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Driving Faster Time-to-Patient
with Real-Time Insights

ACCELERATING BATCH RELEASE

Discover how digital batch tracking eliminates manual handoffs, reduces errors, and cuts release times dramatically.



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ACCELERATING BATCH RELEASE: DRIVING FASTER TIME-TO-PATIENT WITH REAL-TIME INSIGHTS

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EXECUTIVE SUMMARY: THE VISION OF ACCELERATED BATCH RELEASE

In the pharmaceutical industry, accelerating batch release is no longer a luxury, it's a strategic imperative. As companies face increasing pressure to reduce time-to-patient, ensure compliance, and manage complex global supply chains, the batch release process has emerged as a critical bottleneck. Despite widespread adoption of digital systems like ERP, MES, LIMS, and QMS, many organizations still rely on fragmented data sources and manual tools such as Excel, leading to inefficiencies, human error, and delayed decision-making.

This whitepaper explores how digital batch tracking platforms, particularly eschbach's Shiftconnector, can transform batch release from a slow, reactive process into a streamlined, real-time operation. It outlines the key barriers to efficient batch release, including siloed systems, regulatory complexity, and the hidden costs of manual coordination. It also highlights the strategic value of real-time dashboards that provide role-based visibility, enable cross-functional collaboration, and support faster, more reliable GMP decisions.

Drawing on real-world implementations, the paper demonstrates how digital batch release dashboards can dramatically reduce manual workload – cutting daily release management from hours to minutes – and deliver measurable improvements in efficiency and visibility. For CDMOs, these platforms also represent a valuable service enhancement, offering clients greater transparency and strengthening collaborative partnerships.

Targeted at site heads, digital leads, quality professionals, and operational executives, this guide provides a roadmap for moving from manual, paper-based processes to a connected, adaptive manufacturing environment, ultimately accelerating time-to-patient.

Key Insights



Operational Efficiency – daily batch release management shrinks from hours to minutes powered by digital platforms.



Competitive Advantage – faster, more reliable GMP decisions with role-based batch status dashboards, updated in real-time.



Enhanced Client Value – CDMOs provide greater transparency for clients enabled by digital batch tracking.

1 WHY ACCELERATING BATCH RELEASE MATTERS

For pharmaceutical leaders, every delay in batch release is more than a scheduling issue, it means patients wait longer, production capacity is tied up, and valuable revenue is left on the table. Speed is only one part of the equation. What truly matters is ensuring data integrity, reducing costly human errors, and gaining real-time visibility across the entire product lifecycle.

Yet in most organizations, the reality looks very different. Critical information is still scattered across MES, LIMS, and spreadsheets – and sometimes even paper. QA, QP and supply chain teams often lack early warning signs of emerging issues, while communication gaps between shifts and departments mean that problems go unnoticed until it's too late. The result: batch release becomes reactive, slow, and high-risk – rather than proactive, streamlined, and reliable.

This is not just an operational inconvenience; it's a compliance and business risk. Manual reviews and fragmented data increase the likelihood of errors, deviations, and even product recalls. The cost of inefficiency is measured not only in wasted hours, but in regulatory exposure, reputational damage, and delayed time-to-patient. At the same time, compliance and risk management costs continue to rise as teams spend countless hours on repetitive, manual tasks instead of value-adding activities.

A batch release dashboard addresses these challenges by delivering targeted benefits across key roles. **QA and QPs** gain real-time visibility to make faster, more confident release decisions. **Production teams** can identify and resolve issues earlier, improving coordination and throughput. **IT and digital leads** benefit from reduced system fragmentation and manual integration work. **Regulatory** and **supply chain** stakeholders gain better traceability and audit readiness. **CDMOs and sponsors** benefit from secure, role-based access to batch status information data.

A modern approach to access batch status information and batch release is urgently needed. By automating and simplifying time-consuming processes – from data aggregation to review and traceability – organizations can significantly reduce compliance and risk management costs. At the same time, automation helps minimize human error and lowers the risk of product recalls or non-conformance. With greater visibility and automation, organizations gain the confidence to make faster, more reliable GMP release and market-ship decisions.



