Enabling a Healthier World

Lonza

MODA® Electronic Logs Module

Replace Paper with Productivity

Pharmaceutical manufacturers need to maintain meticulous records tracking all workflows and processes, including equipment usage, cleaning procedures, and room entries. Often documented on paper, these logs capture tasks that support a process or are directly involved in manufacturing. Record-keeping is essential for timely product release and to remain compliant with stringent regulatory requirements.

Why Choose the MODA® eLogs Module?

An extension of our powerful MODA® Platform, the MODA® eLogs Module maintains electronic logs for seamless task execution, scheduling, reviewing, and record-keeping.

- **Intuitive and user-friendly:** Built with a focus on the end user, the interface replicates the smooth user experience of modern apps, making it intuitive and easy to navigate, and requiring minimal training to operate (Figure 1).
- **Enforce compliance:** The MODA® eLogs Module enforces workflows as per standard operation procedures (SOP), ensuring accurate data are collected the first time. Complying with data integrity requirements, the system also provides time-stamped audit trails and captures electronic signatures. The risk of using out-of-calibration equipment or working with the wrong instrument for any given step is eliminated.
- **Customizable and flexible:** Workflows can be configured and built out based on the needs and capabilities of each manufacturing facility (Figure 2). When processes evolve, workflows can be easily updated.
- **Integration with other systems:** For seamless end-to-end operations, the MODA® eLogs Module integrates with the MODA-EM® Module for quality control and the MODA-ES® Module for batch records. To provide manufacturing facilities with highly advanced scheduling, logging, and tracking capabilities, it can also be integrated with external systems, such as enterprise resource planning (ERP) or building management software and shop-floor equipment.

