

Cell Therapy and Right First Time Manufacturing



How a Syncade MES solution
reduces process risk



Right Every First Time Manufacturing

In cell therapy manufacturing, each batch must be perfect the first time — because each batch is produced for a specific patient. The next unique batch, for the next unique patient, must be just as perfect as the previous batch.

Cell therapy manufacturers can produce hundreds to thousands of batches per year. Manufacturers depend on operational excellence practices to maintain chain of identity, eliminate manual errors, and manage regulatory compliance.

Implementing the Syncade manufacturing execution system (MES) provides the accuracy, flexibility, and manufacturing stability to help ensure that right first time production is achieved every time in this revolutionary and complex environment.



The solution:

- Electronic chain of identity with repeatability driven into the manufacturing process
- Automation of manual processes for improved quality
- Paperless batch records for accuracy and time savings
- Review by exception to accelerate release time

The result:

- High-quality therapies for patients
- Reduced risk for manufacturers

“Cell based medicinal products are like nothing we’ve ever handled before. We no longer have the luxury of methods that are ‘good enough’. And that means removing unnecessary risks from our methodology.”

— *The Role of Automation in Cell Therapy Commercialization, Medcison.com.*
March 2017.



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

Improve Chain of Identity

Operate with the confidence that your therapy will be delivered to the right patient. And be assured that from sample retrieval to testing to delivery, steps in the process are documented and verified.

Maintain Paperless Manufacturing

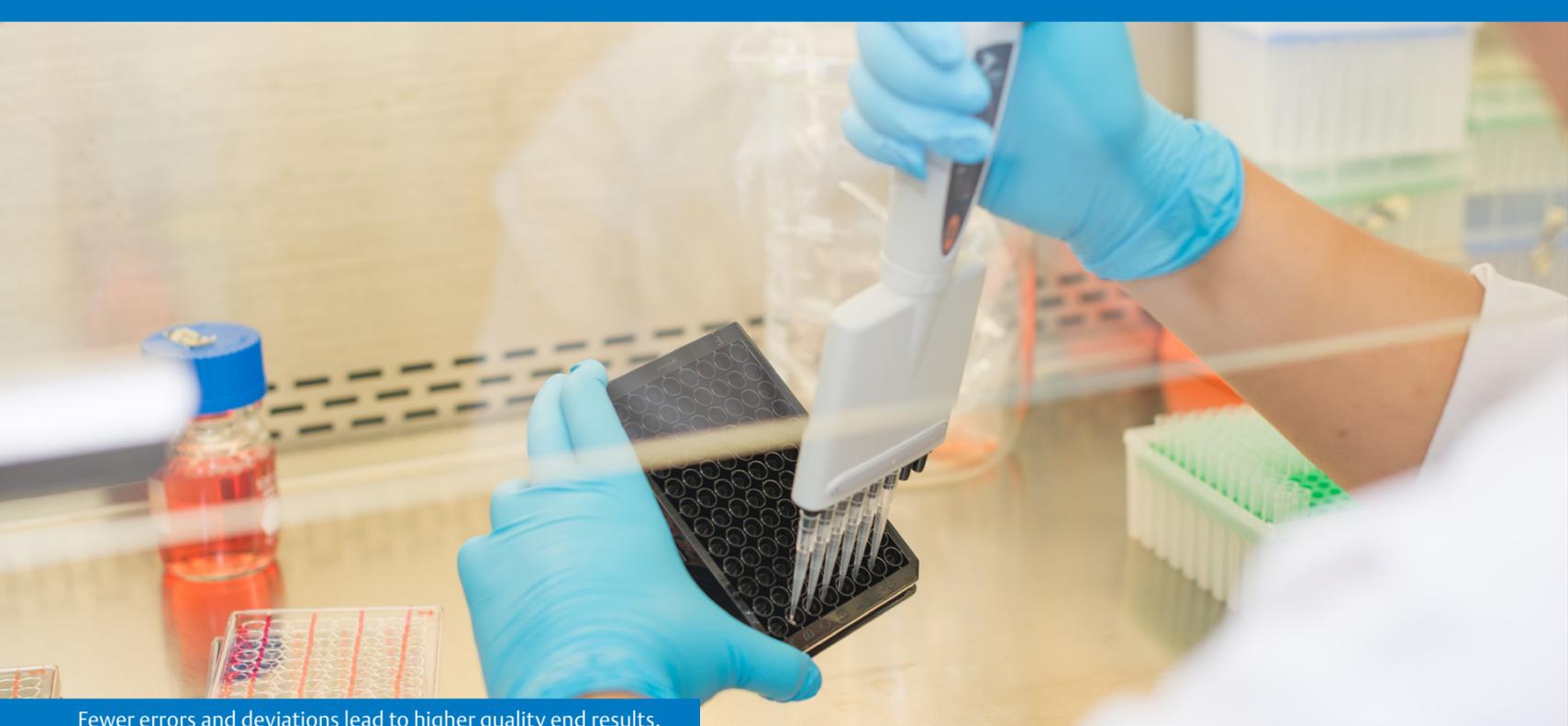
Simplify and streamline documentation efforts by maintaining processes and records digitally. A single, integrated batch record solution provides better documentation control and eliminates printing and storage expenses, a critical issue when creating thousands of batch records per year.

