Enabling a Healthier World

Lonza

Building a Business Case for a Digitalized QC Platform

How to Guide

Investing in automated, paperless solutions is a logical step in driving laboratory productivity, reducing costs, and enhancing regulatory compliance. Any laboratory manager working with paper-based systems will have experienced the challenges they present, and as laboratories come under increasing pressure to do more with less, the case for digitalization grows. Within the wider organization, however, gaining capital expenditure approval requires clear-sighted analysis of existing issues and real understanding of how a chosen solution will help. This guide discusses how to develop a compelling business case that communicates laboratory needs, captures the tangible benefits of the paperless solution, and aligns with corporate strategy.

The Benefits of a Digital Solution

Since they are built on manual processes, paper-based systems are labor-intensive and subject to the data entry inaccuracies associated with human error, necessitating additional checking steps that demand extra time and resource. Manual data collation for trend analysis is cumbersome, and providing compliance and audit information requires significant personnel input. This collation process can be slow, especially when it involves retrieving paper documents from disparate locations. Additional costs to the business stem from the inherent resource intensity of the processes, expenditure on paper and labels, and the financial implications of physical storage.

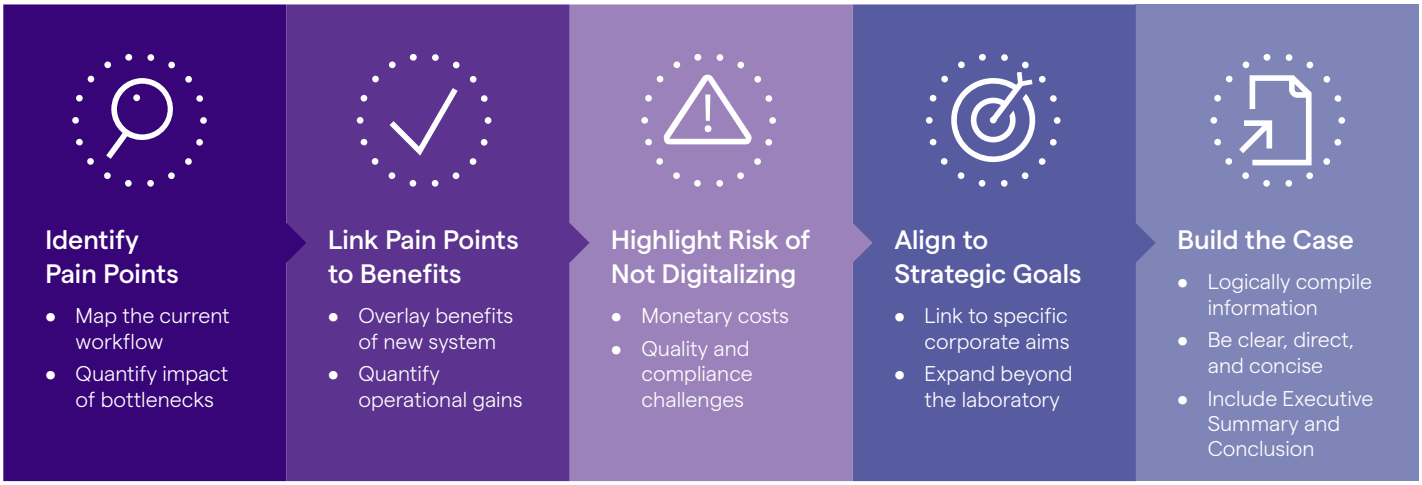

Figure 1. A framework for creating a strong business case.

In the microbiology quality control (QC) arena, laboratory automation addresses the specific challenges of efficiency, quality, and cost. Most notably, a digitalized QC platform can automate all data collection and management across the entire sample lifecycle. Through the elimination of paper records, data reconciliation, and batch data entry, resource requirement for data collection and review is minimized while enabling significant quality and cost benefits.

