



WHITEPAPER

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From Paper to Digital: Implementing a Tulip-Based Electronic Batch Record Solution in Pharmaceutical Packaging

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Executive Summary

Pharmaceutical manufacturing operates within a highly regulated environment where accuracy, traceability, and process control are critical to ensuring product quality and patient safety. **FrontWell Solution's engagement helps manufacturers** replace paper batch records with a digital solution, transforming packaging operations.

The solution streamlines workflows, enhances visibility, reduces errors, and strengthens GMP compliance across multiple SKUs and formats.

This article explores the evolution of Manufacturing IT, current solutions, and implementation challenges, while showcasing FrontWell's expertise in delivering Tulip eBR solutions that empower manufacturers to embrace the future of digital packaging.



Introduction

Our client initiated a digital transformation program to replace paper-based batch records with an electronic batch record solution built on the **Tulip manufacturing application platform**. The initiative covered both primary and secondary packaging operations. By standardizing execution through applications, manufacturers can significantly improve overall equipment effectiveness while maintaining strict regulatory compliance.

Digital batch initiation and guided execution reduce manual interventions, minimizing errors, deviations, and rework. Real-time visibility into line readiness, material availability, and equipment status enables faster decision-making and reduces unplanned downtime, directly impacting throughput and time-to-market. From a quality and compliance perspective, built-in verification steps and in-process controls strengthen data integrity and ensure consistent adherence to cGMP requirements. Electronic records generated during execution streamline quality review and batch release, reducing administrative effort and inspection risk.

This case study outlines the approach taken to implement the digital solution in a live production environment. It intentionally excludes any client-specific or proprietary information.

Implementation Approach

Prior to this implementation, batch documentation was executed using paper-based records. This approach required significant manual data entry and review, increasing the risk of transcription errors, incomplete entries, and legibility issues. At times, the client had frequent updates to paper-based batch records which required significant time and effort to implement, review, and re-approve, making change management slow and operationally inefficient, highlighting the need for a more flexible, digital approach. Moreover, paper records require physical storage space and are difficult to search, retrieve, and audit efficiently.

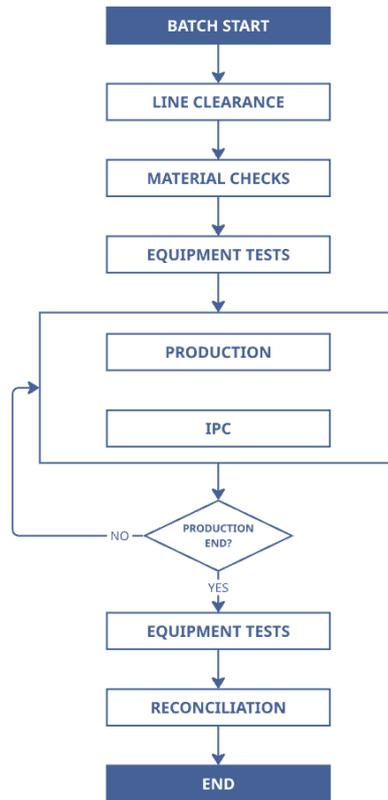
Packaging operations introduced additional complexity due to the variability of products, packaging configurations, and in-process control requirements. Time consuming line changeovers, multiple verification steps, and strict reconciliation requirements placed a heavy reliance on operator adherence to written procedures. These factors collectively created a strong business and compliance case for replacing paper batch records with a digital solution.

Key elements of the implementation included the replacement of paper batch records and packaging documentation with an electronic batch record (eBR) system for enhanced GMP compliance and data integrity. Assessment of processes, identification of GMP-critical requirements, and mapping of workflows to compliant digital equivalents for controlled digitization and enforced sequencing. Digitization of packaging and in-process activities, combined with role-based access, electronic signatures, and audit trails, for improved accuracy, traceability, oversight, and regulatory compliance.

