Building the QA lab of the future

OnQ software

Introduction: the tools you need today, to be ready for tomorrow

Digital transformation has dramatically changed the way numerous organisations work across the globe. But in many ways, quality assurance (QA) laboratories—whether they're in food and beverage, pharmaceutical, environmental science or any number of other fields—are still operating much the same as in the 1990s.

We've got our roots firmly in the laboratory and we know that many are still battling with the same inadequate technology and manual processes. Reflecting our experience of the industry and the clients we speak to, a survey of the life sciences industry across North America and Europe found that:

40% hadn't yet applied digital technologies to R&D or quality control (QC) labs.

37% were still in pilot mode.

But of those who had started, 70% report achieving or exceeding the expected business value.

Using digital technology is becoming essential for businesses across all industries. Of course, the overarching goals for QA laboratories of data integrity, fewer errors, first time right testing and improved turnaround times haven't altered. But challenges are being felt more strongly and it's time for change.

You need systems that help reduce manual tasks and eliminate the human error factor in your data. You need systems that talk to each other and fit with your workflows, so everything is captured. Disrupted supply chains are increasing the need for testing at multiple points in manufacturing. And of course, there's a growing demand to support flexible and remote work practices, a requirement that the COVID-19 pandemic further accelerated.

A myriad of labs are drowning in data, and this is only expected to increase in response to regulatory demands. But when it comes to accessing accurate data for government and third-party audits, are you as confident as you should be? Not to mention the time it takes to collate this information. Furthermore, data driven decision-making in the form of forecasting and prioritisation is becoming critical in demonstrating the importance and value of the lab to the business.

It's time for QA and QC laboratories to embrace digital platforms—becoming paperless, flexible, automated and predictive. Read on to find out the reasons why, what needs to happen and how to ensure your digital transformation puts your business on track to long-term success.

More time for science, less time on administration

The promises of digital transformation for laboratories are significant. As well as enhanced processes for laboratory technicians and analysts, there's a raft of broader business benefits too. Here's an overview of some of the core benefits your business can expect.

- **Enhanced productivity:** reduce time on manual, labour intensive tasks through integration of systems and automation throughout the QA process including:
  - Batch and sample registration and application of testing.
  - Manual generation of worklists.
  - Manual handwritten entry of results from instruments.
  - Report generation and data extraction.
- **Improved data integrity:** eliminate errors and double handling caused by manually entering results in paper-based systems, spreadsheets and additional software as well as other transcription errors. Including all testing specifications in the system can guide technicians through the process to further eliminate errors.

Error reduction: by reducing manual errors, labs can lower investigation workloads by 90 percent

- **Better security:** cloud-based systems reduce reliance on workarounds such as printouts or USB sticks for working remotely. Paper-based records are expensive to store securely and in addition are near impossible to search.
- **Shorter testing times:** developments in barcoding, plus emerging technologies like artificial intelligence (AI), QR codes and RFID can reduce QC lab lead times by 60-70 percent. Also, intuitive interfaces with colour coding and 'drag & drop' tools help to streamline processes.
- **Brand trust:** it's essential to be able to demonstrate to regulators that your product is consistently safe and effective. In the event of an issue like a product recall, a robust and integrated digital platform can help businesses to quickly pinpoint the cause of any issue and identify exactly which products need to be recalled. It also means you can proactively monitor production to prevent issues from reaching the stage of a recall in the first place. Communicating about your robust processes to consumers helps to build confidence in your business.
- **Environmental monitoring:** remote monitoring and predictive maintenance capabilities built into equipment can allow for instantaneous microbial detection for environmental monitoring and could reduce lab lead time by 40-75 percent.
- **Improved financial contribution:** robust processes including automation frees QA to shift from a cost centre to a strategic business partner than can identify gaps in processes, pre-emptively identify potential issues and drive improvements in product development.

What's needed

There are several elements that will ensure your laboratory has the right technology in place to successfully adapt to the evolving needs of the future. Because we've built our software from the ground up, based on our own experience and the real-life feedback of our clients, we've identified the key factors that define the modern QA lab; factors which will help you thrive today as well as being ready for tomorrow.

Cloud based

First of all, a cloud-based system turns a LIMS into a completely managed service, with reduced IT overheads. Additionally, it gives lab managers more freedom and accessibility, ensuring that staff can have real-time access to work whenever, wherever. This includes the capacity for remote work, which is an area that's particularly possible for multiple QA and analysis functions with the right systems in place.

Depending on your operational needs this can include:

- Experiment data capture.
- Workflow management.
- Experiment planning/design.
- Sample and reagent management.
- Data visualisation.
- Instrument integration and automation.

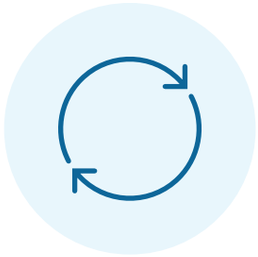
Data security & integrity

It's essential that your LIMS has relevant technical controls including authentication and encryption, as well as procedural and behavioural controls to ensure data accuracy and clear audit trails. Look for software that includes:

- PCI DSS, SOC, ISO/IEC 27001, ISO/IEC 27017, ISO/IEC 27018, CFR 21 Part 11 and ISO 9001 compliance.
- Single sign on.
- Two-factor authentication.

