Enabling a Healthier World

Lonza

MODA-ES® Execution System

Next Generation Electronic Batch Record

The MODA-ES® Platform Digitalizing Quality and Manufacturing

Replace Paper with Productivity

The MODA-ES® Platform bridges the gap that currently exsists between manufacturing and QC to provide a single batch record with a review and approval interface. It is a combined electronic batch record and lab execution software that enables data capture, workflow and analytical tools for expedited product release. With GMP compliance and tracking at its core, the MODA-ES® Platform combines data capture and error prevention with the flexibilty to capture and trend key quality and performance metrics, both in the lab and on the production floor. Built with Lonza Informatics know-how and Lonza's Manufacturing Experience, the MODA-ES® Platform is cost-effective to adopt, maintain and deploy for medium and small biotech organizations with a lower total cost of ownership. The MODA-ES® Platform provides a solution to the industry that is flexible and easy to configure at a price point that allows the entire manufacturing industry to go paperless.

It's Time for a Different Approach to Informatics in Life Science Manufacturing

The MODA-ES® Platform addresses the issue of paper records associated with batch record data capture, long cycle times for review/approval activities, deviations for missing entries, incorrect entries, calculation errors and incorrect workflow decisions. Lonza solved these QC Microbiology issues with the use of the MODA-EM® Software, but still experienced these issues in manufacturing.

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 and it was too expensive for manual intensive processes like Cell and Gene Therapy that do not have a high degree of automation integration.

The Lonza Informatics Team stepped in to help solve the issue. The combination of the subject matter expertise from multiple Lonza Manufacturing Groups combined with 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 experience allowed for a more flexible, cost effective solution to replace paper batch records than other solutions in the market.

How much of your batch record do you have to N/A?

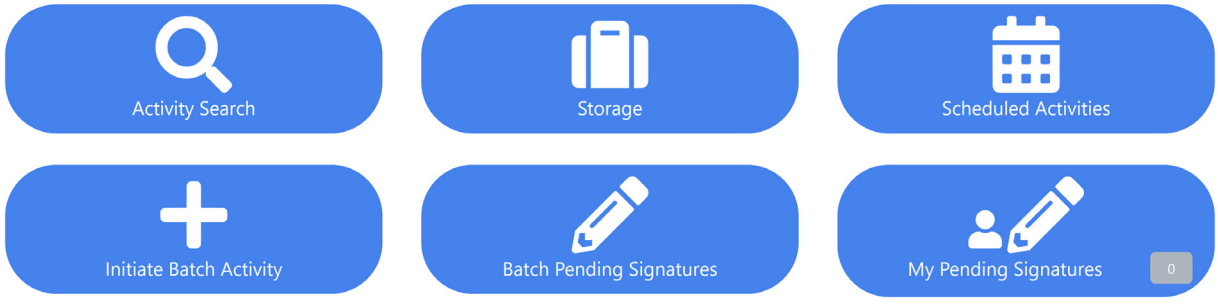
The design of paper batch records means that 30-40% of a record will be marked non-applicable (N/A) due to decisions being made by technicians

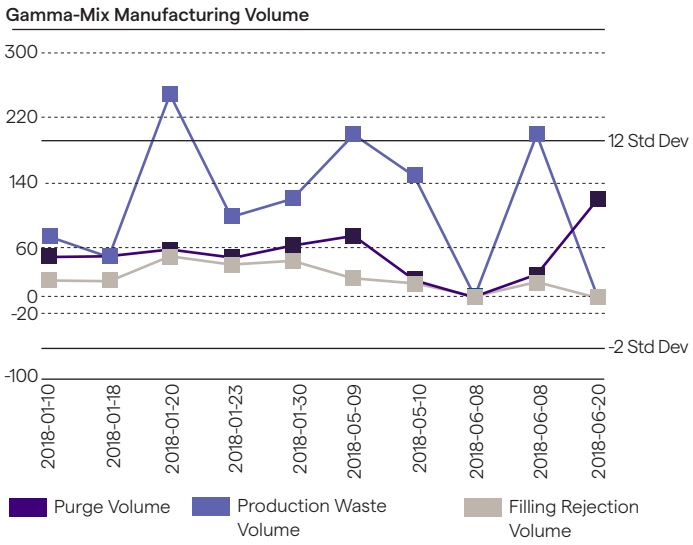
The Hidden Consequences of Silos of Data

The vast amount of data produced by manufacturing and QC included in and surrounding the batch record is spread throughout multiple electronic systems. Where any gaps exist, paper is utilized to capture data which is a system unto itself.

