

**Reduce Manufacturing Risk
with DeltaV™ MES**

**DeltaV™ Manufacturing Execution System
for Cell Therapy**

Right-first-time execution to help manufacturers scale
personalized therapies while maintaining quality, compliance, and consistency.



Right Every First Time Manufacturing

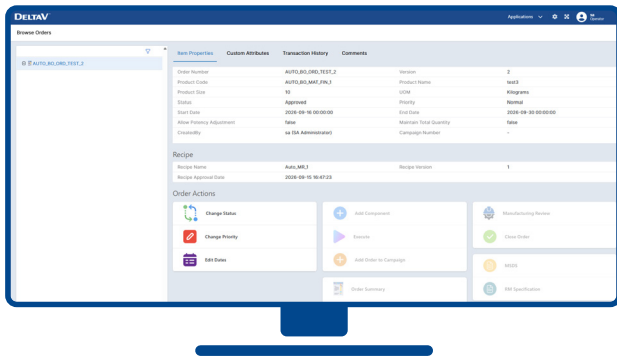
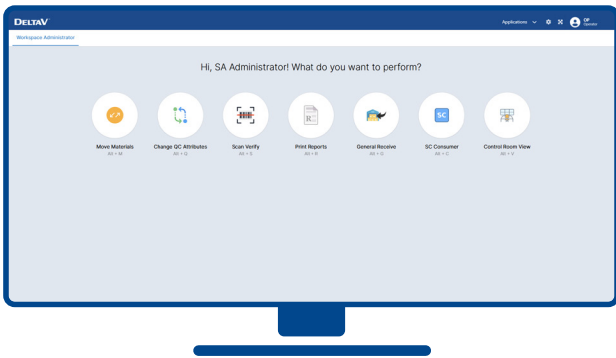
In autologous cell therapy manufacturing, every batch must be right the first time because each one is produced for a specific patient. The next batch, created for a different patient, must achieve the same level of precision, quality, and compliance.

With manufacturers producing hundreds to thousands of patient-specific batches each year, maintaining chain of identity, reducing human error, and meeting stringent regulatory requirements are critical to operational success.

DeltaV™ Manufacturing Execution System (MES) provides the accuracy, flexibility, and workflow control needed to support right-first-time execution, helping manufacturers scale personalized therapies while maintaining quality, compliance, and consistency.



Advancements in cell therapy manufacturing are providing benefits to patients around the globe.



THE SOLUTION

- Electronic chain of identity
- Automated workflow processes
- Paperless batch records
- Review by exception
- Integrated equipment management
- Materials management including kit preparation and dispensing



THE RESULT

- Consistent production of high-quality therapies for patients
- Reduced compliance and operational risk
- Faster batch record review and release through review-by-exception workflows
- Improved manufacturing efficiency and data integrity

How DeltaV MES Reduces Manufacturing Risk



Strengthen chain of identity

Maintain confidence that every therapy is delivered to the intended patient. From sample receipt and processing to testing and final packaging, each step is electronically tracked, documented, and verified to preserve chain of identity and support regulatory compliance.



Reduce execution errors

Reduce errors and deviations by automating manual procedures, integrating with other systems, automating calculations, and reviewing in-process data during the batch. With automated workflows and integrated information, you can reduce the possibility of critical errors.



Enable paperless manufacturing

Maintain complete control of manufacturing records through a single electronic batch record solution.



Ensure product quality

Digital processes improve documentation accuracy, eliminate paper handling and storage requirements, and support scalable operations as production volumes grow.

Strengthen Chain of Identity

In autologous cell therapy manufacturing, maintaining chain of identity is essential because every batch is tied to a specific patient. While upstream collection and downstream delivery systems manage patient sample collection and final therapy administration, DeltaV MES serves as the manufacturing system of record, beginning traceability at material receipt and maintaining it throughout production.

From receipt of patient materials through processing, cell expansion, testing, formulation, and batch completion, DeltaV MES electronically tracks materials, activities, and approvals to create a complete and verifiable therapy genealogy.



DeltaV MES helps strengthen chain of identity by:

-  **Enforcing standardized workflows** that guide operators through validated procedures and ensure activities are performed and documented against the correct batch.
-  **Providing electronic signatures and approvals** that create a secure, auditable record of critical manufacturing activities.
-  **Using barcode-enabled material tracking** to maintain visibility and traceability from material receipt through every stage of production.
-  **Automating batch documentation** to improve accuracy, reduce manual effort, and provide immediate access to a complete audit trail.
-  **Integrating with upstream and downstream systems** to support end-to-end traceability across the patient's therapy journey.

With DeltaV MES, manufacturers can confidently manage chain of identity throughout manufacturing, knowing that the right people are performing the right actions with the right materials on the right patient-specific batch. The result is improved compliance, reduced risk, and greater assurance that each therapy maintains its identity from material receipt through batch release.



Provide operators with the right information at the right time to make the right decisions.

