2025 Life Sciences Line Clearance Benchmark Report

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Foreword

Based on a survey of more than 20,000 Life Sciences professionals conducted in Summer 2025, our latest Benchmark Survey highlights the scale of the issue. Most sites still depend on paper based or hybrid methods, most changeovers take between 30 minutes and 4 hours, and 70 percent of respondents reported at least one clearance failure in the past year. These figures mirror the 2022 benchmark, where 70% of sites also reported failures and 20% faced ten or more in a year. Despite early signs of technology exploration in 2023—44% of sites piloting camera vision systems and 16% trialing AR/VR tools—the industry has yet to convert pilot initiatives into broad deployment. The persistence of manual methods reflects what academic studies have also shown: pharmaceutical OEE consistently lags behind other sectors because clearance delays remain deeply embedded in operations.

Yet the findings also point to a turning point. Organizations are beginning to adopt digital inspection tools, explore vision-based systems, and integrate clearance into broader MES and ERP strategies. The path forward is clear: digitization is no longer optional; it is a strategic imperative.

Research confirms this urgency, noting that reliance on human-led inspection undermines Lean and Operational Excellence in pharma and that validation and training demands remain major barriers to adoption.

This benchmark is designed to give leaders a fact-based foundation for action. It offers not only a snapshot of current practices, but also a roadmap to higher compliance, reduced downtime, and stronger operational resilience. The companies that move first will not only reduce risk and cost—they will create a competitive advantage in speed, quality, and trust.

Catalyx first launched its industry-wide Line Clearance Benchmark Survey in 2023 to help quantify this impact and offer life sciences manufacturers an objective reference point to optimize their own practices. Three years later, we're proud to share our latest insights from 2025: the most complete picture yet of where line clearance stands—and where it's headed.

David Taylor
Product Manager and Line Clearance Subject Matter Expert, Catalyx

Introduction

Manual line clearance remains a critical bottleneck in many life sciences facilities. As product volumes increase and SKU diversity expands, the traditional, paper-based approaches to line changeovers continue to put pressure on throughput and compliance.

Now in its second cycle, the 2025 survey represents input from professionals across global pharma, biotech, and CDMO organizations. It offers a snapshot of current practices, identifies key trends, and reveals the gaps still hindering progress.

What's clear: organizations are continuing to feel the strain of manual or semi-manual processes. In 2023, nearly half of respondents reported piloting camera or vision technologies and a further 16% were experimenting with AR/VR tools. Two years on, however, 63% of sites remain fully dependent on paper-based clearance.

This underlines how pilot initiatives have not translated into broad adoption and reflects the wider barriers identified in academic research—particularly the cost of validation and the training burden associated with digital transformation in life sciences.

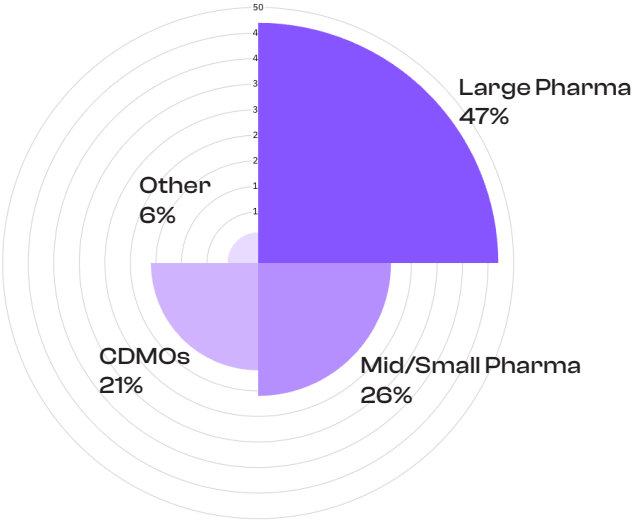
At the same time, the data shows growing interest in digital inspection tools, SOP standardization, and integrated systems that make line clearance faster, safer, and more reliable.

The following report summarizes key findings, from performance metrics and personnel usage to causes of failure and future priorities. It also compares changes since earlier surveys and suggests actions teams can take to improve outcomes.