This data is siloed both in the system of record as well as within the organizational structure. This has lead to many systems with overlapping functionality. An example of this is, Manufacturing Execution Systems (MES) and Laboratory Execution Systems (LES) that both perform similar functions. They have a workflow engine, data capture method, equipment integration and a way to review/approve the data. Why do two systems exist that provide the same functionality? The answer is the first major silo is the organizational silo and the idea that each department has such unique requirements that they can't possibly utilize the same system. This divide creates walls that data must either go over or through to produce a batch record that includes data from all sources.

MODA-ES® Platform





Capture the data that is important to your process with easy to use drag and drop analytics.

Every calculation in cGMP companies is performed 4 times. The performer, verifier, reviewer and approver will all ensure the calculation was performed correctly. Employee's time should be better utilized than having 3 people check 1 person's work.

The second silo is the lack of integration between systems of record. Paperwork, in the gaps discussed earlier, creates the largest silo because the data is not easily accessible, reviewable or transferable. The cost and work associated with maintaining paper records and accessing their data during audits or investigations is tremendous. Electronic systems including ELN, MES, LES, LIMS, ERP, Calibration Management, Deviation/CAPA Management Systems, and Building Managment Systems include information that may all contribute to the batch record. Without an integration strategy companies rely on users to make the right decision or transfer the data between systems correctly which requires extra verification, wasting time of the company's most precious resource; personnel. An example is a user verifying the lot number of a raw material to be used in production and that it is within expiration. Then a reviewer must ensure the user correctly entered in a valid lot number for that raw material, that it was within expiration on the day of it's use and it was not quarantined during it's use as part of an investigation.

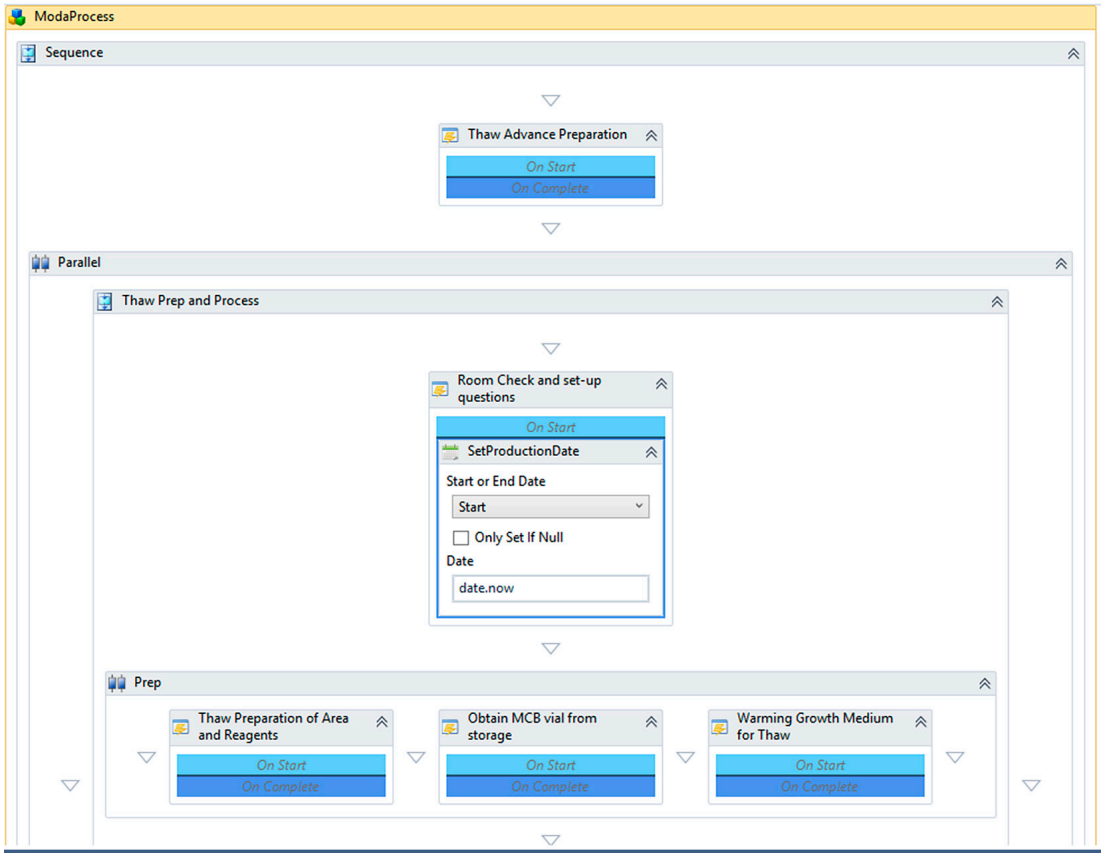
The removal of paperwork within and surrounding the batch record process is key to accessing the data needed to begin to break down the siloed data. Then an integration strategy can make data available to each system when the information is needed without human interaction. This reduces deviations and allows for faster, more accurate decision making.