Barriers to Efficient Batch Release

Due to the reliance on multiple, often disconnected information sources, real-time monitoring of the batch status during production presents several challenges. The following **pain points** highlight the **key complexities** involved:



Excel and Paper-Based Legacy Systems & Manual Processes: Despite advancements in the adoption of digital platforms, a significant portion of pharmaceutical companies still rely heavily on Excel and paper records and manual data entry, review, and approval processes. This leads to:

- **High Risk of Human Error:** Manual entry, transcription, review, and reconciliation of data across disparate systems are prone to errors, deviations, and rework.
- **Inefficiency and Delays:** The sheer volume of documentation, multiple hand-offs, and sequential reviews can extend batch release cycle times from days to weeks or even months, impacting time-to-patient.
- **Limited Data Accessibility and Analysis:** Records spread across systems, Excel and paper make it difficult to aggregate, analyze, and leverage data for process improvement, root cause analysis, and proactive quality management.
- **Audit Preparedness Burden:** Preparing for regulatory audits becomes a laborious, time-consuming process involving physical retrieval and review of extensive paper documentation.





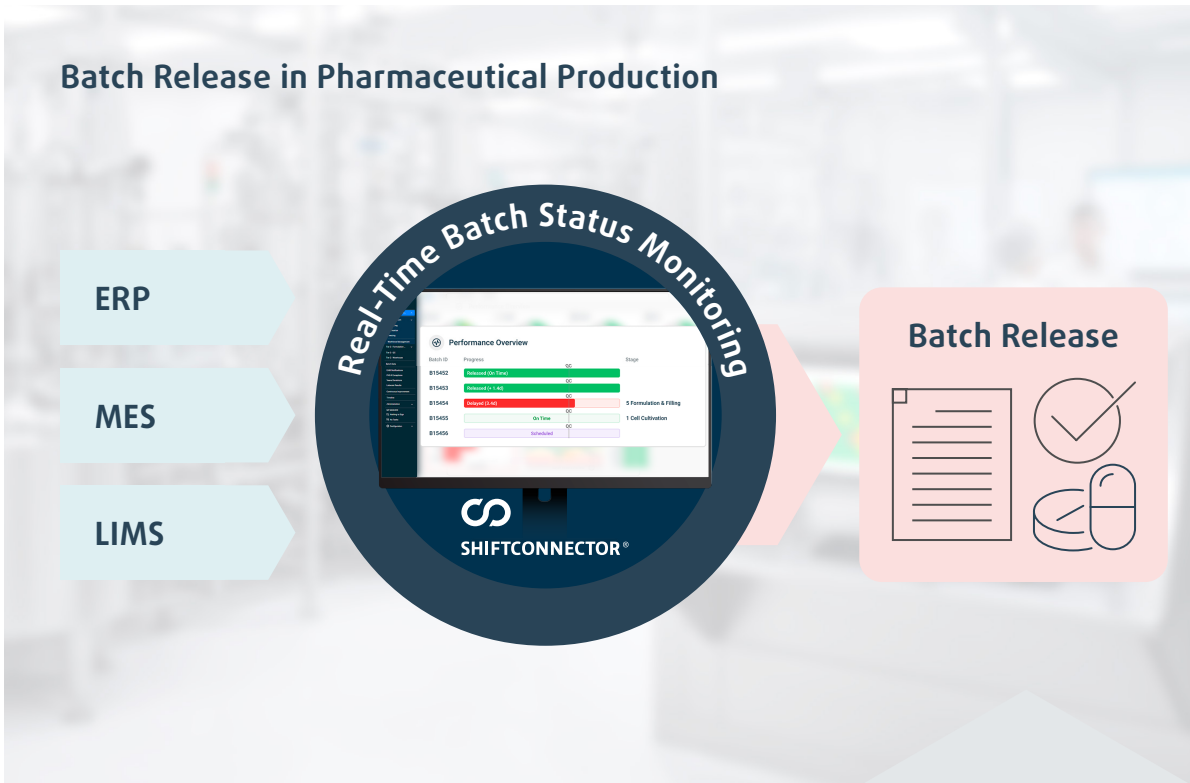
Siloed Systems and Disconnected Data: Even in organizations that have adopted some digital tools (e.g., LIMS, MES, QMS, ERP), these systems often operate in silos with limited interoperability. This fragmentation results in:

- **Lack of End-to-End Visibility:** QA often lacks a holistic, real-time view of all critical parameters from raw material receipt through manufacturing and finished product testing.
- **Data Integrity Concerns:** Reconciling data across disconnected systems introduces data integrity risks and requires manual verification steps.
- **Complex Deviations and Investigations:** Tracing deviations and conducting root cause analyses becomes arduous when data is spread across multiple platforms, increasing the time and resources needed for resolution.
- **Regulatory Complexity and Compliance Concerns:** The pharmaceutical industry operates under stringent and evolving regulatory frameworks, such as EU GMP Guidelines, including Annex 1 (Manufacture of Sterile Medicinal Products), Annex 11 (Computerized Systems) and Annex 16 (Certification by a Qualified Person and Batch Release). This regulatory environment fosters a cautious approach to process changes, particularly when introducing new digital tools. Organizations often hesitate to adopt such technologies due to concerns about potential non-compliance or data security risks. This leads to several challenges:
 - ⇒ **Change Resistance:** Employees familiar with established paper-based workflows may resist transitioning to digital systems, citing concerns over complexity, increased oversight, or potential impacts on job roles.
 - ⇒ **Validation Burden:** Deploying and validating new digital solutions to meet regulatory standards is often a resource-intensive and time-consuming process, requiring significant effort across quality, IT, and operational teams.
- **Talent Shortages and Digital Competency Gaps:** The pharmaceutical industry, like many others, faces challenges in attracting and retaining talent with strong digital and data science skills. This can hinder the effective implementation and utilization of advanced digital tools.



Hidden Costs: These challenges result in substantial hidden production costs. Additionally, teams spend excessive time in meetings and cross-functional reviews to resolve discrepancies and track down missing information, further slowing down time-to-patient and inflating operational overhead. These hidden costs accumulate, undermining both productivity and profitability.

2 UNDERSTANDING THE BATCH RELEASE PROCESS, THE DATA, AND THE COMPLEXITY




In pharmaceutical and biopharmaceutical manufacturing, batch release is a crucial process that ensures only products meeting predefined quality, safety, and regulatory standards reach patients. It is the final gatekeeper before a product enters the market, and its integrity is essential for patient safety, regulatory compliance, and public trust.

What is Batch Release?

Batch release refers to the formal decision to release a specific batch of a pharmaceutical product for distribution or sale. This decision is made only after verifying that the batch has been manufactured and tested in accordance with:

- ➔ **Good Manufacturing Practices (GMP)**
- ➔ **Marketing Authorization (MA)**
- ➔ **Internal quality specifications**
- ➔ **Regulatory requirements (e.g. EMA, FDA, WHO)**