Survey Findings

1. Industry Representation

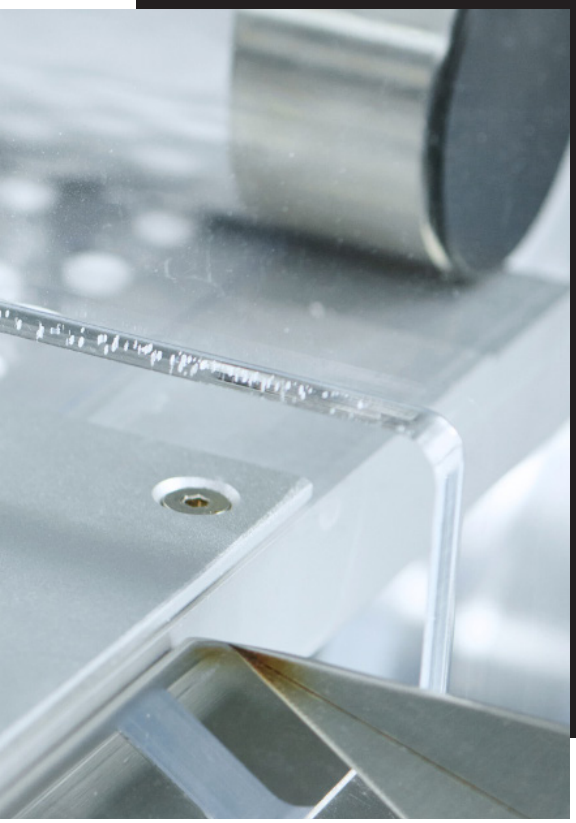
- **100%** of respondents are employed in manufacturing-related roles within life sciences.
- **47%** come from large-cap pharmaceutical companies, **26%** from mid/small-cap pharma, and **21%** from CDMOs.



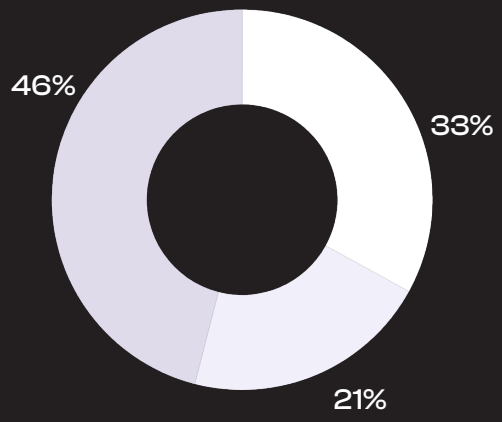
2. Roles and Regions

Respondents primarily represent

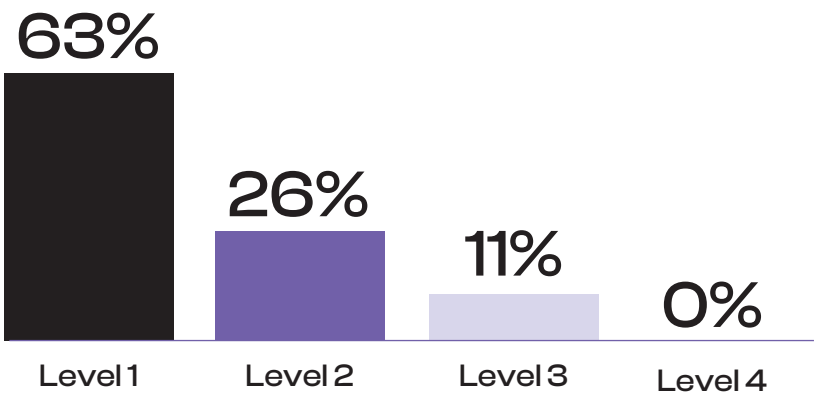
26%	26%	48%
Manufacturing/ Operations	Engineering/ Maintenance	Other Leadership roles



Most operations are based in **North America (21%), Europe (46%)** and **Global (33%).**



3. Process Maturity



Our 2025 survey shows that most organizations remain heavily reliant on manual clearance approaches:

Level 4 – Intelligent & Integrated (0%)
A fully digital, AI-driven system connected to MES, eBR, and QMS. No respondents reported reaching this stage in 2025.