Automated workflows that manage the entire sample lifecycle can also ensure compliance with stringent QC guidelines and standard operating procedures (SOPs). Real-time access to data for investigations delivers early warning for adverse trends, and provision of visual, predictive analytics enables continuous improvement. Ultimately, this means access to better information upon which to make decisions, with deeper insight into manufacturing operations and testing possible.

Demonstrating a Return on Investment

In many organizations, investment in capital projects needs the approval of senior management, who must balance the needs of the business with potentially competing budgetary demands. They will be concerned to establish a genuine need for the investment and to understand the benefits of the recommended solution for the business as a whole. This means examining factors such as return on investment (ROI), the breakeven point, total cost of ownership (TCO), and whether and how this investment helps future-proof the business. Presenting a clear, easy-to-assimilate business case with strong supporting data is essential in securing management support and budget allocation, especially in the face of competing projects.

Figure 1 presents a practical framework for creating a business case for a paperless QC solution. Using this approach, the first step is to identify and quantify the pain points of the current system and their impact on efficiency. Step 2 shows how the identified solution addresses those pain points, and the costs and savings involved. Step 3 sets out the financial and quality risks of not investing. Step 4 links the project into the strategic goals of the organization. The final piece pulls everything together into a concise and comprehensive document or presentation.

Step 1: Mapping the current process and identifying the pain points

Value Stream Mapping (VSM) (see Figure 2) is a useful tool for displaying the steps in the current process, aiding identification and quantification of pain points, and assessing the impact of a potential solution. It enables visualization of non-value added versus value added work, and helps in collecting process data and identifying inefficiencies. VSM includes both process mapping and data analysis.

Essential guidelines for conducting VSM are to:

- Include subject matter experts (SMEs) for each segment of the process to ensure all roles and procedures are captured.
- Be non-judgmental – it is important that people say exactly how they carry out the process, and this might not always conform to the standard operating procedure (SOP).
- Have a moderator who is external to the process and can ask questions that might not occur to those more deeply involved.
- Not discuss solutions or improvements during mapping as the process must be captured as it stands.
- Ensure full information capture (paper or digital tools).

