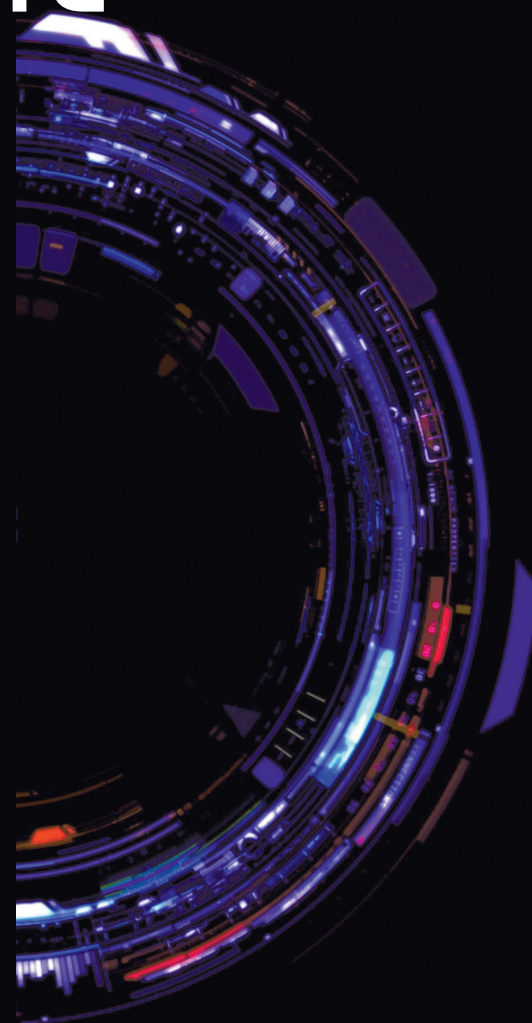


2025

OpenLine LineClearance Assistant™

AI-Powered Line Clearance
- Fast. Compliant. Reliable



 catalyx

OpenLine LineClearance Assistant™

AI-Powered Line Clearance

The OpenLine LineClearance Assistant™ leverages advanced AI and machine vision to automate line clearance manufacturing with zero human error. Instantly detect rogue components, verify clear lines within milliseconds, and maintain uninterrupted production flow. Reduce risk, enhance efficiency, and eliminate manual errors with a solution designed for modern manufacturing environments.

Digital Compliance

Built for GMP environments, LineClearance Assistant™ ensures line clearance manufacturing is compliant with regulations such as 21 CFR Part 11 and EU Annex 11. It maintains a secure repository of evidence for every inspection, providing audit readiness and complete traceability of operator activities. OpenLine is engineered with transparency, accountability, and trust built into its AI. LineClearance Assistant™ aligns with the EU AI Act, ensuring safe, ethical, and explainable AI adoption in regulated manufacturing.

Why LineClearance Assistant™

Minimise Downtime, Maximise Operational Efficiency

LineClearance Assistant significantly reduces changeover times with inspections completed in milliseconds. Keeps production and packaging lines moving and improving Overall Equipment Effectiveness (OEE).

Validation-Ready AI Compliance

Every model update generates a complete Training Evidence Report. Built-in explainability and traceability align with GMP, 21 CFR Part 11, and EU AI Act requirements—ensuring audits are passed with confidence.

Human Oversight, Automated Intelligence

Self-Healing AI continuously improves inspection accuracy in real time, while operators retain full control of recipe approvals. The perfect balance of automation and regulatory governance.



Self-Healing Intelligence

Beyond detection, LineClearance Assistant™ introduces validatable self-healing capabilities that make inspections smarter, compliant, and production-ready.

Automatically retrains when errors occur:

When a false positive or false negative is detected, the inspected image(s) are instantly added to the training and/or testing sets. The model is automatically retrained using the best previously validated hyperparameters—no operator input required.

Built-in validation and safeguards:

Each retraining cycle produces a complete Training Evidence Report, supporting explainability and compliance requirements (GMP, 21 CFR Part 11, EU AI Act). Only if the new model meets or exceeds the performance of the prior version is it eligible for deployment.