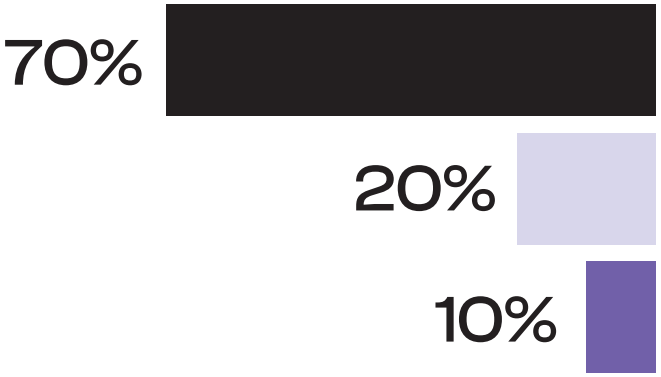
Level 3 – Digital-First (11%)
Key steps digitized through vision systems, electronic checklists, or MES integration. Human involvement continues, but automation drives faster, more consistent outcomes.

Level 2 – Hybrid (26%)
Combines paper with basic digital tools such as spreadsheets or barcode scans. Some efficiency gains, but inspection is still largely manual and data remains fragmented.

Level 1 – Manual (63%)
Paper checklists and human inspection dominate, making the process inconsistent and error-prone.

Compared with 2023, progress has been slower than expected. Two years ago, nearly half of respondents reported exploring vision-based systems and 16% were trialing AR/VR tools. Yet in 2025, most remain at Level 1 or 2, suggesting pilots have not scaled into widespread adoption.

4. Failures and Frequency



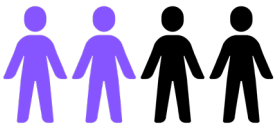
70% of respondents had at **least one clearance failure** in the past 12 months

20% experienced **6 or more failures**

10% reported **more than 10**

This picture is unchanged since 2023, when 70% of respondents also reported clearance failures and 20% experienced ten or more. The persistence of these figures demonstrates the systemic risk posed by manual processes. Human error and inspection inconsistency remain the leading contributors to GMP deviations.

5. Personnel and Duration



2–4 Personnel

Most lines require 2–4 personnel for clearance, with 11% relying on a single person.

These results are nearly unchanged from 2023, when 70% of companies also reported using 2–4 personnel and 26% relied on five or more. Although workforce distribution has shifted slightly, the underlying dependence on manual labor remains constant, reinforcing the inefficiencies in clearance processes.

For **simple** changeovers, **63%** of clearances take between **30 minutes and 2 hours**. For **complex** changes, **68%** take **longer than 2 hours**—with **37% exceeding 4 hours.**

6. Root Causes of Delay

47% Missed Items

47% Setup Issues

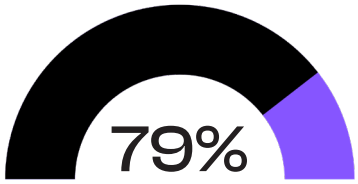
42% Human Error

These three causes stood out as the most common contributors to clearance delays Together, missed items, equipment setup issues, and human error were cited by over 4 in 5 respondents—highlighting the need for standardized inspections, better readiness, and error-proofing at the line.

7. Technology Usage

Despite signs of interest in 2023, technology adoption remains slow, with cost of ownership, validation, and training cited as the top barriers.

8. Investment Drivers



TCO is "**extremely important**" for **79%** of respondents when considering new solutions. Top cost concerns include validation (32%), training (26%) , and hosting (16%).

9. Future Priorities

Teams aim to **reduce** changeover time **74%**

Cut clearance errors, and improve compliance traceability and training. **63%**

Summary of Findings

The 2025 results reinforce a pattern seen since the first benchmark in 2022: manual line clearance remains one of the most persistent barriers to achieving higher OEE and consistent compliance in life sciences operations.

