

Life Sciences Global Line Clearance

Benchmark Report 2023



Table of Contents

- 02 Welcome
- 04 About the author
- 03 Introduction
- 04 Survey findings
- 05 Summary of findings & conclusions
- 06 About Catalyx
- 07 Catalyx Digital LineClearance Assistant™

Life-Sciences manufacturing and packaging leaders face production uncertainty every day. Current manual line clearance procedures exacerbate this situation and expose companies to delays, risk and unwelcome inefficiencies. In 2020, Catalyx investigated the impact that manual line clearance procedures are having on the OEE performance of life science organisations across the globe. This investigation included understanding the methodologies that companies are exploring or deploying to mitigate the line clearance issues and failures experienced. This report is the first benchmark study of its kind in the industry.

Our aim was to establish a readily available, and actionable industry dataset, that would enable Life-Sciences companies to reference, benchmark, and optimise their line clearance process on a forward basis. This dataset has allowed the industry to understand and monitor how widespread line clearance issues are for many global sites year on year. In line with survey findings, Catalyx has also established a community of 100+ like-minded industry professionals from across the globe who support, guide and govern line clearance and changeover procedures in life science organisations. The community meets on a quarterly basis, on a customer led forum to discuss challenges, best practices, current and future developments.

I am delighted that the survey has been authored by a pharma operations expert with over 30 years' experience in senior roles in global life-science corporations. Danny McLaughlin has brought key insights directly from operations, engineering, quality and operational excellence personnel within the life-sciences customer base around the world. The findings generated over the last three years indicate that manual line clearance procedures continue to have significantly negative impact on operational efficiencies, particularly since batch sizes have reduced while demand has increased. It is evident that manual line clearance procedures are not sustainable and will struggle to support the continuously changing landscape of the global life sciences market in 2023 and beyond.

With the help of fellow life sciences professionals like you, we have developed a better shared understanding of the line clearance situation in the market and the best practices in 2023. And for those who were not able to provide their perspectives this year, we look forward to hearing from you in the next annual industry study in 2024.

I would like to also personally invite you to join our quarterly Catalyx line clearance collaboration forum and would encourage you to present on any of your personal perspectives on the data we present here and to use this to improve line efficiency and compliance within your organisations.



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



About The Author

Danny McLaughlin is a Pharma Advisor at Catalyx and has worked closely with the Catalyx innovation and design and development teams during the development and commercialisation of their patent pending Digital LineClearance Assistant (LCA)[™] product since 2019. His extensive experience in engineering and operations roles within life-sciences organisations was hugely beneficial in the development of a successful digital line clearance solution.

Danny has worked with Allergan Pharmaceuticals in various senior Operations and Engineering roles in both European and U.S. facilities over the last 30 years. He was employed as a Production Manager in both the Allergan Ireland and Allergan Puerto Rico FDA approved facilities in the 1990's, followed by a Plant Manager role in the late 90's with Transitions Optical. In 2001, he commenced employment as the Engineering & Technology Director at Allergan Westport, Ireland overseeing the continued expansion of the multi-technology Pharma Site to a 1200 employee operation. In 2015, he moved into an Operations Director role at the site with responsibilities for a growing Sterile Ophthalmic product operation while leading the commercial start-up of a new biodegradable implant operation. Danny retired from Allergan in 2018 and joined Catalyx n 2019 and has been working in an advisory capacity since then.

Line clearances and their impact on line efficiencies is a subject that has been ever-present throughout Danny's career. He has initiated and been involved in Operational Excellence programs in all his site experiences and was therefore excited to work with Catalyx in the development of their patent pending SmartFactory Line Clearance Assistant (LCA)TM.



Danny McLaughlin Pharma Advisor Catalyx

Introduction

In the development and commercialisation process for our Digital LineClearance Assistant[™] (LCA) product, it was apparent that there was a market niche to collect factual data from the industry relating to line changeovers. It was evident that the number of line changeovers taking place on production lines was on the increase. Most, if not all our customers, agreed individually that line changeovers were negatively impacting their line efficiencies and that the situation was growing increasingly challenging every year. Furthermore, with the proverbial compliance crossbar across the Life Sciences industry also getting higher every year, organisations faced an increasing number of production procedural add-ons like serialisation that required additional focus and time during the line clearance process.