More Product Less Paper

The MODA-ES® Platform is designed to be configurable over customizable. The user interface is easy-to-use enabling manufacturing technicians who understand the processes to build the workflows. The configuration of the system includes areas for data recordation (measurements), instructional text (including hyperlinks to SOP's), electronic signatures, sections, and drag and drop workflow. This is done through a series of add buttons, drop-downs and check boxes. The system was built with a modular design that allows individual modules to be validated and data transfer between modules is a configuration verification exercise. This limits the amount of work when a new process is brought into a facility because you can use existing validated modules and only create modules needed for the new process. Additionally, there is a library feature that allows products of the same family to be processed the same way, but with varible differences such as raw materials, fill volumes, and equipment types without needing a completely new process to be built and validated.

The second major component of the system is around the quality batch record review process. QA groups currently have a checklist of items that need to be signed off before a batch is considered complete. We took this concept and created an electronic checklist to be signed off individually as the process goes along, but all checklist items to be signed off before the batch is approved. This allows for real-time review and approval without having to wait for the entire paper record to end up on someone's desk for approval.

The heart of the system is the ability to review and approve by exception. The system ensures that the data is entered correctly, materials and equipment are within their respective date ranges, calculations are validated and any exceptions or deviations for the reviewer/approver to verify before approving. This eliminates 70% of the review/approval process. In addition the MODA-ES® Platform provides



Simplified drag and drop workflow that doesn't require specialized IT skills to create or manage.

data integrity flags built right in review and approval. The system flags any changes and shows the before and current measurement, who performed the actions, when they performed the actions and any meta-data changes associated. Instead of reviewing the audit trial once a quarter to see if there were any issues, you can do it in real time during review and approval and correct any issues before release of the product.

The Lonza Informatics Team has always put the end user experience first. The system is designed to be user-friendly for data entry and signatures. We worked with end users to ensure the system displayed information that was easily visable and accessible. The system was designed to alert the user when an issue had occured and provide notifications to supervisors or QA. The system includes multiple electronic signature types including performer, performer/verifier, supervisor signature, QA signature, participant list and named performer. The named performer is important because performers aren't always able to sign for a section immediately because of work in a BSC or isoloator. It allows the verifier to sign for the section, move the process forward and queues the signature for the performer when they are completed processing and available to sign.
The MODA-ES® Platform is capable of integrating with other cGMP compliant systems. The system utilzes an integration tool that allows for integration to systems such as LES, LIMS, ERP, BMS, QMS, and many others. Additionally, the Lonza Informatics Team has extensive experience integrating directly with equipment to pull information directly from the machine, in a data integrity compliant manner, and transfer it into the MODA-ES® Platform. Transferring data directly from equipment and systems elimates error prone manual transcription removing the need for additional review and ensures accuracy of data.

The MODA-ES® Platform bridges the gap that currently exists between manufacturing and QC to provide a single review and approval interface for batch records. The system has the ability to capture data from the manufactuing batch record process and batch-related QC processes as well. The system allows for workflow-driven, data entry which is applicable to batch records, sterility tests or cleaning forms. The system has a flexible scheduling engine that allows for electronic forms to be scheduled on any frequency required so that your technicians don't miss that important cleaning cycle for the equipment. 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.

Cost Effective Solution to Batch Record Challenges

Electronic Batch Records have been 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. The MODA-ES® Platform equals one record, one platform to move your company into the digital age and allow you to reap the benefits of efficiency, better compliance, real-time reporting and expedited release of your product.

To learn more about the MODA-ES® Platform or to request a demonstration, visit www.lonza.com/moda-es.

Contact Information

North America

Customer Service: +1 800 638 8174 (toll free)
Fax: +1 301 845 8338
order.us@lonza.com
Scientific Support: +1 800 521 0390 (toll free)
scientific.support@lonza.com

Europe

Customer Service: +32 87 321 611
order.europe@lonza.com
Scientific Support: +32 87 321 611
scientific.support.eu@lonza.com

International

Contact your local Lonza distributor
Customer Service: +1 301 898 7025
scientific.support@lonza.com

International Offices

Australia	+61 3 9550 0883
Belgium	+32 87 321 611
Brazil	+55 11 2069 8800
China	+86 21 6305 8866
France	0800 91 19 81 (toll free)
Germany	0800 182 52 87 (toll free)
India	+91 124 6052941
Japan	+81 3 6264 0660
Luxemburg	+32 87 321 611
Singapore	+65 6521 4379
The Netherlands	0800 022 4525 (toll free)
United Kingdom	0808 234 97 88 (toll free)

Lonza Walkersville, Inc. – Walkersville, MD 21793

RT-BR022 02/22

www.lonza.com/moda-es