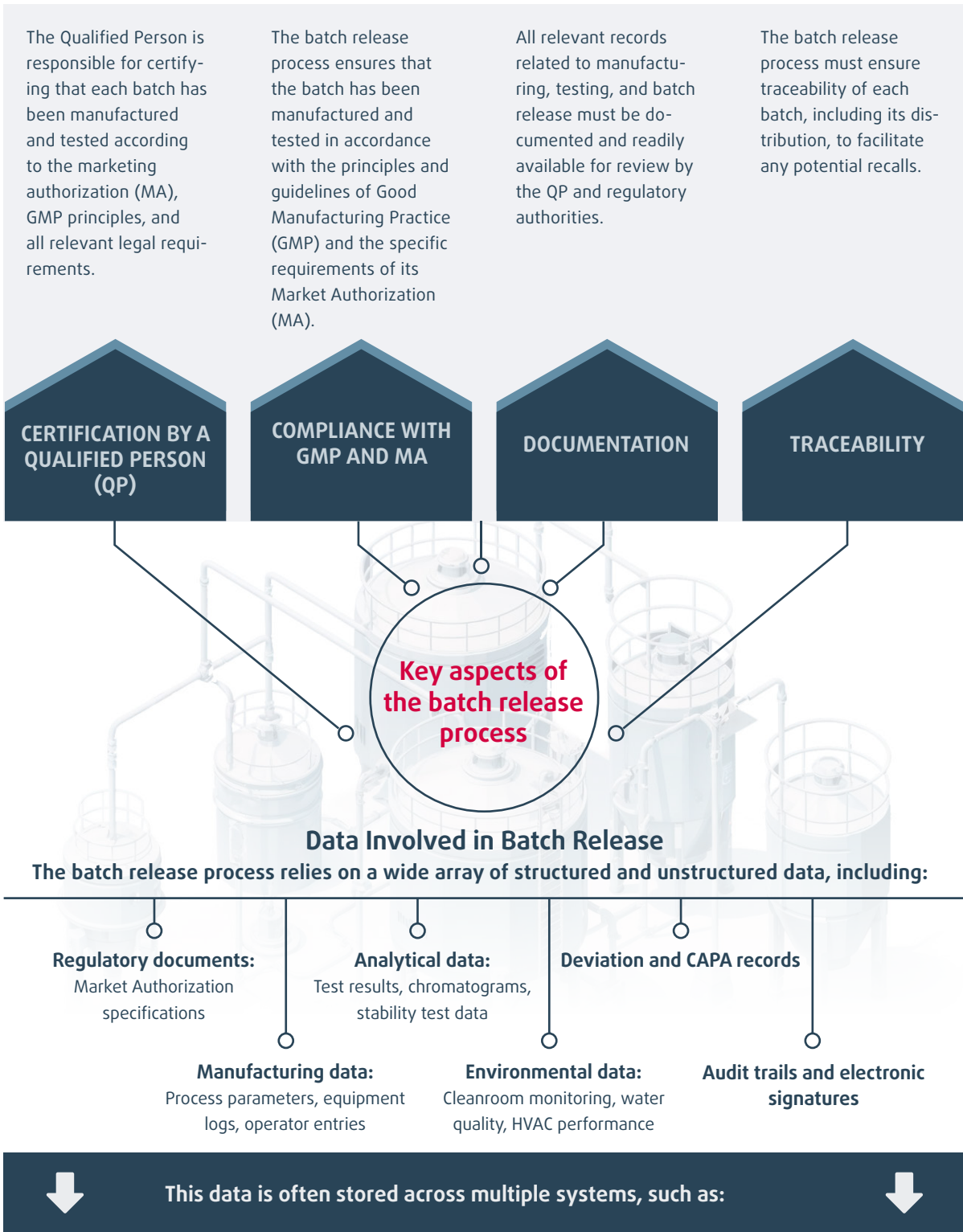


The release is typically authorized by a Qualified Person (QP) in Europe or a Responsible Person (RP) in other jurisdictions, who certifies that all necessary checks and documentation are complete and compliant.

In Europe the Good Manufacturing Practice (GMP) Guidelines, specifically Annex 16 (Certification by a Qualified Person and Batch Release) provide the regulatory background and guidance on the batch release process, including cases where a batch has had different stages of production or testing conducted at different locations or by different manufacturers, for example CDMOs.

The batch release process is not a single event but a complex orchestration of interdependent activities involving multiple stakeholders, systems, and data streams. Traditionally manual and paper-based, this process is undergoing a digital transformation to meet the demands of modern supply chains and regulatory scrutiny.





- ERP (Enterprise Resource Planning)
- MES (Manufacturing Execution Systems)
- LIMS (Laboratory Information Management Systems)
- Document Management Systems (DMS)
- Quality Management Systems (QMS)
- underlying automation systems

Data fragmentation across systems and departments is considered as the biggest challenge within the batch release process. This results in lack of real-time visibility of the batch status during the manufacturing process and avoidable delays for the release of the batch.






Key Actors and Organizations Involved

The batch release process involves collaboration across several internal and external stakeholders:



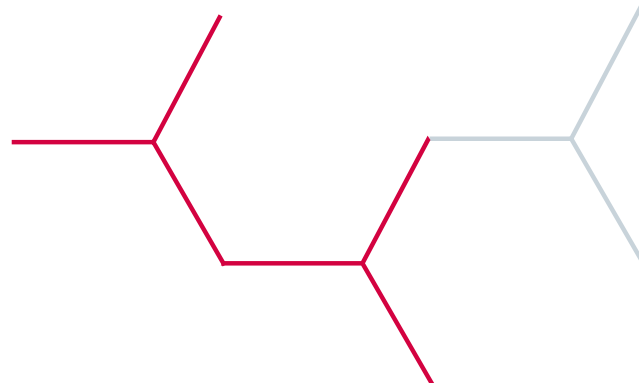
To address the complexity of the batch release process, many pharmaceutical companies are investing in digital batch tracking & release platforms that integrate the relevant data and automate the batch release workflow.

Key enablers for a digital batch release are:

-  **Electronic Batch Records (EBRs):** Replace paper with real-time, validated digital records.
-  **Automated Data Capture:** From equipment, sensors, and lab instruments.
-  **Integrated Quality Systems:** Seamless flow of data between MES, LIMS, QMS, and ERP.
-  **AI and Analytics:** Predict deviations, optimize release timelines, and ensure data integrity.
-  **Digital Batch Status Dashboards:** Provide a consolidated view of batch status and readiness in real time.

Given the scale and complexity of the batch release process, especially the volume and fragmentation of data, it is no longer feasible to manage it sustainably using conventional tools such as Excel or PowerBI. These tools lack the integration, real-time visibility, and workflow orchestration capabilities required for a compliant and efficient release process.