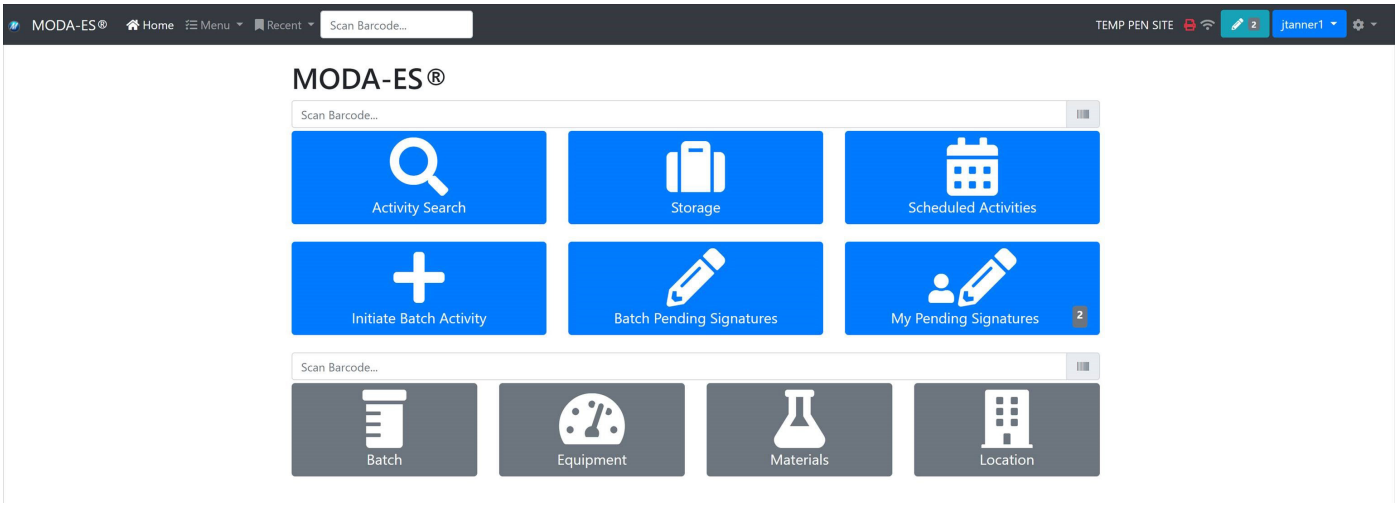

Figure 1. Intuitive user interface

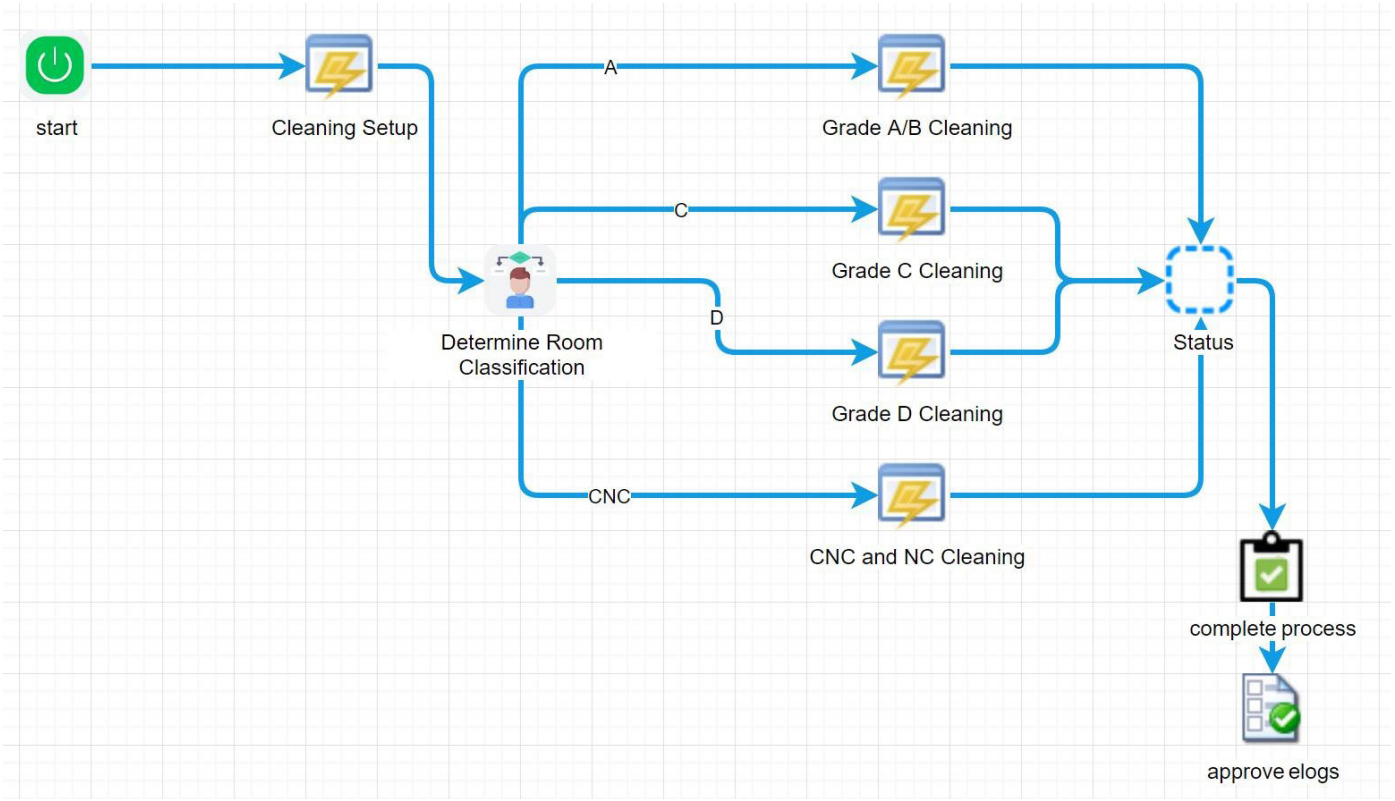

Figure 2. Easy-to-use, flexible workflow builder powered by FlowWright.

The Burden of Paper-Based Logbooks

Omission errors and inaccuracies

Errors or inconsistencies with data input or time/frequency entries cannot be checked in real-time. Incorrect entry can therefore go unnoticed until records are reviewed, or processes get investigated.

Ambiguity and illegible handwriting

Illegible writing in paper-based logs is a serious issue, as ambiguity around information captured can trigger a feedback loop of reviews involving multiple individuals, delaying or disrupting timely production.

Disparate, unsearchable records

During investigations, paper-based records need to be manually located, reviewed, and scanned, making reviewing entries across logs time-consuming and tedious.

Cumbersome storage

Paper records often require a dedicated storage space, and regularly filing and labelling these documents to maintain audit trails can quickly become a paralyzing time sink.

Cleanroom compatibility

To meet stringent cleanroom air quality requirements, time and resources are needed to control contamination from paper logs, accompanying pens, clipboards, and packaging, presenting an additional roadblock to more streamlined manufacturing.