Human-in-the-loop control:

Even after successful retraining, the updated model is not activated automatically. Operators must manually approve the new recipe version, ensuring production line clearance remains under human oversight.

With self-healing intelligence, manufacturers benefit from:

- Reduced downtime from false stops and manual retraining
- Audit-ready transparency through automatically generated evidence reports
- Improved accuracy with every inspection, reducing false positives and negatives
- Compliance by design with human approval before use in production

This is a step toward autonomous yet fully governed line clearance—future-ready, intelligent, and regulator-compliant.

Proven Business Impact

85%

Faster Line Clearance

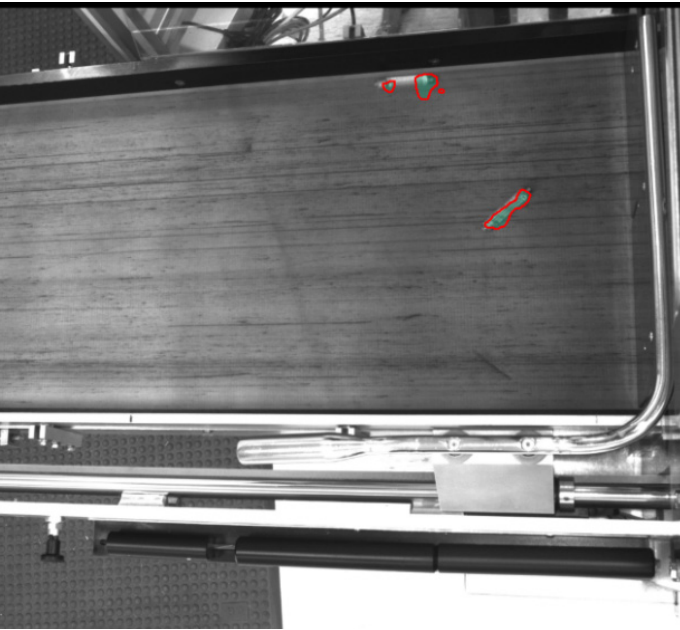
20%

Boost in Capacity

ROI in as little as

3 Months

Minimize downtime and speed up product changeovers. Increase output without increasing overhead. Fully GMP-integrated with payback in just 3 months.



Effortless Integration and Future Readiness

LineClearance Assistant™ is designed to fit seamlessly into modern pharmaceutical and medical device environments. With a fully documented OpenAPI HTTP REST API and OPC/UA connectivity, it can integrate directly with existing production line systems including Programmable Logic Controllers (PLC), Electronic Batch Records (eBR), Manufacturing Execution Systems (MES), and Enterprise Resource Planning (ERP) platforms.

This deep interoperability means inspections are no longer isolated — they become part of a connected digital ecosystem that supports GMP compliance, data integrity, and real-time decision-making, maximizing line investment and enabling true Factory of the Future operations.

The Hidden Cost of Manual Line Clearance

We surveyed a group of life sciences manufacturing professionals as part of the 2025 Life Sciences Global Line Clearance Benchmark Report. The results are clear: manual clearance is still slowing teams down and driving unnecessary risk.

- **70%** of sites reported at least one clearance failure in the past year
- **20%** experienced six or more failures annually, with some reporting more than 10 failures
- **68%** of complex clearances take over 2 hours, and **37%** exceed 4 hours
- Most lines require **2–4 personnel** for every clearance, adding cost and variability

Line Clearance Award-Winning Innovation

Trusted by top-tier companies and honored by leading organizations, it sets the standard for innovation and impact.

Pack Expo 2023 – Innovation of the Year (Healthcare & Pharma)

Bionow Awards 2022 – Product of the Year

PPMA Awards 2022 – Vision Solution of the Year





Why Catalyx?

Because we don't just design inspection systems, we validate, deploy, and support them across the globe.

Because we partner with the world's most trusted life sciences manufacturing, and deliver proven results year after year.

Because we unite global reach with local presence, our expert teams are embedded throughout North America and Europe, always close to your operations.

Because we bring 30 years of machine vision expertise, pioneering inspection systems purpose-built for regulated life sciences manufacturing.

Let's power your next phase of operational excellence, together.

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