Catalyx commenced the collection of information relating to line changeovers among our global Life Sciences customer base in 2020. We conducted a confidential survey and presented our results at our Catalyx Life Sciences Line Clearance Collaboration Forum in Q2 2021. (1) We then followed this up with a second similar survey in late 2022 and presented the output at the Catalyx Life Sciences Line Clearance Collaboration Forumin Q1 2023.

This 2023 Catalyx Line Clearance Industry Benchmark Report presents the findings of both the 2020 and 2022 reports and compares the feedback. We intend to repeat this Catalyx line changeover Survey in 2024 with the intention that we will continue to grow a market reference dataset across global Life Sciences production floors in relation to line changeovers.

The findings are broken down into the following areas:

- Who participated with what roles they had in their organisation
- Types of shift patterns
- Number of personnel performing line changeovers changeover times
- Factors affecting line efficiencies number of line clearance failures
- Technologies being investigated for line changeovers

The report concludes with a synopsis of high-level learnings that we hope can be utilised by organisations when assessing their current line clearance processes.

1 Catalyx host a quarterly virtual discussion forum with Life Sciences professionals to share and discuss line changeover processes and best practices. Details can be found at www.cxvglobal.com/events.

Survey Findings

1. Industry Participation -Sector & Organisation Position



2. Industry Shift Patterns



The 2022 Survey indicates that there is a 20% increase in the use of 24/7 shifts versus the 2020 Survey. There is also a corresponding decrease in the use of the 16/5 shift in the Same time period. This may indicate a higher focus on utilizing a third shift to help achieve higher output and also improve line efficiencies OEE%.

Lines broadly running the same shift patterns:

- 24 hours/7 days per week ~ 27% (2020) to 33% (2022)-up 20%
- 24 hours/5 days per week ~ 35%
- 16 hours/5 days per week ~ 27% (2020) to 20% (2022)-down 25%

3. Personnel Performing line Changeovers

- 5% utilising only one person.
- ~70% utilising 2-4 personnel.
- ~26% of respondents are using 5 or more people to perform Line Clearance's.

Not surprisingly, the vast majority of respondents (70%) are utilising 2-4 personnel during the Line Changeover process. The use of 5 or more personnel (~26%) may be driven by the need to possibly improve the speed of the line changeover. The use of one person by 5% of respondents to perform a line changeover procedure seems odd and is unexpected in a highly compliant environment. More detail would certainly be required in order to make rational conclusions on this particular piece of feedback.



4. Line Efficiency Measurement - OEE1%



OEE1% Measures production efficiency in a 24/7 environment, 365 days/year.



Measurement coverage has improved, but, majority of OEE1% still relatively low.

- ~10% of respondents weren't measuring OEE1% in 2020!
- 5% of Lines measuring OEE1 % at >80%.
- 60% lines running at <50% OEE1%.

It is hard to believe that almost 10% respondents were not measuring OEE1% in 2020 and it encouraging to see that this figure has dropped to approximately 2% in 2022. An average of 60% of respondent production lines are running at OEE1% of 16% - 50%, which clearly indicates that there are still big opportunities for line performance improvements.

5. Line Efficiency Measurement - OEE2%

OEE2% Measures production efficiency while removing weekends, holidays, unused shifts.





Majority of OEE2% still in 31% - 80% range.

- Reduction from 20% (2020) to 5% (2022) "not measuring." Increase in >80% OEE2%
- Significant decrease in 51% to 80% OEE2% Increase in number of changeovers maybe?
- Significant increase in 31% to 50% OEE2% Lean/OpEx initiatives and increase in number of changeovers perhaps.

There is still a wider than expected variation in the reporting and measurement of OEE%. Perhaps due to company specific definitions or measurement criteria this may skew these findings. Overall OEE2% in the Life sciences industries appears to be lagging behind best-in-class manufacturing and packaging operations.

6. Factors Affecting Line Efficiency



Line changeovers have an increasingly negative impact on OEE%.

- Strong and very strong negative impact of line changeovers on line efficiency. - Increase from 41% (2020) to 55% (2022).
- Machine issues still the biggest negative impact on line efficiency (55% 2022).
- Training issues running at 24% strong negative impact in 2022.

55% respondents (up from 41% in 2020), indicated that line changeovers continue to have a "strong negative impact" on line efficiency. It is worth noting that approximately 55% of respondents also indicated that machine issues continue to have a "strong negative impact" on line performance. Furthermore, almost a quarter of respondents highlighted that "training issues" continue to have a "strong negative impact" on line efficiency.

7. Average Number of Changeovers per week



Positive Trend

Number of changeovers per week are rising.