Here are the key takeaways:

Manual processes remain dominant.
Despite growing awareness and multiple pilot programs reported in 2023, the majority of respondents in 2025 still rely on paper-based or hybrid systems. A small number of sites have adopted a digital-first approach, and none report fully integrated clearance connected to MES or QMS platforms. This lack of progress underscores the difficulty of moving from experimentation to enterprise-scale adoption.

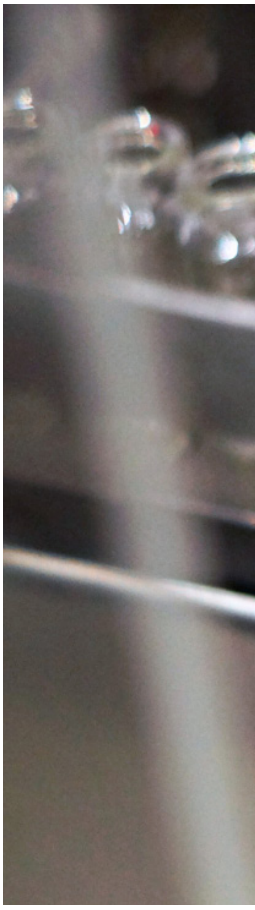
People are still carrying the burden.
Most sites continue to require two to four personnel for clearance, essentially unchanged since 2023. This continued dependence on manual labor highlights both the inconsistency of human-led processes and the opportunity cost of skilled operators tied up in repetitive tasks. This reliance undermines efficiency and prevents organizations from realizing the full potential of operational excellence programs.

Failures are frequent and unchanged.
In both 2023 and 2025, 70% of sites experienced at least one clearance failure in the past year, with a subset reporting ten or more. These repeated failures translate directly into unplanned downtime, rework, and audit exposure. Human error remains the leading root cause of GMP deviations, which means reliance on manual inspection will continue to produce compliance risk.

Technology adoption is lagging expectations.
In 2023, nearly half of respondents reported exploring vision systems, and AR/VR was emerging as a support tool. In 2025, however, the vast majority remain locked in manual processes, with only isolated examples of advanced adoption. This suggests a plateau, where early pilots have not yet crossed the threshold to standard practice.

Changeover times remain lengthy.
While earlier surveys suggested a downward trend in clearance times, the 2025 results show that most changeovers still take between 30 minutes and 4 hours. For complex changes, over one-third of sites exceed four hours. Compared with 2023, there has been little measurable improvement, despite years of Lean and Operational Excellence initiatives.

Conclusion



Despite growing awareness of the need for digital transformation, survey results highlight the immaturity of technology adoption in the line changeover process. Two-thirds of respondents still rely primarily on paper-based checklists, often supported by multiple personnel at each clearance. Hybrid approaches are beginning to emerge, but progress toward intelligent and integrated procedures remains slow. Paper reliance leaves operations highly exposed to clearance failures, inconsistencies, audit risk, and inefficiency, underscoring the gap between aspiration and reality. At the same time, regulatory frameworks are evolving in ways that make traditional approaches increasingly unsustainable. The EU AI Act, for example, places strict obligations on explainability and traceability for AI systems, which may directly impact digital inspection technologies in regulated environments. Organizations adopting digital-first approaches—such as vision systems integrated with audit-ready AI—are therefore not only improving efficiency but also preparing to remain compliant in a future where regulators demand transparency, data integrity, and explainable outcomes. The industry is still at the beginning of this wider transformation, but the direction of travel is clear: digitization is no longer optional; it is becoming a regulatory imperative.

Line clearance duration continues to be a major concern. For simple changeovers, most still take between 30 minutes and 2 hours, while complex changeovers frequently extend beyond 4 hours. Nearly half of reported delays stem from missed items and human error, reflecting the limitations of human-led inspections. These inefficiencies directly reduce throughput, increase the burden on staff, and elevate compliance risks. Without tools that can standardize inspection, automate error detection, and provide real-time assurance, progress will remain incremental. The emergence of intelligent inspection approaches offers a pathway to error-proofing at speed, reducing both the time and risk inherent in manual clearance.