A **dedicated batch tracking and release platform** addresses these limitations by serving as a centralized system of engagement for all stakeholders, providing a **single source of truth** for the batch status. It **aggregates and visualizes critical data** across systems, **supports real-time monitoring** of batch status, and enables **faster, more reliable decision-making**. Ultimately, such a platform enhances operational efficiency, ensures regulatory compliance, and supports the timely delivery of high-quality medicines to patients.



3 REAL-TIME RELEASE AS A FOUNDATION OF THE ADAPTIVE PLANT

The **Digital Plant Maturity Model (DPMM) Level 5 (Adaptive Plant)** represents the journey to the pharma smart factory or factory of the future. The Adaptive Plant is characterized by autonomous processes, self-optimizing, and plug-and-play functionality. At this level, the plant operates as a fully integrated, self-optimizing system capable of adapting in near real time to both internal and external factors. One of the most critical enablers of DPMM level 5 is a digitally orchestrated batch tracking and release solution.



Real-Time Visibility and Decision-Making

To operate adaptively, an organization must shift from static, retrospective decision-making to dynamic, real-time insights and actions. Digital batch release platforms provide this capability by:

- Aggregating structured and unstructured data across systems (e.g., MES, LIMS, QMS, ERP).
- Continuously updating release status dashboards in real-time.
- Generating alerts when deviations, delays, or data gaps threaten release timelines.

The real-time visibility into batch readiness allows internal and external release stakeholders to anticipate issues and resolve them without waiting for full batch closure.





Human-in-the-Loop Adaptability

While automation and AI play growing roles at DPMM Level 5, the human-in-the-loop paradigm remains essential, particularly in regulated batch release decisions. Batch tracking and release platforms enable contextualized human input, foster collaboration between Operations and Quality, and retain full traceability for compliance and continuous improvement. This interplay of human judgment and digital augmentation is a significant characteristic of adaptive capability.



Cross-Functional Alignment through Role-Based Dashboards

Adaptive plants require all actors to operate in full synchrony. Role-based dashboards and structured data visualization ensure that:

- All functions view the same data but with context relevant to their responsibilities.
- Workflows are aligned around batch status, not siloed by system or function.
- Team members can act in a coordinated, proactive manner.

This supports the “right information to the right people at the right time” principle that underpins both 360° connectivity and adaptive manufacturing.



Closed-Loop Feedback and Continuous Improvement

At DPMM Level 5, the plant doesn’t just execute processes, it learns from them continuously. A digital batch tracking solution captures release bottlenecks, deviation trends, and cycle time data across hundreds of batches, feeding improvement initiatives and predictive, AI supported analytics. Over time, this builds a feedback-rich environment that evolves toward optimal performance and regulatory resilience.



Scalability and Responsiveness in Complex Modalities

Batch tracking solutions are essential for managing the complexity of modern production modalities, from personalized cancer vaccines with batch sizes of one, to multi-batch fill-and-finish operations across global sites. At the Adaptive Plant level, flexibility and responsiveness are as important as efficiency. A well-architected batch release solution offers:

- Configurable workflows
- Modular integration across global sites
- Adaptability to new regulatory requirements and production models

Reaching DPMM Level 5 is not possible without a **robust digital foundation for batch tracking and release**. A batch tracking and release platform doesn’t just accelerate release, it integrates the intelligence, agility, and connectivity needed to run an adaptive pharmaceutical plant. It accelerates the batch release process, resulting in **faster time-to-market** and **quicker availability of life-saving medicines**.

In this context, batch release is no longer a bottleneck, it becomes a **strategic capability**.

4 THE DIGITAL ECOSYSTEM ENABLING BATCH TRACKING AND RELEASE

As elaborated above, structured and unstructured data from various sources within your digital manufacturing systems landscape are required to track the batch status in real-time and accelerate the batch release process. Data such as manufacturing process parameters, quality test results, deviation records, and other critical information are managed and stored across various production systems, including ERP, MES, LIMS, QMS, and others.

