Enabling a Healthier World

Lonza

MODA-ES® Platform for Cell and Gene Therapy

Next generation electronic batch record

Bringing the power of paperless execution to cell and gene therapy

Cell and gene therapy is a rapidly changing area of pharmaceutical manufacturing experiencing significant innovation. Currently, process and sample data are captured manually using paper batch records, but these are slow, error-prone and can be difficult to trace across the manufacturing lifecycle. To enable more efficient, effective and flexible data capture, **Lonza has developed the innovative MODA-ES® Platform:** a paperless batch record solution combining manufacturing and QC data designed to meet the needs of cell and gene therapy manufacturing.

The MODA-ES® Platform is **purpose-built by the end user, for the end user.** This is reflected in the intuitive nature of the system, which enables quick and easy implementation, while innovative in-built features offer deep insight into operations and processes, bringing valuable efficiency gains.

Compared to traditional approaches, the MODA-ES® Platform is designed to provide a range of configurable options for **expedited implementation and validation** at an affordable price point and with a lower total cost of ownership. With a flexible, user-friendly workflow that is suitable for manufacturers of any size, the MODA-ES® Platform brings **the power of paperless execution** to cell and gene therapy.

The challenges of paper-based batch record management

Paper-based approaches to batch record management have proven time-consuming, error-prone, resource-intensive and costly. Paper records must be completed, copied, transported and shared physically, resulting in **a broken, disjointed process that is time-consuming and inefficient.**

Purpose-built by the end user, for the end user, the innovative MODA-ES® Platform brings the power of paperless batch record execution to cell and gene therapy manufacturing.

Throughout each workflow, technicians spend precious time ensuring they have filled in the right documentation correctly, and reviewers and approvers must subsequently check every entry to verify critical information is not missing or incorrect. Errors and omissions lead to deviations, resulting in ill-informed decisions and can even cause the loss of an entire batch of product.

Lonza has developed the MODA-ES® Platform to help cell and gene therapy manufacturers overcome these challenges and benefit from **a flexible, paperless approach to batch record management**.

Built by the end user, for the end user

The developers of the MODA-ES® Platform have first-hand experience of the complex challenges facing cell and gene therapy manufacturers. Consequently, they have a deep understanding of these challenges — and know precisely how to solve them.

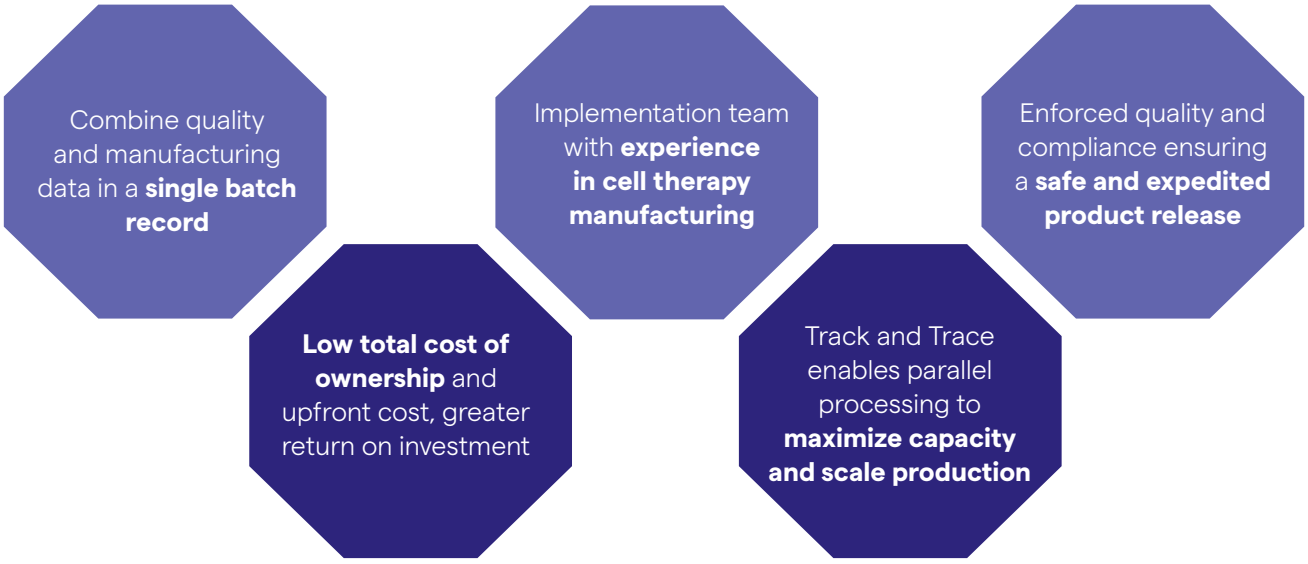
Building upon a wealth of domain knowledge and experience, the MODA-ES® Platform brings together Lonza's Cell and Gene Therapy Manufacturing Expertise and the MODA® Software Platform to create **a compliant solution that puts the user first**. Unlike other approaches, which are prohibitively expensive, the MODA-ES® Platform prioritizes the needs of the end user to ensure both cost-effectiveness and usability.