A particularly significant finding relates to Total Cost of Ownership (TCO), cited as the primary driver of investment decisions. It is essential to distinguish between the upfront setup costs required to validate an inspection solution for PQ and the recurring costs of maintaining reliable performance over a three-year period. Setup costs often include hardware, software, validation, and training, while ongoing costs involve sustaining inspection performance, retraining models, and managing deviations. Solutions that appear inexpensive at first but require frequent retraining, extended downtime for testing, or repeated revalidation can quickly erode their value. By contrast, platforms designed with lifecycle efficiency in mind—such as those incorporating limited self-healing capabilities—can sustain performance with minimal intervention. By automatically correcting minor anomalies and reducing the need for prolonged retraining cycles, these systems help maintain inspections at peak efficiency without constant engineering effort. This lifecycle perspective shows why TCO is not just an accounting metric but a decisive factor in investment decisions: the ability to minimize hidden costs over the long term can be the difference between a solution that scales and one that stalls.

The survey also reveals a tension between the industry's two most pressing priorities: reducing changeover times and reducing errors. On the surface these goals appear aligned, but in practice they can conflict. Driving faster changeovers without robust error-proofing risks more mistakes, while building in additional checks to prevent errors often extends clearance duration. The challenge for manufacturers is to strike a balance—using digital tools and automation to compress timelines while simultaneously improving accuracy. Advanced inspection systems, particularly those that adapt and improve without lengthy retraining or revalidation, represent a promising way to reconcile this tension. Success will depend on adopting approaches that are both agile and reliable, ensuring speed gains do not come at the expense of quality.

Catalyx remains committed to supporting the evolution of process maturity in line changeovers. We believe a new standard is within reach, one that increases throughput, strengthens compliance, and gives teams the confidence to scale. The benchmarks in this report are designed to help you assess your current state and chart a smarter path forward.

Catalyx has partnered with leading pharma, biotech, and device manufacturers to tackle these challenges directly. If your teams are facing pressure from long changeovers, rising error rates, or growing compliance demands, we invite you to reach out. Let's discuss the realities of your line clearances and explore how we can help accelerate your transition toward faster, safer, and more reliable operations.

References

Catalyx (2023). Life Sciences Line Clearance Benchmark Report 2023.

About Catalyx

Catalyx is a global automation and machine vision company helping manufacturers in highly regulated industries achieve next-generation levels of quality, compliance, and throughput.

With over 30 years of experience, 3,000+ successful projects, and 550+ experts across 9 global offices

We design and deliver smart systems that integrate people, process, and technology. From precision robotics and digital inspections to embedded engineering and compliance platforms, our solutions keep complex production lines running sharper, faster, and safer.

When the solution doesn't exist, we build it. That's why industry leaders trust Catalyx to solve critical process challenges—and deliver results at scale.

Catalyx OpenLine Digital LineClearance Assistant™ (LCA)

LineClearance Assistant™ (LCA) is a **fixed-camera vision system** designed to eliminate the guesswork, delays, and risks of manual inspections.

It rapidly scans the entire line, detects rogue components, and flags areas needing operator intervention — transforming hours-long manual checks into **fast, exception-based inspections.**

Now enhanced with limited self-healing intelligence, LCA can automatically resolve minor anomalies, reduce false stops, and keep production flowing without compromise.

Proven to cut clearance times by up to 85%, free thousands of additional production batches, and deliver rapid ROI, LCA integrates **seamlessly into GMP environments** and provides a validated digital audit trail for every clearance event.

Built with transparency and accountability at its core, it is **EU AI Act ready**, ensuring safe, ethical, and compliant AI adoption.

Deployed globally across Life Sciences and CDMO sites, **LCA empowers teams** to reduce errors, boost capacity, and stay audit-ready every day.

About the Author

David Taylor is a Product Manager at Catalyx and serves as the company's Line Clearance Subject Matter Expert. He works closely with global pharma, biotech, and medical device companies to develop solutions that drive performance and compliance across regulated production lines.

David has led customer-focused design and implementation programs for Catalyx's LineClearance Assistant™ across Europe and North America, helping operations teams transition from paper-based clearance to digital-first processes. He brings a practical understanding of GMP requirements, real-world manufacturing constraints, and the technologies that bridge the two.

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