Enabling a Healthier World

Lonza

Digitalizing Cell and Gene Therapy Manufacturing

MES solutions can remove paper from the manufacturing floor once and for all — while boosting operational efficiency and saving costs

Executive Summary

- Standard paper-based approaches were being used at four Cell & Gene Therapy (CGT) manufacturing sites
- In a phase-by-phase deployment project, each of these sites implemented the MODA-ES® Platform to digitalize manufacturing
- The MES system replaced manual data entry, making the chain of custody more reliable
- By adopting digitalization, these sites are now able to provide near-real-time updates to all stakeholders and coordinate logistical activities with ease

Impact

Lonza's MODA-ES® Platform enabled the CGT sites to:

- Expand manufacturing capacity by enabling parallel processing
- Reduce production hours and review times by going digital with data entry
- Minimize running costs due to faster, more efficient operations

Challenge

Managing the operational complexity of CGT manufacturing

In manufacturing CGT products, the operational complexity of handling and tracking individual patient or donor samples from the clinic to the manufacturing site and back to the patient poses an unprecedented level of logistical challenges. As each product needs to be tracked to the corresponding patient, maintaining a chain of custody and traceability across the entire manufacturing pipeline is indispensable.

These challenges are especially acute for autologous Cell Therapy products with typical timelines ranging from 10 to 14 days, schedules in CGT manufacturing are tight, further adding pressure on the supply chain. Any delays in delivering the therapy can directly affect the patient's health outcomes. Along every step, the involved parties — patients, sponsor companies, hospitals, manufacturers, and couriers — need to receive regular updates on the manufacturing status. "It's important that we're able to provide the right information to the right audience at the right time without additional burden and cost to the site," says Walter Bagni, CGT Center of Excellence Lead at Lonza.

Incidentally, most of these time-sensitive manufacturing activities are recorded on paper or spreadsheets. Technicians manually fill out the details in a document, while approvers review and verify the information in person. These records are then copied and physically stored. Manufacturing timelines are tracked on spreadsheets, while schedules are set over phone calls or emails. Unsurprisingly, when an entire operation, from sample receipt to product shipment, is held together by manual tasks, errors and omissions are inevitable.

Moreover, managing documents that hold sensitive and confidential patient information requires regular administrative upkeep, making the entire process highly resource intensive. "The fact that paper records are physical entities increases the risk of losing or misplacing them," notes Bagni. "They can also increase the risk of contamination when taken into clean rooms."

Solution

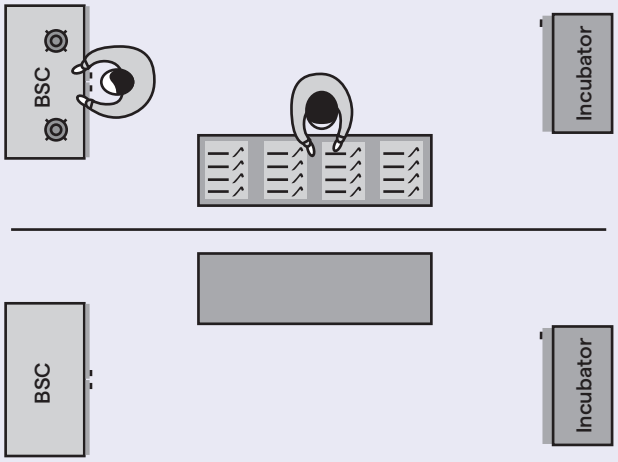
Deploying the MODA-ES® Platform across a Global CGT Manufacturing Network

Starting in early 2019, Lonza's CGT manufacturing sites in Houston and Portsmouth (USA), Geleen (the Netherlands), and Singapore underwent a phase-by-phase digitalization process using the MODA-ES® Platform. During the first phase, the goals of the project were to digitalize the chain of custody/identity and traceability at the Houston and Portsmouth sites. The MODA® Implementation Team provided hands-on support to install, configure and validate the platform to best suit each site's needs. Next, the 'flexible recipe modeler' was used to customize the site's manufacturing workflows, i.e., the sequence of events, materials, schedules, and other details. Progressing simultaneously, both Houston and Portsmouth sites underwent performance checks and went fully digital with 'track and trace' by early 2020.

"I truly appreciate the CGT knowledge that the MODA® Implementation Team brings," says Bagni, who oversaw the entire digitalization operation. "Because of their expertise and dedication, we were able to shorten the implementation timelines to less than 9 months — one of the fastest deployments I've seen in my career." Upon completing phase 1, phase 2 commenced at the above US sites. This time, the goal was to digitalize the entire manufacturing process and implement electronic batch recording. Meanwhile, at the sites in Singapore and the Netherlands, phase 1 was initiated and is currently in progress.

