acodis

Automation of Batch Record Review for a Leading CDMO Company

Enhancing Accuracy, Compliance, and Efficiency with Intelligent Automation

Task

- Automated data capture
- Review-by-exception workflows
- Compliance and auditability

Scope

- Thousands of batch records with millions of data points across production, quality and compliance

Key Benefits

- Average batch review time reduced by 60%
- Quality and production teams freed from repetitive manual checks
- Access and transparency to data for analytics and yield optimisation

The Challenge

The client, a global CDMO, faced significant challenges in batch record review across its network of production sites. With more than 10'000 batches annually, each requiring extensive manual reviews, the company struggled with:

- **Lengthy release times:** Batch review often took 7-10 days.
- **Significant error rates:** Manual entries introduced compliance risks and unnecessary investigations
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- **Resource burden:** Hundreds of staff hours spent preparing, checking, and archiving paper records.
- **Delayed Batch Releases:** Lengthy review cycles can slow down batch releases, impacting production timelines and supply chain efficiencies.
- **Regulatory pressure:** Increasing scrutiny on data integrity and traceability.

> “Automated review of batch records enables our experts to focus on what matters while keeping our high level of quality and compliance. Onboarding was fast and seamless, which helped in driving adoption from out QA teams.”
> Director, Quality and Compliance

Solution

Executives recognized that inefficiencies in batch record review delayed product release, tied up working capital, and ultimately limited the company's ability to scale production in line with market demand.

- Implement tailored machine learning models: Developed based on the company's available set of historical batch records, enabling intelligent recognition of data patterns and streamlining review.
- Embed validation rules and business logic: Automated checks ensured regulatory compliance and consistency, while reducing manual verification effort.
- Review by exception with user-friendly application: Quality teams shifted from reviewing every entry to focusing only on deviations, with a simple, intuitive interface supporting adoption.
- Validation & change management: A cross-functional team ensured regulatory compliance and trained users to adopt the new way of working.

Acodis solution is easy-to-use and unlocks data to use for analytics process optimization while ensuring our high compliance and security standards.

Outcome

Impact: 60% faster review time, faster cycles and structured data to analyse trends

Within the first year of implementation, the time from batch completion to product release could be reduced by several days across multiple facilities. This acceleration not only improved efficiency, but also strengthened supply reliability and compliance

READY TO IMPLEMENT SMART AUTOMATION ? GET IN TOUCH !

Acodis enables pharma and biotech manufacturers to accelerate digital transformation by automating batch record review and ensuring compliance. Our solutions help clients improve efficiency, reduce risk, and deliver life-saving products to market faster.