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.

Ensure Product Quality

Easily avoid process exceptions before they occur or identify and resolve them before the batch is complete to reduce release time and ensure quality.



Fewer errors and deviations lead to higher quality end results.

Improve Chain of Identity

Chain of identity is crucial in autologous cell therapy manufacturing. Materials must be tracked as a batch moves from receipt of the patient's cells to cell expansion through the activation process to final formulation and delivery to the patient.

Across the chain of identity, the process must be documented. Records include receipt of patient materials, sample tracking, the cell growth process, and patient delivery. Documentation must also include activities related to the process. These manual tasks can be streamlined with tools that help ensure the batch is executed according to the recipe.

Emerson's Syncade MES helps implement and confirm the chain of identity:

- **Ensuring proper procedures** leads to documented accuracy, verifiable regulatory compliance, and complete therapy genealogy. Workflows prevent operators from deviating from the validated process, while ensuring that the right actions are performed and recorded against the right batch record. In addition, electronic signature capabilities track and document approved activities for proof of proper chain of identity.
- **Embedded barcoding** means that materials are tracked from point-of-receipt through the complete manufacturing process, resulting in an accurate material genealogy at each stage of production.
- **Automatic documentation** streamlines the record-keeping process while maintaining accuracy. With electronic document management, a complete record of document history is easily viewable at any time to show proper chain of identity.

Manage the chain of identity with confidence, knowing that the process was accurately documented and verified. The Syncade MES helps ensure the right people are doing the right things with the right materials on the right batch.

Reduce Execution Errors

In an industry that requires accuracy and faces tight deadlines, any errors in development, manufacturing, or documentation 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 the Syncade MES, you can:

- **Reduce process errors** by verifying materials, samples, process manipulations, and equipment state. Automate calculations to eliminate the possibility mathematical errors.
- **Integrate with automated systems** so that data is shared accurately and deviations are easier to eliminate.
- **Review by exception** to find and fix errors more quickly to ensure quality, timely manufacturing, and faster release to patients.

Reduce errors in manufacturing and validate data between information and control systems to move toward right first time production.

Maintain Paperless Production

When producing thousands of batches each year, maintaining paper records for each batch is a time-consuming, error-prone, and costly process. Ensuring that thousands of pieces of paper are accurate and easy to access is difficult, to say the least.

To make document management easier, many are turning to paperless procedures in manufacturing. With digital documentation, accuracy and accessibility are improved and it is easier to validate batch history for compliance audits.

The Syncade MES helps implement a digital environment with:

- **Electronic Batch Records** that reduce errors and ensure the identity, potency, purity, and quality of products.
- **Material management** that provides real-time verification during production and easy access to material data for review and compliance requirements.
- **Comprehensive reports** that offer aggregated information from multiple process historians, capturing manufacturing intelligence, equipment state, and quality documentation in a single location.

Syncade simplifies document management while maintaining accuracy, efficiency, and agility. A single source of truth for process information, stored digitally, makes it easier to find information quickly and eliminates the expense and storage of paper records.



Identify and resolve process exceptions early to reduce batch release time and guarantee quality.

Ensure Product Quality

Product cycle times are short and exceptions must be found and addressed quickly. To simplify the review process and help ensure accurate products, exception reporting is a critical capability for each of the thousands of batches per year.

Using the Syncade MES review by exception functionality, you gain:

- **Integrated exception reports** to expedite the quality review processes, allowing you to quickly identify, review, and resolve issues during the batch production process.
- **Automatic verification** that data is within the expected range, with operator alerts about any abnormal situations. This consolidated data enables operators to take corrective action during the batch process, rather than after the batch is completed.

By enabling review by exception, the Syncade MES enables groups of batches to be auto-released, closing the gaps between production, product release, and patient delivery.



Improve manufacturing operation to drive
your production goals.

Learn more at www.emerson.com/syncade.

Emerson
1100 W. Louis Henna Blvd.
Round Rock, TX 78681-7430

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