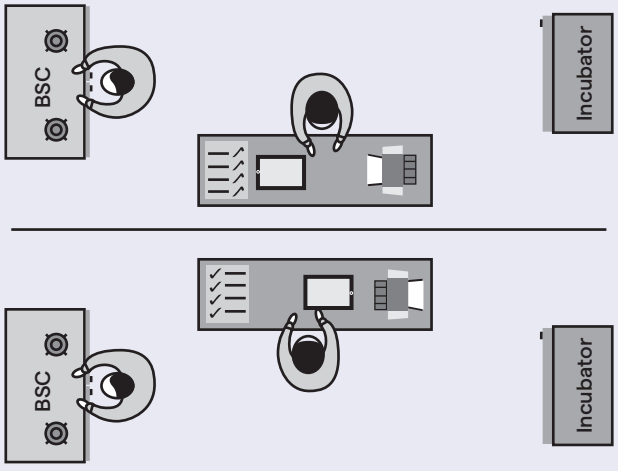
Without MODA® Track & Trace

Only one batch can be processed in a clean room at any given time



With MODA® Track & Trace

Parallel processing of batches is possible



Results

Open Parallel Processing and Paper Removal with Digital 'Track and Trace'

Capacity expansion: The main reason behind prioritizing 'Track and Trace' digitalization was to facilitate open phase parallel processing at the CGT manufacturing sites. Previously, with paper-based tracking, the Lonza sites could only process one batch in a clean room at any given time due to higher risks of cross-contamination or mix-ups. Enforcing a systemized, digital chain of custody has now made it possible to run multiple open phases in parallel, either for the same patient or for multiple patients, within the same clean room. As a result, the degree of equipment utilization has also increased. By expanding the manufacturing capacity on-site without additional overhead, the MODA-ES® Platform has helped decrease the overall cost of production.

Paper elimination: Electronic record-keeping for traceability has eliminated the use of paper on the manufacturing floor at the Houston and Portsmouth CGT sites, where data is now captured and stored digitally. Instead of writing on pre-printed labels, technicians can print labels on-demand. Dedicated clean room barcode scanners help input or retrieve information. With no more transcription errors or inadvertent omissions stemming from paper-based documentation, the number of batch rejections on-site has drastically reduced, making the operations more cost-effective.

Most important of all, technicians can now focus on the task at hand instead of manually filling out paperwork while juggling everyday activities. The ability to queue electronic signatures for approvals on the MODA-ES® Platform eliminates frequent interruptions during the workflow. Patient records remain safe and secure, and can be readily accessed by authorized personnel at any time without having to request physical files. Lastly, the manufacturing status of the drug product is now recorded in real-time so that couriers, sponsors, and patients can receive timely notifications.

Real-time updates: Digital 'track and trace' using the MODA-ES® Platform provides a complete overview of the facility's operations by the minute. Even if production volumes increase in the near future, site managers can easily monitor progress or troubleshoot issues from one platform. The CGT sites now digitally provide near-real-time updates to all stakeholders instead of sharing spreadsheets or making phone calls. Scheduling pick-ups and coordinating deliveries are hassle-free, eliminating logistical delays from an already tight timeline.

Long-Term Success Criteria for Digitalizing CGT Manufacturing

Vendor domain knowledge:
The MODA® Team brings years of business expertise and hands-on experience as it relates to CGT. "Very often, MES vendors master the technology but not the process," notes Bagni. "The MODA® Team, however, not only has deep knowledge about the system but also fully understands the CGT manufacturing process. That's why they're able to recommend the best path towards digitalization for a particular site."

Fast setup and low maintenance:
The MODA-ES® Platform can be readily configured based on the site's needs and infrastructure, making it possible to go from installation to 'live' in just a few months. Once deployed, changes and additions can be easily made to keep up with emerging needs.

Easy-to-use platform:
Digital transformation in a busy manufacturing facility is only effective when every staff member readily embraces the new technology. As technicians prepare to step away from familiar paper-based approaches, having a user-friendly software system encourages adoption and compliance.

Benefits

Flexible and cost-effective digitalization boosts overall efficiency

Flexible workflows to meet business needs: The MODA-ES® Platform is specifically designed to serve CGT manufacturing needs. As such, it's easy to make process modifications when the project moves from clinical to commercial, or if a technology change is implemented during a project. Based on the latest regulatory requirements, instructional text can be updated to capture new information at any point during the workflow.

Highly efficient operations enhance product quality: Rapid and accurate data entry using digital tools expedites the review and approval process, thereby advancing projects faster. As handwritten notes and manual calculation get replaced with digital 'track and trace' methods, human errors are eliminated, and consequently, protocol deviations or batch rejections are reduced. All around, the reliable chain of custody maintained using the MODA-ES® Platform directly upholds data integrity to keep the entire operation compliant with regulations.

Tangible reduction in production costs: Digitalized operations using the MODA-ES® Platform can reduce data entry and review times by 50–70%, thereby allowing technicians and supervisors to focus on higher-value tasks. Implementing electronic batch recording can shrink production hours on the manufacturing floor by 10-20%, directly reducing the overhead costs of the operation. Finally, even if deploying an MES system can seem like an investment upfront, the multifaceted applications of a single platform to expedite all aspects of the manufacturing workflow — from sample arrival to product release — lowers the total cost of ownership.

Conclusion

Maintaining paper-based records, although a deeply rooted practice in manufacturing, can negatively impact the overall efficiency of the site, especially in CGT operations where delivery times are short and data accuracy is paramount. Implementing an MES, such as the MODA-ES® Platform, not only eliminates manual errors but also accelerates production timelines. With the added ability to perform open phase parallel processing, the site's manufacturing capacity expands without any additional overhead costs.

To learn more about the MODA-ES® Platform deployment project at the four CGT manufacturing sites, watch our webinar **"Digitalizing Cell and Gene Therapies Manufacturing - A Lonza Case Study"**.

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