TECH OFFER

AI-Powered GMP Documentation Compliance Platform & Smart Data Analytics

KEY INFORMATION

TECHNOLOGY CATEGORY:
Manufacturing - Assembly, Automation & Robotics
Infocomm - Data Processing

TECHNOLOGY READINESS LEVEL (TRL): TRL6
COUNTRY: UNITED KINGDOM
ID NUMBER: TO175504

OVERVIEW

Manufacturing organisations operating under GMP regulations face significant delays and compliance risks due to manual or semi-manual documentation review processes. Batch records, whether paper-based or electronic, require extensive checking for calculation errors, missing entries, transcription mistakes, and regulatory non-compliance. These processes are time-consuming, error-prone, and resource-intensive.

This technology provides a controlled and structured automated documentation review and data verification platform designed to quality check batch records against ALCOA+ principles and GMP requirements. It detects calculation discrepancies, missing data, data limit breaches, transcription errors, time/date inconsistencies, and compliance gaps within a second per page or less. The system works with both paper-based and electronic batch records and produces structured, audit-ready outputs to aid manufacturing teams giving them time back to make more product and it supports QA and QP oversight.

Potential collaborators are pharmaceutical, biotech, cell and gene therapy, and other GMP-regulated manufacturers (cosmetics,

FMCG, medtech / device etc) seeking to accelerate batch release, reduce deviations, and improve compliance reliability. The technology addresses a critical market need by reducing review time from days or weeks to minutes, strengthening regulatory compliance, and enabling advanced data trending for continuous process improvement.

TECHNOLOGY FEATURES & SPECIFICATIONS

The technology consists of:

- ALCOA+ handwriting recognition engine (for paper-based records)
- Document format detection and template intelligence
- Calculation detection and cross-page verification module
- Data limits detection and verification
- Missing entry detection
- Transcription verification across sections and documents
- Time and date validation with duration calculations
- Signature and initials verification
- Damaged, missing page, and documentation stream detection
- Structured QA/QP audit-ready reporting engine
- Optional advanced data extraction, trending, and correlation module
- API integration layer for DMS, EBR, ERP, EQMS, and LIMS systems
- Secure cloud or hybrid deployment architecture with encryption and role-based access controls

The platform processes scanned documents (recommended 600dpi) or electronic batch records, applies configurable logic aligned to company SOPs, and generates deterministic compliance reports. It supports hybrid environments transitioning from paper to full electronic systems.

POTENTIAL APPLICATIONS

This technology can be deployed across GMP-regulated industries including:

- Pharmaceutical manufacturing
- Biologics and vaccine production
- Cell and gene therapy manufacturing
- Contract manufacturing organisations (CMOs)
- Nutraceutical and regulated healthcare manufacturing
- Pharmaceutical distribution

Products and solutions enabled by this technology include:

- Automated batch record review systems
- GMP documentation compliance platforms
- QA/QP review acceleration tools
- Data integrity monitoring systems
- Manufacturing analytics and trending dashboards
- Hybrid paper-to-digital transition support tools

It can be embedded within existing quality systems to enhance structured review, deviation reduction, audit readiness, and operational excellence initiatives. The technology can also be adopted by other industries that requires reviewing documentation against any set parameters as a quality check e.g. cosmetics, FMCG, aerospace, or use cases outside of manufacturing e.g. distributors in supply chains for reviewal of Certification of Analysis (COAs).

MARKET TRENDS & OPPORTUNITIES

Global pharmaceutical and biologics manufacturing continues to grow, driven by advanced therapies, stricter regulatory enforcement, and increasing data integrity requirements. Regulatory bodies are placing greater emphasis on ALCOA+ principles, data traceability, and inspection readiness. Simultaneously, manufacturers face pressure to reduce operational expenditure while increasing throughput. Manual documentation review remains a bottleneck even in facilities using electronic batch record systems, as many platforms capture data but do not deterministically validate compliance. The market opportunity lies in augmenting existing systems with automated verification and analytics. Independent industry research indicates that digitised, compliant workflows can reduce operational expenditure by up to 30% and increase yield by approximately 10%.

UNIQUE VALUE PROPOSITION

This technology significantly improves upon the current state-of-the-art by introducing automated, deterministic quality checks into documentation workflows that are traditionally manual or semi-manual. It is comparatively easier to implement than a full-fledged Electronic Batch Record System (EBMR), as the document control and data analytics components can be integrated with existing entry processes.

Key value propositions include:

- Reduction in batch review time from days/weeks to minutes, with past use case of up to 99% productivity gains (4000h to 3h of documentation review)
- Hybrid paper–electronic compatibility, enabling digital control while preserving professional judgement and human oversight; this reduces human error and deviation rates without displacing QA/QP accountability.
- Audit-ready, fully traceable outputs aligned with Annex 11, 21 CFR Part 11, and GAMP 5, strengthening data integrity and ALCOA+ compliance.
- Structured and traceable QA/QP review outputs with cross-batch data correlation and optional advanced trending capabilities to support process optimisation.
- Lower compliance risk during regulatory inspections through built-in controls, traceability, and validated system logic.