Value Stream Mapping – Current Process

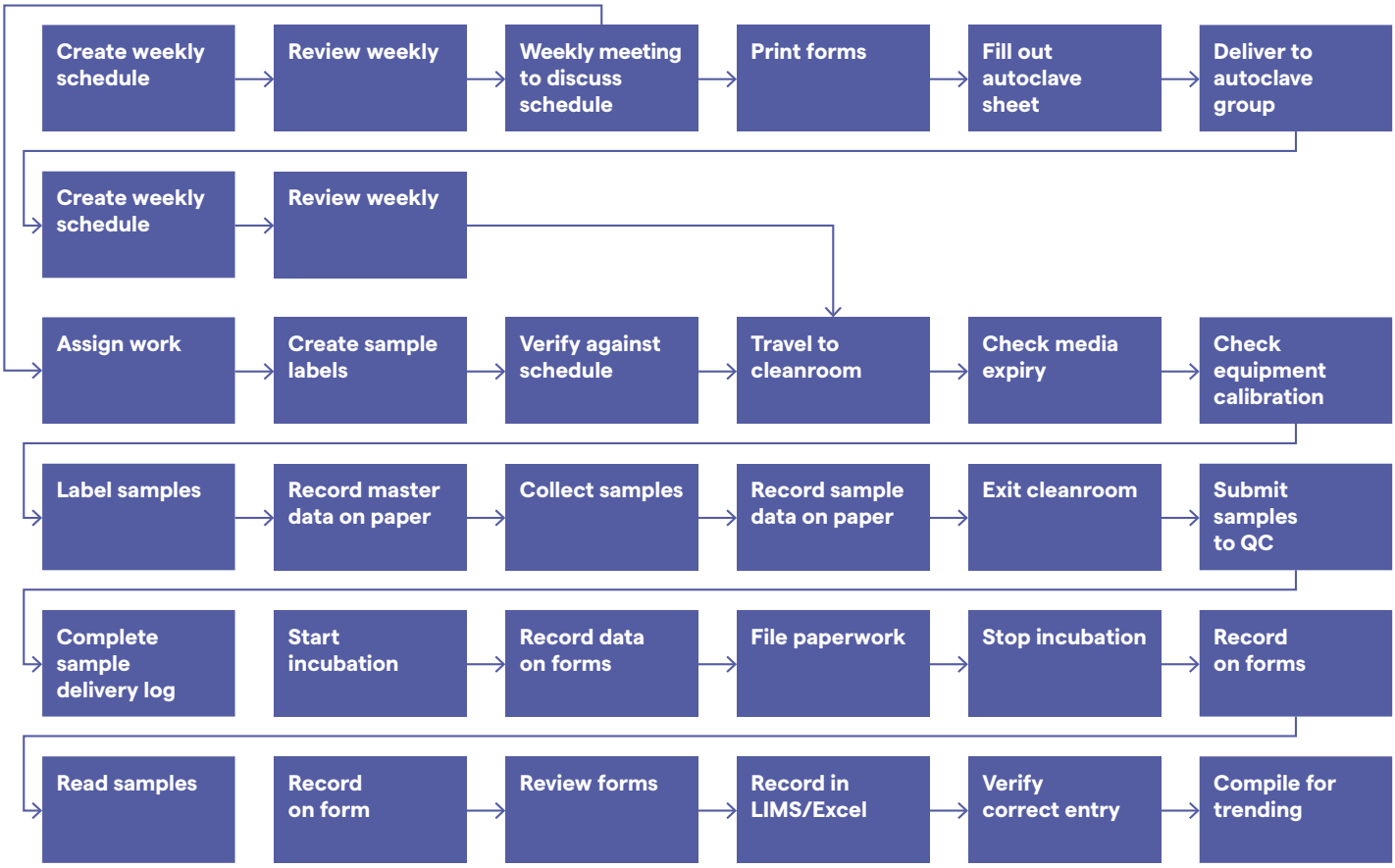

Figure 2. Example of a Value Stream Map.

Choose a starting point and an end point. It is important to select the true start point for the process, which may precede the sampling step. The end point should include an output such as a trend report. For every process step, capture the data: how long does it take, and how many people are performing each step? Beware of jumping too soon to the next step, as thoroughly quantifying each pain point is vital. Then look at the cycle time to the next step.

Figure 3 illustrates the type of data required for each process step. In capturing this information, the pain points will emerge.

Value Stream Mapping – Data

Process Step	Amount of Time	Per Unit	# of People	Cycle Time
Create weekly schedule	1 hour	Week	1	0
Review weekly schedule	1 hour	Week	1	1 Day
Print forms	1 hour	Day	5	0
Create labels	1 hour	Day	5	0
Take samples	2 hour	Day	5	0

Figure 3. Typical data capture required for each process step.

Step 2: Linking pain points to the benefits of a digitalized platform

Following identification and quantification of the pain points in the current process, the next step is to overlay the benefits of the identified solution. Pain points might include for example:

Value Stream Mapping – Future State

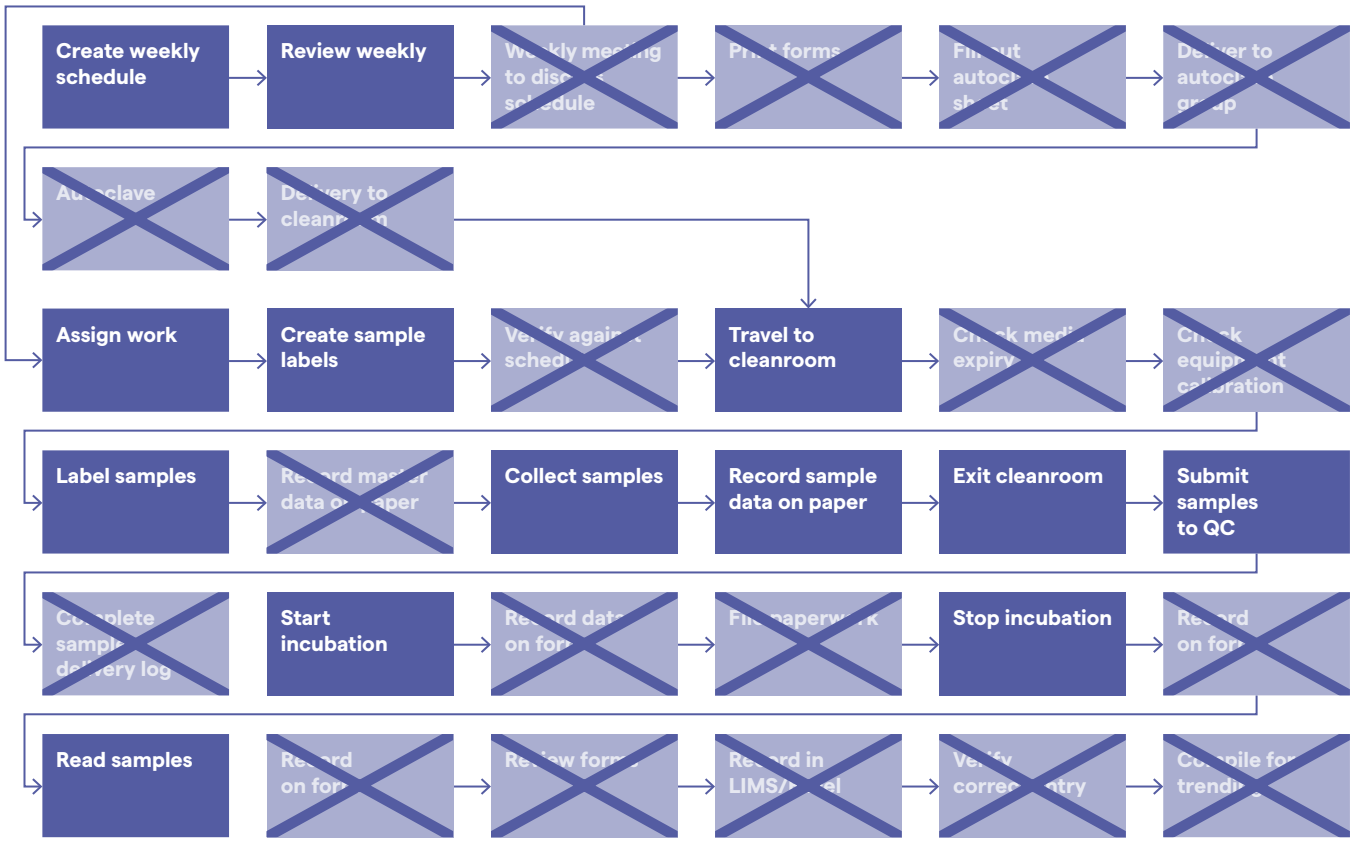

Figure 4. Visual identification of where an automated solution will provide benefit.

- Time and effort spent scheduling and in weekly review
- The need to continuously monitor and correct manual data errors
- Delays owing to slow review processes
- Time and resource implications of data transfer from paper to spreadsheets
- Lengthy compiling of information for trending, as well as time taken to perform trend analysis

At every stage, scientists could be carrying out more value-added work if freed from essentially administrative or checking functions.

Figure 4 visualizes points at which the solution eliminates or reduces steps, while Figure 5 exemplifies the quantification and annualization of benefits.

Determining total annual savings requires some additional information, including the fully burdened labor cost per hour for each department involved in the process. Once the annual and monthly savings are determined, these can be set against the costs associated with a new solution, enabling ROI determination, breakeven analysis, and projections of future benefits.

Solution Benefit – Qualification

Process Step	Amount of Time	Per Unit	# of People	Cycle Time	Annual Time Spent
~~Create weekly schedule~~	~~1 hour~~	~~Week~~	~~1~~	~~0~~	~~52 hours~~
Review weekly schedule	1 hour	Week	1	1 Day	52 hours
~~Print forms~~	~~1 hour~~	~~Day~~	~~5~~	~~0~~	~~1,300 hours~~
~~Create labels~~	~~1 hour~~	~~Day~~	~~5~~	~~0~~	~~1,300 hours~~
Take samples	2 hour	Day	5	0	2,600 hours
Total savings	—	—	—	—	2,652 hours

Figure 5. Annualiztion of time and savings for each step aids in evaluating ROI.