Reduce Execution Errors

In an industry that requires accuracy and faces tight deadlines, any errors can mean a missed treatment window for patients as well as financial and regulatory consequences for companies.

Cell therapy manufacturers can avoid errors and deviations by adopting technology that automates procedures and provides operators with the right information at the right time to make the right decisions.

With DeltaV MES, you can:

-  **Reduce operator errors** with verification of materials, samples, equipment states, and process steps before critical activities occur.
-  **Increase data accuracy** through automated calculations and electronic data capture that eliminate manual entry errors.
-  **Reduce deviations** by integrating with automation and control systems to ensure consistent data across manufacturing operations.
-  **Improve operator performance** with guided workflows that provide the right information at the right time.
-  **Accelerate batch review and release** with review-by-exception capabilities that quickly identify potential issues.



DeltaV MES provides a single source of truth for manufacturing information.

Ensure Product Quality

In cell therapy manufacturing, every batch matters. Patients are waiting for their treatment, leaving little room for delays caused by investigations, rework, or lengthy quality reviews. To maintain product quality and accelerate delivery, manufacturers need the ability to quickly identify, assess, and address issues as they occur.

Deltav MES supports product quality with review-by-exception capabilities that:



Accelerate quality review
with integrated exception reports that quickly identify, prioritize, and resolve issues during manufacturing.



Detect process deviations early
through automatic verification of critical data and real-time alerts when operating conditions fall outside expected limits.



Enable faster corrective action
by providing operators with immediate visibility into abnormal situations while the batch is still in process.



Reduce batch release time
by focusing quality review efforts on exceptions rather than reviewing every process step manually.

Enable Paperless Manufacturing

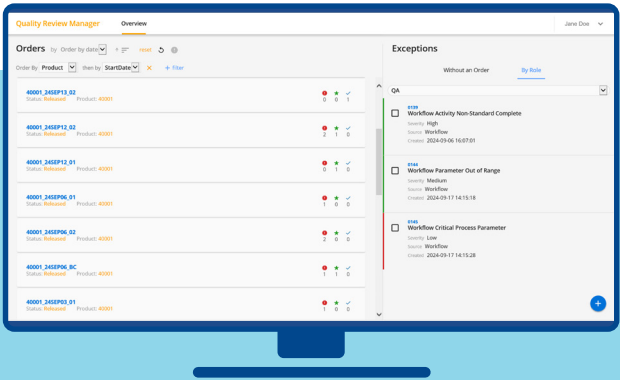
Managing thousands of patient-specific batches each year creates a significant documentation burden. Paper-based records can slow operations, increase the risk of errors, and make it difficult to quickly access critical manufacturing data during reviews and audits. By digitizing batch execution and record management, manufacturers can improve data accuracy, simplify compliance, and eliminate the costs associated with printing, storing, and maintaining paper records.

DeltaV MES transforms batch documentation from a paper-based process into a digital workflow that:

- **Improves record accuracy** with electronic batch records and automated data capture.
- **Accelerates batch review** using review-by-exception capabilities.
- **Strengthens material control** with real-time verification and complete material genealogy.
- **Centralizes manufacturing data** in a single source of truth for process, equipment, and quality information.
- **Simplifies compliance audits** with secure electronic records and complete audit trails.



DeltaV MES provides a single source of truth for manufacturing information, replacing paper-based processes with a digital platform that improves accuracy, increases efficiency, and supports scalable cell therapy production.



By identifying and resolving issues earlier, DeltaV MES streamlines quality review, shortens release cycles, and helps close the gap between production, product release, and patient delivery.



Part of the DeltaV | Life Sciences Platform

DeltaV MES is one element of a best-in-class automation and software portfolio purpose-built for life sciences. Together, these solutions span the full lifecycle from lab to life, accelerating tech transfer, enabling flexible manufacturing, and moving the industry toward real-time release.

Life sciences manufacturers strive to create innovative products that help people lead healthier lives. Emerson has the automation expertise, industry experience, and technology to solve your greatest cGMP manufacturing challenges, improving data management, real-time product quality, reliability, and operating costs. From design to implementation and start-up to ongoing Operational Certainty, rely on Emerson to help you get better at helping people get better.

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 DeltaV Distributed Control System (DCS)

Orchestrate, automate and control processes and equipment while capturing data for batch reporting.

 DeltaV Manufacturing Execution System (MES)

Manage workflows, recipes, batch records, equipment, materials, and more to enforce actions and capture data electronically.

 DeltaV Process Knowledge Management (PKM)

Develop and maintain process specifications, steps, attributes, and parameters; evaluate risks; and transfer recipes.

 DeltaV Real-Time Scheduling (RTS)

Optimize schedules, evaluate the impact of unplanned events, and plan for efficient maintenance activities.

► Every system feeds a unified data foundation, the platform for analytics, AI assistance, and continuous intelligence across your operations.