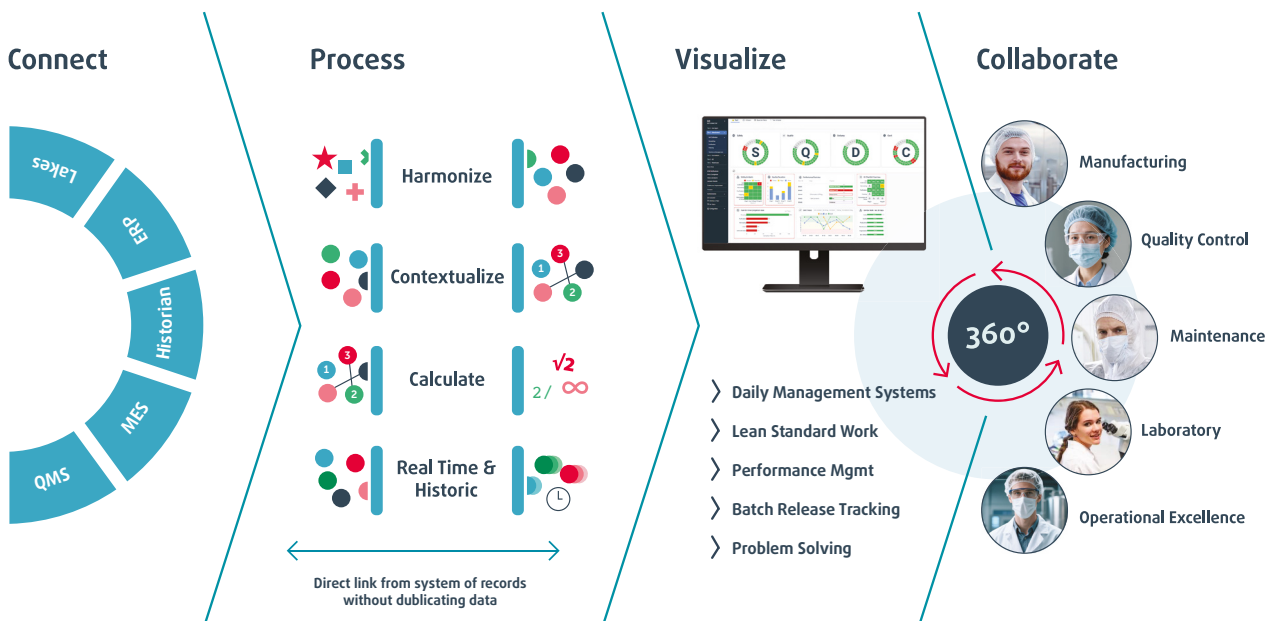
Why Excel is not the Best Solution

While tools like MS Excel are often used to aggregate data from ERP, MES, QMS, and LIMS systems into dashboards, this approach comes with significant drawbacks. Excel requires manual data entry or complex integrations, both of which are time-consuming and error-prone. These manual processes introduce hidden costs through increased risk of human error, delayed insights, and the need for frequent cross-functional meetings to resolve discrepancies. Moreover, Excel lacks real-time data synchronization, meaning dashboards are often outdated by the time they're reviewed—hindering timely decision-making and slowing down batch release.

In contrast, integrated solutions like Shiftconnector provide a centralized, real-time view of batch status by seamlessly connecting to existing systems. This reduces manual effort, improves data accuracy, and enables proactive decision-making, ultimately accelerating time-to-patient while ensuring compliance and operational efficiency.

Systems of Records and System of Engagement

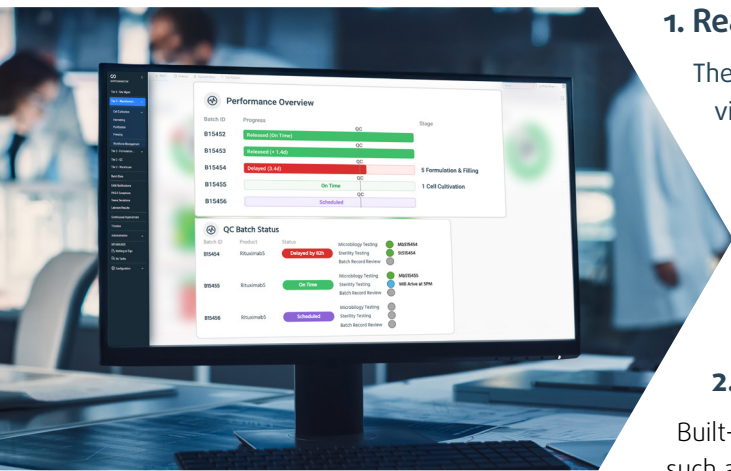
The source systems will continue to serve as the systems of record for all manufacturing and quality data. However, **the batch tracker platform will act as the system of engagement for both internal and external stakeholders**, supporting all activities related to real-time batch status monitoring and batch release.