- Decrease in 0-5 changeovers per week due to continued fragmentation of SKU's.
- Increase in 6-10 & 11-15 changeovers per week.
- Decrease in 16-30 changeovers witnessed.

The number of line changeovers per week appears to be on the increase. Respondent production lines with 6-10 and 11-15 changeovers per week are on the increase at 31% (from 14% in 2020) and 23% (from 14% in 2020) respectively. This trend is possibly driven by increase in the number of SKU's being produced as a result of dedicated country regulatory requirements. There appears to be a decrease in the 16-30 changeovers per week – this may be driven by the transfer of smaller SKU's away from the higher speed lines and also may indicate the elimination of very small inefficient SKU quantities from high speed lines.

8. Changeover Times - Same Product, Different Language



Changeover times are getting shorter - still major opportunities though.

- ~20% respondent lines (2020) reduced to ~2% respondent lines (2022) had changeovers lasting 3-4 hours.
- ~30% lines have changeovers lasting 1.5 to 3 hours.
- Big increase in respondents completing changeovers in 30-60 mins. (12% to ~30%)

Overall, it is clear that there is a downward shift in changeover times, most probably driven by Lean initiatives and Operational Excellence programs. More detail would be required to better understand the data indicating line changeovers in excess of four hours.

9. Changeover Times - Different Product, Different Size



Different size changeover times are also exhibiting a downward trend.

- Significant shift to 90-180 mins from 2020 to 2022
- 20% feedback highlighting changeover times > 4 hours.

It is evident that there is a downward trend in changeover times in the two-year timeframe. 0-30 mins and 30-60 mins changeovers have increased significantly, while there appears to be a significant drop in 180-240 minute changeover times to the 90-180 minute changeover time. A surprising figure that 20% of respondents are carrying out 240+ mins changeover in 2022 which will need root cause analysis.

10. Line Clearance Failures Over The Past 12 Months



- ~30% feedback had 0 L/C failures in previous 12 months.
- ~70% feedback had L/C failures in the last 12 months.
- 60% feedback experienced \geq 2 L/C failures in previous 12 months.
- 20% feedback had ≥10 L/C failures in previous 12 months

The standout figure in the above feedback is the sizable jump in 10+ failures in the 2022 survey. Industry experience continues to show a broader awareness of clearance failure numbers across our survey base. Whilst root cause analysis of line clearance failures is not currently within the survey remit, additional categorisation of failures will be extended into the 2024 survey.

Even without the underlying causal data such a failure increase suggests increasing pressures and dependency on extensive clearance controls remain at the forefront of industry needs.

11. Technologies Begin Investigated / Used For Line Clearances



Technology use is on the rise. There is clearly an upward trend in the use of technology to help improve line changeover processes. Almost half of the respondents are utilising some form of camera/vision technology and there's been a significant jump in the number of respondents utilizing AR Technology. The use of drone technology would be an interesting discussion subject at one of our quarterly collaboration forum, if approved by the relevant respondents.

The underlying message here is that the manual process is inadequate and digital technology has a clear role to play in improving success rates.

Summary of Findings & Conclusions

The following conclusions are drawn from the Catalyx surveys completed in 2020 and 2022, in which 80%-90% of respondents were pharmaceutical professionals while 10-20% were medical device professionals. The data collected in the survey is interpreted through in-depth industry knowledge and expertise

Shift patterns are changing

- Noticeable swing from the 16hr/5-day week to the 24hr/7day week in 2022.
- 30% of respondents are utilising a 24/7 shift.
- 30% are using a 24/5 shift.
- 20% are using a 16 hr/5-day week shift.

More opportunities for line performance improvements

- 70% of respondents are utilising 2-4 personnel for the line changeover process.
- 25% are using 5 or more personnel in the 2022 survey.
- 10% respondents were not measuring OEE1% in 2020 reduced to 2% in 2022.
- 60% of respondent production lines are running at OEE1% of 16% 50%, which clearly indicates that there are still big opportunities for line performance improvements.

Still a number of familiar factors negatively impacting line efficiencies

- 55% respondents (up from 41% in 2022), indicated that line changeovers continue to have a "strong negative impact" on line efficiency.
- 55% of respondents also indicated that machine issues continue to have a "strong negative impact" on line performance.
- Almost a quarter of respondents highlighted that "training issues" continue to have a "strong negative impact" on line efficiency.