The platform has a configurable modular design that is intuitive to use and can be scaled up or down without compromising on quality or compliance. It provides drag-and-drop capabilities, for easy process building, without the need for specialized technical abilities or excessive training prior to implementation.

By focusing on **flexibility, configurability and scalability**, the MODA-ES® Platform developers have created an electronic batch record solution that brings innovation and efficiency to cell and gene therapy.

A streamlined electronic batch records workflow

Bringing innovation to cell and gene therapy manufacturing



Enable parallel processing with Track and Trace

Track and Trace implementation is the base to industrialize the manufacturing processes of Cell Therapy and maximize the utilization of manufacturing suites. With its Track and Trace functionality, the MODA-ES® Platform offers an electronic overview of everything in the facility at a given time, enabling parallel processing and preventing cross contamination.

The MODA-ES® Platform enables a paperless manufacturing process from the moment material enters to when it leaves a facility, for batch records and electronic logs, and across all stages of review and approval. With paper records, manufacturers must sift through copious amounts of paperwork to identify the location or status of a specific material.

With Track and Trace, data is logged and accessible through all stages of storage, processing and shipment, without the need to physically move or re-enter data into different systems or at different facilities. This transparency, accessibility and connectivity are crucial for accurate, efficient manufacturing that supports patient health: it ensures that processes are fully compliant, error-free and progressing as planned. The system has cGMP compliance and tracking at its core, and ensures that data and trends are visible, organized, accessible and available in real-time.

Track and Trace implementation for Cell Therapy manufacturing is the prerequisite to enable parallel processing and state of the art compliance for scale up of cGMP manufacturing.

Paperless productivity

The innovative MODA-ES® Platform offers a unique way to optimize and streamline batch record management. It combines electronic batch record and laboratory execution software to bridge the gap between manufacturing and quality control. The platform ensures that all data and calculations are correct and within expected, verified parameters, and flags records that require manual review or verification. Rather than needing to review the entirety of every record as a matter of course, reviewers need only review aspects flagged as requiring a second person verification.

This flexibility and adaptability allows cell and gene therapy manufacturers to detect errors in real-time and react accordingly. Users can configure the system to alert them when parameters are not met, resulting in improved accuracy and quality, and the ability to prevent errors before they even occur. These real-time detection and response capabilities also prevent common deviations and enable a demonstrable chain of custody for built-in data integrity.

More Science. Less Paper.®

The MODA-ES® Platform renders paper redundant. The purpose-built system brings real value and innovation to the cell and gene therapy manufacturing space. It provides unique benefits at all levels — from individual technicians to entire facilities and overarching workflows — and transforms batch records into a streamlined, accurate and highly efficient process in terms of time, cost and labor.

The intuitive platform is built to prioritize the user, it is highly configurable and offers a low total cost of ownership for manufacturers of any size. Furthermore, the MODA-ES® Platform ensures that materials and data are traceable and accessible at any time to ensure compliance and expedite product release. The system facilitates a truly innovative and cost-effective transition from paper-based to electronic record-keeping. It allows facilities, data and staff to be more connected, up-to-date and efficient, so cell and gene therapy manufacturers can focus on what matters: the science.

Easy configuration, integration and validation

Removes redundancy and strengthens data integrity

Rather than being customizable, **the MODA-ES® Platform is configurable**, meaning that customers can upgrade to the newest and most compliant versions of the software without worrying about customization issues or needing to re-verify.

The user-friendly interface offers multiple options for instructional text electronic signatures, drop-downs and checkboxes. New modules can be created for new processes when needed and existing modules can be used as library templates for when a process is similar but has variable parameters (raw materials, equipment use or fill volume, for instance). Users need not always build a new module completely from scratch, but can instead adapt an already validated and established workflow, reducing the amount of labor needed to manage manufacturing operations.

The platform can be integrated with various equipment, automation layers and enterprise systems, further reducing the chance of operator error and strengthening data integrity.

The MODA-ES® Platform streamlines cell and gene therapy manufacturing and quality assurance workflows. The platform **reduces redundancy and ensures that manufacturers are only investing in functionality that is truly needed**.

The MODA-ES® Platform enables review by exception, accelerating the review and approval process, facilitating streamlined, expedited workflows, and reducing the risk of errors and delays.

Cost effective approach to batch record

Electronic Batch Records have been perceived as unattainable to most of the industry due to cost constraints and flexibility concerns. Lonza Informatics is changing that with the **MODA-ES® Platform and providing additional benefits to your organization by facilitating paperless execution** across the manufacturing and QC processes.

Our implementation team has extensive experience implementing paperless solutions. This, combined with our knowledge of cell therapy manufacturing has resulted in a batch record solution that is highly flexible, configurable and scalable to meet the business needs.

The MODA-ES® Platform was **built with a modular design and utilizes an intuitive drag and drop workflow** that doesn't require specialized IT skills to create or manage. This limits the amount of work when a new process is brought into a facility because you can use existing validated modules and reduce the time needed to implement and validate the new process.

Combining ease of setup, daily use and ongoing maintenance in an off-the-shelf product that minimizes initial setup and validation as well as ongoing internal IT support, the MODA-ES® Platform is a cost effective solution for your batch records.

Ready to rethink your approach to cell and gene therapy manufacturing batch record management with the MODA-ES® Platform?

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