- **Real time access to data:** the MODA® eLogs Module offers the ability to view, in real time, the status and state of equipment and rooms, enabling smart scheduling of manufacturing campaigns. This data is then available in an easily searchable format to support timely investigations and decision-making.
- **Expedited QA approval time:** By eliminating the effort required to manage, maintain, and store paper logbooks, the MODA® eLogs Module frees up valuable time for QA personnel. Users can also streamline checks through review by exception workflows, as the system ensures all required data is inputted before users can proceed to the next step.
- **Backed by an experienced implementation team:** With decades of experience in pharma manufacturing operations, the MODA® Implementation Team brings extensive industry expertise and technical know-how to help build your workflows, make recommendations, and offer comprehensive troubleshooting support.

The Benefits of Electronic Logs

Paperless tracking and execution of all manufacturing processes, as supported by the MODA® eLogs Module, not only saves time and resources but can also be a powerful starting point for your digital transformation initiatives. By automating data capture and facilitating broader automation capabilities, organizations can reap end-to-end efficiencies that improve their entire operation.

Efficient operations

Real-time review: Electronic log systems carry out real-time checks that instantly catch omissions during data input, preventing the user from moving forward until the missing field is populated (Figures 3 and 4).

Enforcing procedures and routines: Scheduling of routine activities and adherence to SOPs can be automatically enforced without having to manually keep track of the details.

Streamlined data management: Datasets from multiple log entries are collected and stored on a centralized platform and can be curated based on the equipment or product batch number. Unlike paper records scattered across locations, it is possible to access an electronic log in real time from any location.