Number of changeovers on production lines is increasing

- Respondent production lines with 6-10 and 11-15 changeovers per week are on the increase at 31% (from 14% in 2020) and 23% (from 14% in 2020) respectively.
- Lines performing 0-5 changeovers per week have decreased from 42% respondents in 2020 to 28% respondents in 2022.
- Significant decrease in the >16 changeovers per week lower figures possibly driven by the transfer of small SKUs from high speed more efficient lines to the low speed less efficient lines or by the discontinuation of really small inefficient SKU products.

Line Changeover times are on the downward trend–major opportunities remain

- 30% of respondent lines are performing changeovers in 30-60 minutes, up from 10% in 2020.
- 30% of respondents are still performing line changeovers in the 90-180 minutes range, as was noted in 2020.
- 20% respondents are taking up to 4 hours to perform a changeover for a different product size. Large opportunities for improvement here in an OEE% driven environment.

Line Clearance failures are not uncommon

- 70% of respondents experienced one or more Line Clearance failures in the previous 12 months.
- 20% of 2022 respondents indicated that they experienced 10 or more failures in the previous 12 months a jump from 10% in 2020.

Many Line Clearance technology options are being explored

- The industry is continuing to investigate the use of different technologies to help improve their line changeover processes, ultimately they all involve digital image acquisition.
- 44% of respondents are using or investigating camera/vision technologies and there appears to be a definitive trend in the use of augmented reality technology (3% in 2020 up to 16% in 2022).
- 8% are investigating drone technology, interesting even though unexpected.

Catalyx intend to continue utilising the same survey template with some extensions in our 2024 survey to ensure we can continue to benchmark the line changeover trends within the Life Science industry. Additional areas to be included in the 2024 survey at the request of our industry peers include categorisation of line clearance failures, environmental health and safety concerns associated with newer high-speed lines and a more expansive quality and safety section.

To Life Sciences professionals, Catalyx would like to use this opportunity to thank you again for your feedback on the prior surveys. Although this data is only a snapshot of feedback in your very busy schedules, we are of the opinion that the data collected from the industry is directionally correct. Line efficiency is becoming increasingly important. Line changeovers have an increasing strong negative impact on line efficiency and effective technology solutions are being pursued to help address this important challenge.

If you are a Life Sciences professional, then we would encourage your participation in the 2024 Catalyx survey. We are continually extending our participant community and thereby expanding our industry benchmark data on a year over year basis. We look forward to your support in helping us drive both compliance and efficiency throughout the line clearance processes as they evolve over the coming years.

About Catalyx

30+ Years. The Vision to Do What's Never Been Done Before.

Catalyx is a machine vision and automation company that integrates technology and people to help global manufacturers and logistics companies achieve next-generation levels of quality and throughput. For over thirty years, the minds behind Catalyx have been at work maximizing operational processes across highly regulated industries by inventing new technology applications and supporting companies with technical experts.





Our Story

Catalyx has a rich history rooted in machine vision, automation and innovation. We bring the best of 4 brands together to optimize processes for complex, multinational value chains in highly regulated industries.

Xyntek

VistaLink

Crest Solutions

Panacea Technologies

Together, Catalyx is well equipped to provide a comprehensive suite of solutions and services for entire process lifecycles.

Catalyx LineClearance Assistant™(LCA)

LCA uses a network of fixed position cameras that are deployed across the entire line, covering the risky and hard to reach areas of the line. LCA inspects the entire line in seconds and highlights areas where rogue components are detected. Operators manage the Line Clearance by exception and rapidly handle these detections which means the Line Clearance checks are completed in lightening quick time.

LCA increases line availability and minimises downtime by reducing the time taken to complete a line inspection by up to 85%, when compared with human observation, thereby dramatically improving OEE2% and increasing line capacity utilisation by as much as 20%. All Line Clearances executed provide a digitally stored record of each process executed alongside a full clearance report, available to review at any future date.

Many years of research and development have gone into creating the LCA. Throughout the conceptual development stage Catalyx worked with six global pharmaceutical companies and piloted in their live manufacturing environments over a 24-month period. This industry endeavour has resulted in a multi award winning product recognised by industry peers as a truly innovative solution at the forefront of the industry's needs. Catalyx are market leaders in anomaly detection systems using state-of-the-art algorithms to deliver quantifiable business value to customers. Return on investment calculations of a recent global business case saw:

- 69% Reduction in line clearance time
- 26K Additional batches can be created with free time
- Potential for billions in additional revenue generated over 5 years.



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