5 FROM DELAY TO DECISION: THE BATCH TRACKER PLATFORM

A next-generation batch tracking and release platform is designed to address the complexity, data fragmentation, and cross-functional collaboration that define pharmaceutical manufacturing today. By replacing manual tracking tools like Excel with a centralized, automated, and GMP-compliant system, such a solution enables real-time visibility, faster decision-making, and continuous improvement in batch release operations.

Core Features of the Solution

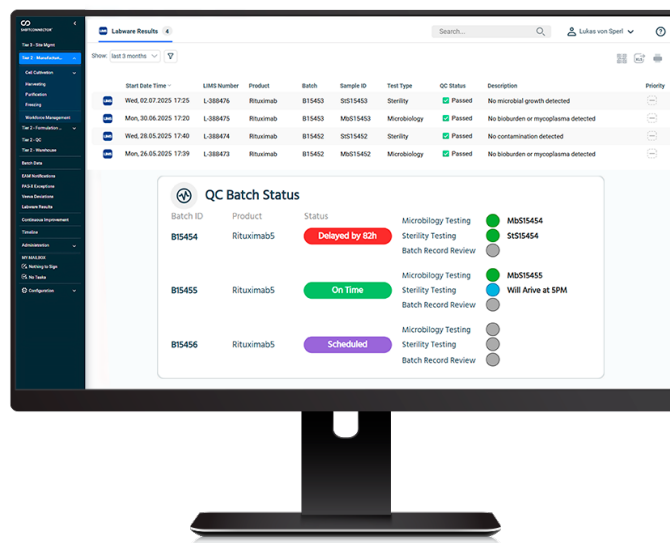


1. Real-Time Batch Status Dashboards

The solution provides live, role-specific dashboards that visualize the progress of each batch across manufacturing, quality control, and quality management operations. This enables users, from shift leaders to plant managers and external stakeholders, to see exactly what the current status of the batch is and where delays occur, enabling to take timely and informed actions.

2. Automated Data Integration

Built-in connectors allow seamless integration with systems such as MES, LIMS, ERP, QMS and others. Batch data is updated automatically from source systems, eliminating the need for manual consolidation and ensuring that all stakeholders work with consistent and up-to-date information.



3. Manufacturer-Agnostic Architecture

The platform is designed to work across different IT landscapes and is compatible with widely used systems such as SAP, Veeva, most MES and LIMS solutions, historians and others, enabling smooth adoption across global networks, including legacy infrastructure, and contract partners.

4. Retrospective Analytics and Continuous Improvement

In addition to real-time tracking, the solution supports retrospective analysis of batch data. Users can drill down into data identify recurring delays, understand root causes, benchmark performance, and define golden batch profiles, turning production data into a driver for operational excellence.

5. Support for Internal and External Collaboration

The system provides tailored access for internal users (e.g., production, quality, regulatory) and external partners such as CDMOs and sponsors, facilitating transparent, fact-based collaboration and reducing the need for back-and-forth communication.



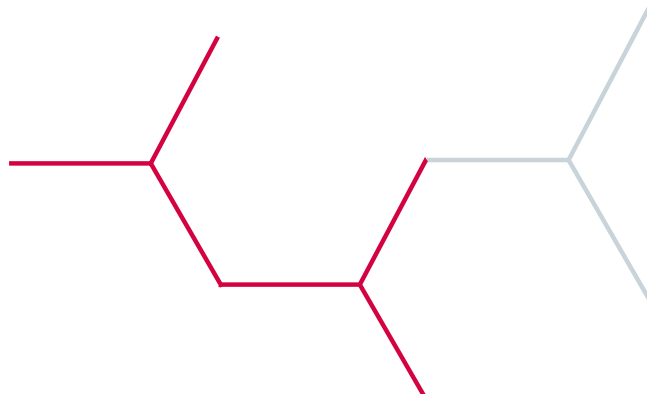
Rapid Implementation and Scalability

With a modular setup, the solution can be deployed quickly, even without full system integration in the initial phase. Teams can begin with milestone tracking and scale up to full automation and advanced analytics as readiness increases. Real-world deployments have shown implementation times in weeks rather than months, even under challenging conditions.

A solution with these features becomes more than just a batch tracking dashboard, it becomes a strategic tool for managing the batch release process efficiently, compliantly, and proactively. It empowers pharmaceutical manufacturers to accelerate time to market, reduce risk, and improve overall performance across their production network.

Validated and GMP-Compliant Platform

The system operates in full compliance with GxP requirements, offering audit trails, access controls, and electronic signature support. Its GAMP 5 validation-ready design ensures it meets regulatory expectations across global markets.