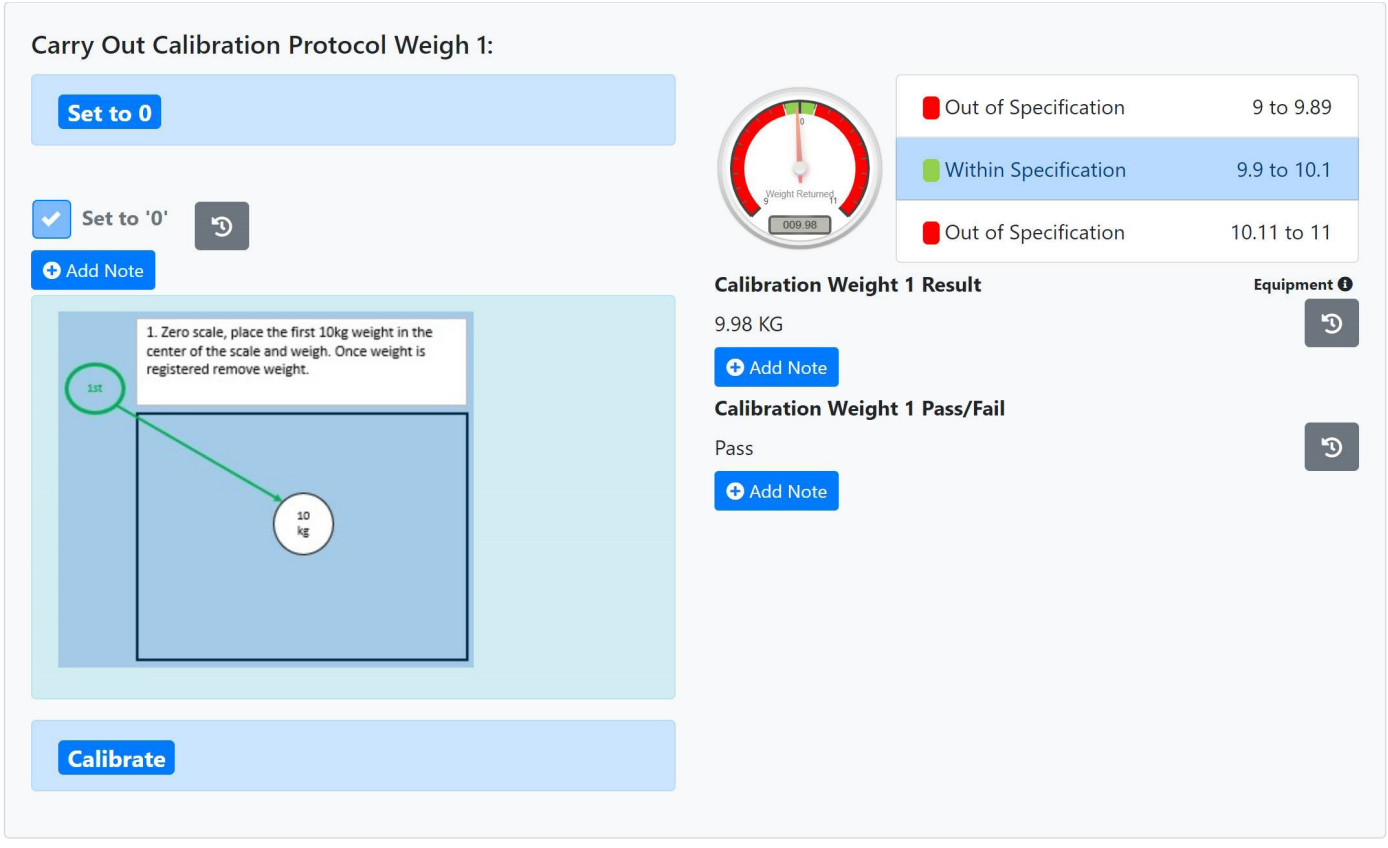

Figure 3. Overview of the end-user screen

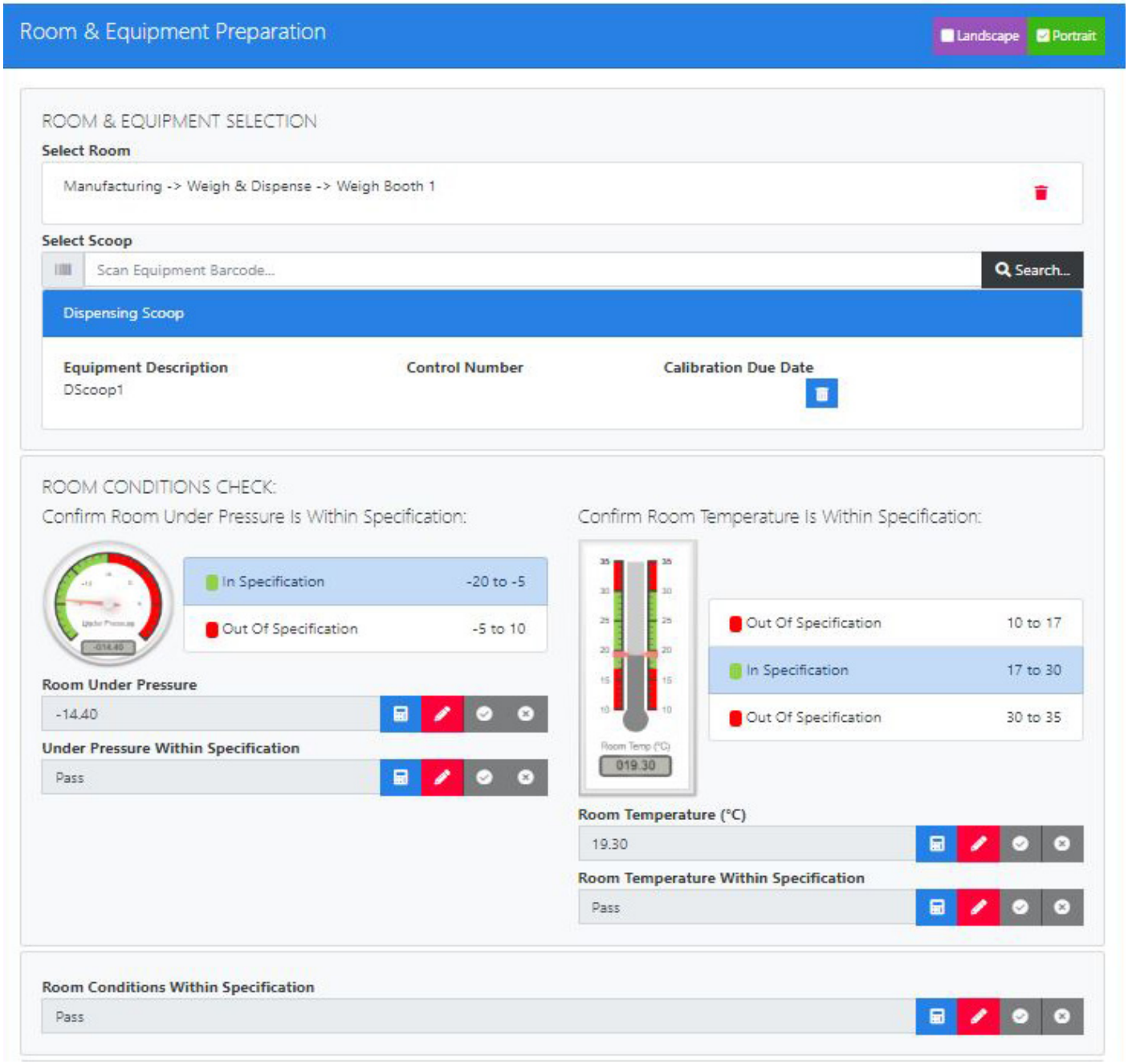

Figure 4. Real-time visualization of data entered

Streamlined investigations and audits

Built-in controls: An electronic system that catches GDP errors in real-time and enforces procedures and schedules, all while collecting data at every step, makes investigations time-efficient and productive. When real-time controls are built into the data capture process, the time spent back-tracking past activities is vastly reduced.

Convenient search feature: With logs easily accessible via the search feature, it's no longer necessary to physically locate, scan and attach documents during an investigation or review.

Faster issue resolution: Rather than poring over paperwork that might be unrelated to the issue at hand, electronic record-keeping allows the investigation to promptly isolate areas of risk and perform a root cause analysis. By eliminating non-value tasks that don't directly contribute towards troubleshooting, issues are resolved with greater efficiency.

Improved traceability: An electronic system that maintains audit trails can significantly improve traceability. With the MODA® eLogs Module, users can conveniently search for and find any past record based on an instrument, room, batch number, user, or even a particular date – all from one consolidated database.

Key considerations for transitioning from paper-based to an electronic log system:

Is the system easy to use?
Transitioning from traditional paper-based methods to novel electronic systems is a significant change for team members and can be met with apprehension. To improve user buy-in and shorten the learning curve, a system should be user-friendly and easy to use.

Is it easy to maintain?
Once installed, an electronic solution needs to be flexible enough to accommodate the evolving needs of a manufacturing company. Choose a system that can be readily adjusted when workflows or regulations change, without having to request technical support or make additional investments.

Does it improve operational efficiency?
To be effective in the long run, electronic logs need to offer more benefits than simply digitalizing paper-based record-keeping. Consider whether the system streamlines the entire operation by automatically tracking time, checking errors, scheduling activities, providing real-time updates, and expediting reviews.

