Matrix Req

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Application Lifecycle Management (ALM) Buyer's Guide

Making a business case for a requirements management solution

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Executive summary

Advances in artificial intelligence, machine learning and data analytics have made it possible to build far more sophisticated software for medical devices: SaMD (Software as a Medical Device), SiMD (Software in a Medical Device), or the broader concept of SxMD (Software as or in a Medical Device), which covers the full spectrum. The pace of the industry and the demand for better healthcare solutions also mean shorter development cycles. Teams are under pressure to deliver complex products faster without compromising on quality or compliance.

To keep up, your requirements management solution needs to support the full software development lifecycle. It should manage the relationships between design inputs, design outputs and risk management. It must offer robust traceability, respect data privacy regulations, comply with industry standards and support your compliance documentation. And it has to stay flexible enough to fit your processes, support collaboration and integrate with your other tools.

Without the right tools, the result can be quality issues, product recalls and financial losses. You know it is time to look for a better requirements management solution, but there is a catch. A new ALM system is a substantial financial commitment, and it is not easy to get sign off for a new tool in your tech stack, especially if you are still pre-market.

> One of the first projects we managed using [Matrix Req] cleared the first stage of the Medical Device Regulation (MDR) approval process without a single non-conformity. With [Matrix Req], we passed an initial MDR audit in just six months, significantly faster than the same process would have taken us in the past.
>
> **Marco Milani, Project Manager, Tecres**

Building an ALM business case

At this point you need a robust business case. That means showing comprehensive research and a clear plan for moving from your current system, whether paper-based or digital, to a better one.

If you are doing this for the first time, the process can feel daunting. This guide is built to help you write the business case for a new ALM solution, present it to your management team, and plan a smooth transition from your existing system to one that supports the growth of your MedTech company.

> From the moment I started, it was clear that [Matrix Req] has been designed by experts in the medical device development field. The solution is extremely intuitive. We rolled it out to our team and were using it in production in less than a day.
>
> **Thomas Gustafsson, Senior Consultant, Spirotronic**

Identify business needs and objectives

Are you aiming to speed up development, improve quality control or secure regulatory compliance? When you select Application Lifecycle Management (ALM) software for SxMD, identifying your business needs and objectives is the cornerstone of a compelling business case, because precision and compliance are paramount in this sector.

Start by identifying who will use the ALM and the key requirements each of them has. Prioritise those requirements so they line up with your organisation's long-term goals, strategy and regulatory needs, such as those from the EU and the FDA. Decide who in your team will validate the effectiveness of the tool. When you can show how an ALM meets your core objectives, and you have measurable key performance indicators (KPIs) in place to evaluate it, your case becomes far more focused and persuasive.

Steps to identify your needs and objectives

- Identify all users and stakeholders
- Identify all regulatory needs
- Create a list of key requirements for each user
- Align requirements to organisational goals and objectives
- Identify who will validate the tool

> **Tip:** gathering key requirements from each user of the new ALM system makes sure it meets their different needs, which builds buy-in and makes adoption smoother across the organisation.

Analyse current processes

Analysing your current processes is a critical step in selecting the right ALM solution. There are many options on the market and they all work a little differently, especially in the SxMD space. The analysis shows you inefficiencies, compliance gaps and areas for improvement, so the new system fits your organisation's needs. Use this checklist:

- **Document existing workflows.** Map your current workflows in detail, including development, testing, deployment and maintenance.
- **Gather team feedback.** Collect insights from the teams using your current tools: their pain points, challenges and suggestions.
- **Review compliance.** For SxMD, review how well current processes meet the relevant regulatory requirements, for example FDA and EU regulations, ISO 13485, ISO 14971 and ISO 27001.
- **Analyse performance metrics.** Look at KPIs such as development cycle times, error rates and response times.
- **Identify bottlenecks and gaps.** Pinpoint where processes slow down or fail to meet requirements.
- **Evaluate integration.** Assess how well your tools connect with the rest of your software.
- **Assess scalability.** Decide whether your current tools can scale as the company grows.
- **Examine user experience.** Evaluate ease of use and user satisfaction with the current system.
- **Review past incidents.** Analyse past incidents or failures for signs of underlying weaknesses.
- **Compare with best practice.** Benchmark your processes against industry standards and best practice in SxMD.

Market research and options analysis

Thorough market research and a structured comparison of ALM systems are what make an informed decision possible. The goal is a system that meets your current needs and is still the right choice in the long term.

The difficulty lies in the range of solutions, the complexity of their features, how critical regulatory compliance is, and how quickly the technology moves. A careful evaluation, often

with input from technical and regulatory experts, is essential.

To make this easier, use the key capabilities section of this guide as your comparison checklist. Score each shortlisted ALM against every capability, weight the scores by your own requirements, and you have a structured, defensible way to choose the solution that fits your SxMD business.