Integration into Packaging Operations

At the core of **the Tulip eBR solution** is batch-driven execution. Operators begin by selecting the Work Order then Tulip automatically builds the full execution flow for that specific batch in the background. Instead of using a static master record, the system activates only the relevant steps, checks, and controls, based on product, format, and market requirements. This ensures each batch follows a purpose-built process path, allowing different products to run with different material checks, equipment tests, and IPC Sampling frequencies while maintaining full compliance and operational efficiency. Operators are guided through line clearance, pre-checks, material verification, and equipment tests with enforced compliance and real-time validation. Packaging execution and IPC sampling are digitally controlled with live data capture. Finally, reconciliation and batch closure are performed automatically, producing a complete, review-ready electronic batch record.

The solution is built from the ground up to meet the highest standards of data integrity and regulatory compliance, fully aligned with ALCOA+ principles. Every action and data entry is securely attributable to authenticated users through controlled access and electronic signatures. All records are captured in real time, presented in clear, standardized digital formats, and stored as original electronic entries. A built-in validation logic ensures accuracy, completeness, consistency, and long-term availability of data. The system was configured to support electronic records and electronic signatures in accordance with regulatory expectations.



Business and Operational Benefits

The eBR implementation delivered measurable benefits for the client across operations, quality, and compliance. Documentation accuracy and completeness we're improved through standardized GMP-compliant practices, leading to reduced documentation-related deviations and improved data integrity and audit readiness. Batch record review and release processes we're optimized while maintaining full GMP compliance, and operator errors we're reduced through clear instructions and standardized workflows. Early Quality stakeholder involvement, together with standardized templates, modular components, as well as defined governance and exception handling, supported controlled deployment, scalability, and long-term GMP compliance.

These outcomes confirm the eBR system as a key driver of operational excellence and regulatory compliance.

Real-World Impact by FrontWell Solutions

The Tulip-based digitalization of the packaging process was delivered as a Proof of Concept (PoC) to validate feasibility, value, and user adoption on the shop floor. Even at this early stage, the PoC demonstrated strong impact: paper-based packaging records were replaced with guided digital workflows, helping operators execute tasks in the right sequence and capture data accurately in real time. Key activities such as line clearance, material verification, and in-process checks were digitized, reducing the risk of errors and deviations.

The PoC proved that structured digital data can significantly improve visibility and compliance. Quality teams were able to review packaging records faster, with clearer traceability and fewer manual corrections. Supervisors gained better insight into line performance, stoppages, and execution status, confirming the value of real-time, connected operations.

Based on the success of the PoC, a full-scale implementation was discussed and approved with the client as the next step. The future rollout will extend the solution to multiple packaging lines and products, enable parallel batch execution, and embed Tulip as a core execution layer in packaging operations. This engagement shows how a digital transformation with Tulip can create a clear, validated path toward a scalable, compliant, and fully digital packaging environment.

Our Company

FrontWell Solutions is the global front-runners in shaping the digital future of global Life Sciences ecosystems, generating value beyond. We are setting industry standards and shaping the digital future by intelligently connecting data, processes, systems, and people business partner and in the life sciences sector - powered by deep expertise and leading technologies.

FrontWell Solutions is an expert in the digital transformation of the pharmaceutical manufacturing process. Our team of experts is engaged in providing digital solutions to 12 of the 20 leading pharmaceutical, biotechnology, chemical, and medical device companies and suppliers spanning Europe, the United States, and Asia.

Our domain expertise lies across deep and differential specialized consulting services, primarily centered around Manufacturing Execution Systems (MES), Laboratory Information Management Systems (LIMS), Data and AI, Compliance seamlessly integrating these Level 3 systems with Enterprise Resource Planning (ERP) platforms and driving Manufacturing Intelligence initiatives such as Overall Equipment Effectiveness (OEE) reporting.

Moreover, we have partnered with prominent digital solutions platforms in the market, showcasing our proficiency in leveraging cutting-edge technology.

Next Steps

Thinking about taking your next steps towards the digitalization journey? Our experts are ready to support you! Contact us under ReachUs@frontwell-solutions.com or via +49 (6101) 595 89 85.