Step 3: Highlighting the risks of not digitalizing

Having identified inefficiencies that can be remedied, it is important to highlight the risks to the organization of not investing. Undoubtedly costs will continue to rise, and scaling for future growth will require more people to perform processes that could have been made more efficient through automation.

In many industries, regulatory compliance is a growing concern, with increasing emphasis on data integrity driving tighter surveillance and encouraging many towards digitalization and automation. Making data easily accessible in real time enables more timely investigations, rapid deviation detection, and greater insight into process operations. This contrasts with the risks associated with paper-based systems, where data analysis is often after the fact and provides only a retrospective view of what is happening.

Step 4: Aligning with the corporate strategic goals

Linking a project to the strategic goals of an organization or department demonstrates understanding of the bigger picture. Aligning to a specific strategic goal will catch the eye of senior management. Look out for key words that fit with the project benefits. Strategic statements on quality, efficiency, delivery, and employee satisfaction, for example, can be highlighted as part of justifying investment in the solution. "This project will help us to provide a better-quality environment to manufacture our products that are designed for individual patients" is a simple example of how this might work as part of the business case, expanding the argument beyond being only about the laboratory.

Making a Business Case – The Essential Facts and Figures

Making a successful case for investment in automation means demonstrating the benefits to the business as well as to the laboratory. A paperless microbiology QC solution, such as the MODA® Platform, delivers cost savings, improves efficiency, and helps future-proof business operations.







Putting It All Together

Having gathered all the information, it's time to compile the business case document. This requires a logical and straightforward approach that focuses on facts. Clear, direct, and jargon-free language helps the audience quickly grasp the problem, understand the solution, and appreciate the benefits to the organization:

- Define the problem and identify how it prevents the achievement of operational and strategic goals.
- Concisely discuss the VSM process and show the current state VSM.
- Present the solution, linking it to the pain points and showing the future VSM, to demonstrate an improved process.
- Present graphical representations of the benefits, savings, ROI, and future gains. These are easier to assimilate than tables of information.
- Identify the risks of not investing, and discuss how automation will help future-proof the laboratory and the organization.
- Align the solution to strategic goals.
- Include an Executive Summary and Conclusion to ensure those with little time can easily access the key points.

MODA-EM® Paperless QC Microbiology

Lonza's MODA-EM® Platform enables laboratories to:

- Automate the full spectrum of QC activities, including environmental monitoring, utility testing, and product testing
- Eliminate manual, error-prone paper records
- Enforce compliance with SOPs and regulatory requirements
- Move to review by exception workflows
- Seamlessly integrate with laboratory devices to consolidate data in a single solution
- Gain real-time access to data for investigations, trending, and reporting
- Swiftly advance green initiatives through elimination of paper

Your data, supported by our informatics experts

Digitalized platforms such as the MODA-EM® Solution play a pivotal role in delivering laboratory efficiencies by combining, mobile data acquisition, device integration, and advanced analytics. However, investing in such solutions often means seeking approval at senior management level, which requires a compelling business case that looks at the benefits not only to the QC lab but to the company as a whole. Putting this together demands critical thinking and a clear approach to documenting the current process and the advantages of an identified solution.

Developing a compelling business case therefore requires rigorous attention to data gathering, analysis, and presentation. The Lonza Informatics Team has extensive experience in supporting digital transformation in laboratories around the world and in understanding the business benefits that ensue. We can work in partnership with you from the outset to add extra guidance, knowledge, and expertise to your case building.

For further support in building your business case, or for more information on how the MODA-EM® Platform can help you digitalize your QC processes, please visit: www.lonza.com/moda

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Less Paper.®



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