6 THE VALUE FOR CDMOS AND CUSTOMERS

As pharmaceutical companies increasingly rely on external manufacturing partners, the complexity of managing multiple CDMO relationships has grown substantially. Traditional, pre-digital processes - often centered around spreadsheets and manual coordination - struggle to keep pace with the demands of modern supply chains. This is where a Batch Release Dashboard becomes a strategic asset.

By integrating real-time data from ERP, MES, LIMS, and QMS systems, CDMOs can offer their clients a transparent, centralized view of batch status without exposing internal records. Each customer sees only their relevant data, enabling tailored visibility and secure collaboration. This not only improves trust and communication but also enhances supply chain coordination, helping sponsors plan more effectively and respond faster to market needs.

For CDMOs, the dashboard is more than a tool, it's a value-added service that can be monetized. Offering real-time batch tracking as a premium feature strengthens the CDMO's portfolio and differentiates them in a competitive market. It also supports internal efficiency: transitioning from Excel to a dedicated dashboard reduces daily batch release management from several hours to just minutes, enabling scalability and agility.

A digital dashboard transforms batch release into a collaborative process, benefiting both CDMOs and their customers.



7 CONCLUSION: A STRATEGIC IMPERATIVE

For pharmaceutical companies, embracing digital transformation in batch release is no longer a luxury but a strategic imperative. It's about moving beyond simply meeting compliance to driving true operational excellence. By investing in integrated digital solutions, the industry can significantly:

- > **Accelerate time-to-patient:** Faster batch release means quicker availability of life-saving medicines.
- > **Gain full transparency at a glance:** A centralized batch tracker provides a single source of truth, allowing users to easily access all relevant data without navigating multiple systems.
- > **Improve efficiency and reduce costs:** Streamline workflows, minimize rework, and optimize resource utilization.
- > **Strengthen product safety:** By ensuring higher quality products reach the market faster and with greater assurance.

The journey to a fully digitized batch release process is complex, but the path forward is clear: a phased approach starting with digital maturity assessments, strategic investment in integrated platforms, robust change management, and continuous upskilling of the workforce. The Qualified Persons, are at the forefront of this transformation, tasked with ensuring that quality remains paramount in this evolving digital landscape.





FROM MANUAL TO REAL-TIME: THE PATH FORWARD

Accelerating batch release is not a single initiative. It is a long-term commitment toward data contextualization, human-centric digital tools, and collaborative culture.

Eschbach's Shiftconnector Suite is built to guide pharma and biopharma operations through this transition, step-by-step, from paper to dashboards, from silos to connectivity, from reactive to proactive.

Take Action: Transform Your Batch Release Today

The tools, insights, and platforms to accelerate batch release are no longer aspirational. They are available, proven, and ready to deploy. What remains is a decisive step forward.

If you're a Site Head, Digital Lead, Quality Executive, or CDMO Partner, the opportunity to lead this transformation is in your hands. By embracing a real-time, digital batch release strategy, you're not just improving operations, you're accelerating time-to-patient and future-proofing your manufacturing network.

Why Act Now?

- Every day of delay costs time, money, and patient access.
- Manual processes are no longer sustainable in a world of complex modalities and global supply chains.
- Digital batch tracking is not a trend – it is a strategic capability that differentiates leaders from laggards.

Your Next Steps

1. Assess your current batch release maturity: Identify bottlenecks, manual dependencies, and data fragmentation.
2. Build your adaptive plant roadmap: Leverage dashboards, analytics, and collaboration tools to move toward DPMM Level 5.
3. Partner with experts: Let eschbach guide your journey with proven, GMP-compliant platforms, and deep industry expertise.
4. Start small, scale fast: Pilot Shiftconnector at one site to demonstrate measurable impact.

Discover how Shiftconnector's Batch Tracker empowers your teams with real-time visibility, automated data integration, contextualization, and collaborative batch release workflows. See how you can cut daily release management effort from hours to minutes.



Visit eschbach.com now and take the first step toward faster, smarter, and safer batch release.

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About eschbach

eschbach, headquartered in Bad Säckingen, Southern Germany, with a subsidiary in Boston, USA, develops intelligent operations platform software solutions. Shiftconnector® provides a new level of team communication to ensure safety and improve plant effectiveness. The award-winning solution is trusted worldwide by leading manufacturing companies such as Bayer, DuPont, BASF and Roche. For more information visit www.eschbach.com.

We inspire industrial teams to work smarter.