Advanced capabilities

Automated use logs: When integrated with an electronic batch record (EBR) system, automatic use logs can be generated in chronological order. For example, as details are entered for a batch record while placing materials in an incubator, an electronic log can be simultaneously created for incubator use, thereby tracking the order, time, and frequency of activities linked to the equipment being used.

Comparing data logs: During a review, rather than having to locate separate logs (e.g., for incubator cleaning, reagent use, and system calibration), MODA® eLogs Module users can simply pull up an equipment report that lists all activities performed on that instrument with timestamps on data entries made before, during, or after batch production. Records can be viewed in stand-alone formats or in comparison with other logs for that equipment.

Enforcing room states and equipment status: By integrating the MODA® eLogs Module with EBR systems, users can benefit from greater operational control by reporting room states and equipment status in real time. For example, upon utilizing an instrument or entering a room that requires a subsequent cleaning step, the status can be automatically updated to 'not clean' and a cleaning task scheduled to prevent further use. The need for in-person reviews is also eliminated, with reviewers having a snapshot overview of all equipment and room statuses through an intuitive dashboard.

To increase revenue and scale operations, replacing tedious and error-prone paperwork with electronic logging systems is key. In addition to tangible end user benefits, such as automatic data entry checks and real-time monitoring, the MODA® eLogs Module also improves the overall efficiency and drives compliance across the entire site. For data to be leveraged as a powerful decision-making tool, it is important to have a centralized digital platform that collects, stores, and maintains accurate records.

Achieving enterprise-wide automation is a goal for many manufacturers, and it all begins by taking the first step: digitalizing everyday paperwork.

Ready to replace your paper with productivity? Get in touch with the Lonza team to request a demo of the MODA® eLogs Module: www.lonza.com/moda-elogs

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