flexible, modular, and easy-to-configure solution at an accessible price.

Designed to be configurable over customizable, it has an easy-to-use interface, meaning manufacturing technicians who understand the processes can build the workflows. The configuration of the system includes areas for data recording (measurements), instructional text (including hyperlinks to SOPs), electronic signatures, sections, and drag-and-drop workflow.

The MODA-ES® Module design means deployment is rapid and lowers the total cost of ownership. Individual processes can be created and validated, reducing the workload when bringing a new product into a facility. Companies can simply re-use existing validated processes, minimizing the need to create new ones. Additionally, flexible standard methods mean manufacturers can process products of the same family, without needing to build and validate an entirely new process.





**Affordable —**  
more cost-effective than  
traditional systems.



**Scalable —**  
a solution that can support  
your business needs as you  
expand operations from  
clinical to commercial.



**Rapid Deployment —**  
processes can be created,  
validated, and used across  
different products.



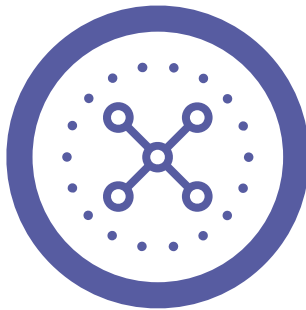
**Modular Process Creation —**  
create standard processes  
for products of the same  
family, with the flexibility  
to vary the raw materials, fill  
volumes and equipment types.



**User-Centric —**  
intuitive, simple user  
interface and workflow-  
driven data entry for batch  
records, sterility tests, and  
cleaning forms.



**Expedited Review and  
Approval by Exception —**  
with electronic checklists  
and deviation alerts to  
trigger timely intervention.  
Manufacturers unlock  
expedited product release.



**Seamless Integration —**  
with other cGMP-compliant  
systems and production  
equipment for effortless,  
reliable data transfer.



**Domain Knowledge —**  
our team have wide ranging  
experience to help support  
all stages of the project from  
creating a business case to  
implementation and validation.



# MODA® Electronic Logs

The MODA® eLogs Module maintains electronic logs for seamless task execution, scheduling, reviewing, and record-keeping.

This user-friendly, compliance-enforcing system is a powerful starting point for your digital transformation.

- **Intuitive** — a smooth, app-like user experience. Easy to navigate, with minimal training needed
- **Enforced compliance** — enforce SOP-compliant workflows for right-first-time data collection
- **Improved data integrity** — time-stamped audit trails, electronic signatures, and protection against use of out-of-calibration equipment ease the path to regulatory compliance
- **Configurable and flexible** — configure and build out workflows based on your company’s needs and capabilities. Easily update workflows when processes change
- **Seamless end-to-end operations** — Smoothly integrates with other MODA® Platform Modules and external systems for automatic scheduling, logging, and tracking
- **Reduce deviations** — automatically schedule logs after equipment and room use with enforced tracking of status and state to ensure manufacturing occurs with only released areas
- **Real-time data access** — easily search data for quick investigations and decision making. All logs for one piece of equipment together to understand the full picture
- **Expedited review and approval** — Review-by-exception workflows streamline log checks. Eliminate the need to manage, maintain, and store your paper logs





# The MODA® Platform for Cell and Gene Therapy

The MODA® Platform for Cell and Gene Therapy is a scalable manufacturing execution system (MES) built for cell and gene therapy. The system consolidates all cell and gene therapy manufacturing and batch related quality data, into one digital record that enables track and trace of human materials to ensure patient safety.

With data integrity, compliance, and traceability at its core, the MODA® Platform for Cell and Gene Therapy captures trends and quality and performance metrics while eliminating the errors of paper-based systems. The result is real time insight into operations and processes, and valuable efficiency gains.

Unlike traditional approaches, the MODA® Platform for Cell and Gene Therapy provides a range of configurable options for expedited implementation and validation at an affordable price. With a flexible, user-friendly workflow suitable for manufacturers of any size, this platform brings the power of paperless execution to cell and gene therapy.







**Affordable —**  
more cost-effective  
than traditional systems.



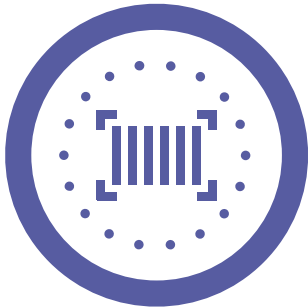
**Single-Record Solution —**  
combines manufacturing  
and quality data in one system.



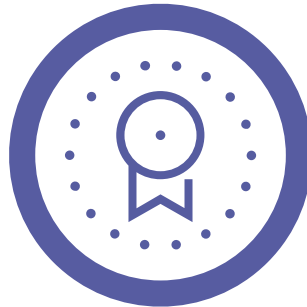
**Built By and for End-Users —**  
flexible, with simple workflows  
suitable for companies of  
any size.



**Rapid Deployment —**  
modules can be created,  
validated, and used across  
different processes.



**Track and Trace —**  
to enable parallel processing  
while ensuring patient safety  
and maximise capacity and  
support scale up of production.



**Quality and Compliance —**  
built into the process to  
drive the workflow and  
ensure a safe and expedited  
product release.



# Implementation and Validation Services



## Domain Knowledge

We have extensive experience in pharmaceutical manufacturing and informatics, having worked with customers around the world, across all therapeutic modalities. Partnering with us gives you the expertise needed for timely implementation and long-term digitalization success.



## Proven Approach

Join 5000+ users across 175+ sites in 90+ companies who are already using the MODA® Platform to optimize their operations.



## Validation Support

We provide a comprehensive risk based documentation package for validation of the core MODA® Applications. Our experts combine their experience of executing multiple global projects with an understanding of industry requirements to help support your validation effort.



# Useful Resources

**Case Study:** Nephron - Developing an Electronic Batch Record Solution That Meets Pharmaceutical Manufacturers’ Needs ➤

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**Case Study:** Nikon CeLL innovation Co - Microbiology and more – unleashing the power of the MODA-EM® Solution ➤

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**Case Study:** Digitalizing Cell and Gene Therapy Manufacturing ➤

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**Webinar:** MES for the Future ➤

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**Webinar:** Electronic Logs: Replace Paper with Productivity ➤

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**How To Guide:** Building a Business Case for a Digitalized QC Platform ➤





# The MODA® Platform: Digitalizing Quality and Manufacturing

## Contact Us

**North America**

Customer Service:  
+ 1 800 638 8174 (toll free)  
order.us@lonza.com

MODA® Support:  
+ 1 800 521 0390 (toll free)  
moda.support@lonza.com

**Europe**

Customer Service:  
+ 32 87 321 611  
order.europe@lonza.com

MODA® Support:  
+ 32 87 321 611  
moda.support@lonza.com

**International**

Customer Service:  
+ 1 301 898 7025  
Fax: + 1 301 845 8291

MODA® Support:  
moda.support@lonza.com

## Learn More:

The Lonza MODA® Platform ▶

MODA-EM® Paperless QC Microbiology ▶

MODA-ES® Next Generation Electronics Batch Records ▶

MODA-ES® - MES for Cell & Gene Therapy ▶

MODA® Electronic Logs ▶

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