Many labs are currently relying on a combination of paper-based and digital systems that don't integrate. This means there's significant scope for human error as data is manually entered from paper-based systems, spreadsheets and other software. On average, humans will make 3-6 mistakes for every 1000 results transcribed from an instrument. If any maths or stress is involved, this increases to a typical error rate of 30 for every 1000 results.

Integrated digital systems ensures comprehensive audit trails can be automatically generated and retained to meet regulatory requirements. The enhanced ability to analyse and extract information from data also helps to improve products and product safety.



Automation

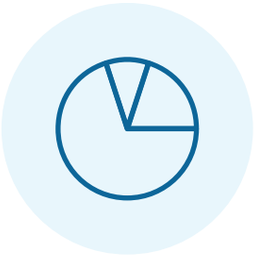
Automated processes, including automated data transcription between equipment and systems, are essential to create time savings from manual data entry. This comprises equipment connecting with systems such as enterprise resource planning and integrating throughout the business process chain to give improved data visibility throughout the organisation. Other areas for automation include testing workflow and next steps guidance based on testing results, worksheet generation and automatic scheduling of sample and batch generation for routine testing.

20-30 percent of time across several roles in pharmaceutical companies is taken up by low value work that could be eliminated by digital transformation. This limitation extends to labs in many other industries, from dairy to water.

Even if that percentage is lower in other sectors, that's still a significant amount of time that can be freed up for higher value activities. The same report estimated that QA teams are spending 40-50 percent of their time on document review and report preparation, which could be automated with the right systems in place.

Just reducing the time spent on manual report writing can result in massive cost savings. For example, a 20% reduction in time writing reports for 7 staff members could save $154,000 per year. Or this time could be redirected to revenue generating activities.

Finally, with more labs operating around the clock to meet demand, an integrated system to ensure efficient handoffs between shifts is essential.



Analytics & predictive technology

Knowing what needs to happen and being ready to respond quickly to changing circumstances is essential to keep pace with ever-growing demands for processing more tests in less time. This is where cutting-edge software can speed up decision-making and help you to deploy the right resources, at the right time. Clear, easily reviewed reports provide all the information exactly when you need it so that testing processes can be adjusted and streamlined based on sample results.

Furthermore, advanced data analytics, optimised scheduling and predictive maintenance all streamline operations to save time and decrease downtime of equipment. For example, at a large global pharma, lab productivity increased by 30 percent with advanced schedule optimisation and analytics reduced deviations by 80 percent.

Configurable and intuitive

Of course, any software is only as good as how it's used. With our roots in the laboratory, we're only too aware that software that doesn't fit to existing processes is essentially useless. We work collaboratively with our customers to ensure our products include the features you need so you can achieve the benefits that make a difference to your work and the results your business can rely on.

The ability to configure software to your specific needs, as well as access to effective support, helps users get up to speed. Intuitive software that adapts to existing workflows also reduces friction. This means faster implementation of testing processes for new products, more self-serve options and gives the lab independence from relying on the IT department and vendors.

The keys to a successful transformation

The right technical elements are only one part of the picture. Just as important, if not more so, is support for the necessary cultural and behavioural changes throughout the organisation.

We've spent years working both in labs and with labs, so we know what it takes to ensure your implementation is a success and achieves the necessary results.
To realise the benefits, you need to:

- **Know what your vision is,** both in the immediate term and for the future, based on your lab's volume of work and operational set up.
- **Understand the business case** and the full capabilities of what the system can do and the benefits it can generate. This can help prevent the rollout of partial solutions where data still needs to be manually transferred between systems and also helps maximise return on investment. Additionally you can gain benefits beyond your initial goal, for example productivity gains as well as enhanced compliance with data integrity regulations.

- **Look for the quick wins** with testing and scaling high-value solutions before an end-to-end prototype. Scheduled automation and optimisation can be a great place to start for many labs. In addition, with rapid developments in this area, an iterative rollout rather than a big end-to-end deployment can prevent problems with a LIMS's capabilities becoming obsolete before they're fully rolled out. Cloud-based platforms that allow you to progressively turn on the features you need can also prevent this.

- **Dedicate time to boost staff skills,** as well as a robust change-management program. Success relies on up-front investment in culture change to get buy-in throughout the business and ensuring staff are supported with training. As well as investing in existing staff, also look to hire new employees with the required skills to accelerate system adoption and scale-up.

- **Nominate LIMS champions** to lead the roll out and bring team members on board throughout the change management process.

Conclusion

The QA and QC lab of the future needs to be faster, more reliable and ready to adapt to ever-evolving regulatory demands. The right technological foundations can ensure your business keeps pace with a higher volume of work, while supporting staff to work remotely and maintain, or even increase productivity.

The complexity of QA in laboratories is only likely to continue with greater product diversification, faster time to market and increased compliance. Laboratories need to have the right tools and processes to stay agile and effectively collaborate in this challenging environment.

It's time to tame the data deluge and start using information to more effectively collaborate, both within your lab and with others. It's time to stop spending time on manual data entry, systems integration and maintenance so you can do the science that makes a difference. And it's time to feel confident in the integrity and security of the data your lab generates.

Moving to the lab of the future starts with getting the digital foundations in place with pilot programs that help your business to achieve its initial objectives and see what could be possible. Shifting from a reactive to predictive function based on real-time data, you can further explore new and emerging developments in AI, machine learning, robotics and other automations to enhance lab performance and manufacturing, becoming a strategic advisor to your business.

If you're ready to start, OnQ Software is here to guide and support you.