Cost-benefit analysis

A thorough cost-benefit analysis is crucial when you consider a new ALM system. It gives a full picture of the financial and operational impact of the investment so you can weigh the expected benefits against the costs. Look beyond the obvious factors such as purchase price, implementation cost and efficiency gains, and include the less visible ones: the long-term cost of training and support, the opportunity cost of not investing (lost market share or continued inefficiency), and the effect on employee satisfaction and productivity.

In SxMD, the risks and costs of regulatory non-compliance should never be underestimated. Including all of these factors gives you an accurate, complete view of the investment and its immediate and long-term implications.

Key elements of a cost-benefit analysis

- **Initial purchase price.** The upfront cost of acquiring the new ALM system.
- **Implementation costs.** Setting up and integrating the new system, including any customisation.
- **Training costs.** The investment in training employees to use the system well.
- **Maintenance and support costs.** Ongoing costs of maintaining and updating the system, including vendor support fees.
- **Operational efficiency gains.** Estimated time and cost savings from better processes and workflows.
- **Quality improvement benefits.** The value of better product quality and lower error rates.
- **Compliance benefits.** Cost avoided by meeting regulatory standards, which is especially important in SxMD.
- **Opportunity cost.** The cost of not investing, such as lost efficiency or competitive disadvantage.
- **Employee productivity and satisfaction.** The effect of the new system on morale and work efficiency.
- **Scalability benefits.** The long-term value of a system that grows with the company.
- **Risk and non-compliance costs.** The financial and reputational risk of staying on an outdated or non-compliant system.

- **Market share impact.** Potential gains in market share from better capabilities and compliance.
- **Long-term financial implications.** Costs or savings that are not immediately visible, including future upgrades or expansion.

Return on investment (ROI) projections

ROI projections are a critical part of evaluating any new investment, including an ALM system such as Matrix Req. They quantify the financial return and give a clear picture of the economic benefit.

Understanding ROI is essential for justifying the investment and showing that it fits your company's financial objectives. To help, Matrix One offers a transparent, configurable ROI calculator where you enter data about your own operations and costs to estimate the time and money Matrix Req could save you.

Weighing the tangible and intangible benefits against the costs gives you a complete view of the value the system brings to your organisation.

Results Matrix Req customers have reported

80%
faster generation of technical documentation
Limbus AI

2x
faster document reviews thanks to automated change controls
Diabeloop

95%
faster management of test cases
Cognoa

60%
increase in efficiency when creating product documentation
Roche

1 FTE
saved by streamlining quality management activities
Qvin

15%
improvement in development efficiency
Gabi SmartCare

Calculate your savings

Presenting the business case

Preparing and presenting a compelling business case is how you secure approval and funding.

Start with the specific challenges and inefficiencies your organisation faces today and show how the proposed ALM solution addresses them. Include the cost-benefit analysis and ROI projections to quantify the financial impact. Highlight the strategic benefits too: stronger compliance with industry standards, better product quality and a stronger competitive position. Bring in feedback from key stakeholders so the case lines up with wider organisational goals. When you present, keep the tangible and intangible benefits clear and concise, and support them with data and real examples.

In the end, your business case should justify the investment financially and show how the ALM solution moves the organisation towards its strategic objectives.

Key capabilities

An effective ALM solution streamlines development and makes sure you meet strict regulatory standards. Look for one designed specifically for the SxMD industry. This section covers the capabilities that support operational efficiency, regulatory adherence and product quality without slowing your speed to market.

Operational efficiency

Operational efficiency is the lifeblood of any SxMD project, where time to market and use of resources can decide success or failure. Automated workflows, real-time collaboration and project management, and integrated tools are not just features. They are what drive efficiency, so SxMD projects run with maximum productivity, minimal waste and the best use of every resource.

> With [Matrix Req], we've replaced time-consuming reviews and re-work with a lean and efficient process based on accurate, trusted data. In fact, [Matrix Req] now enables us to complete quality reviews within days, not weeks, around 85% faster.
>
> **Nick Alexander, System Engineer, Lima Corporate**

Automated workflow management. A system that automates routine tasks reduces manual effort, speeds up development and cuts errors by giving the process structure. A strong ALM offers easy-to-use, enforceable digital workflows to standardise review and approval, configurable workflow states for real-time project status, and custom workflows that match your organisation's processes.

Real-time collaboration and project management. A solution that supports seamless communication between team members, wherever they are, improves productivity and reduces delays. A strong ALM supports online collaborative review and approval of items and documents, controls viewing and editing through permission-based access, and includes eSignatures compliant with FDA 21 CFR Part 11.

Tool integration. An ALM that integrates with your mission-critical applications and development tools lets teams work in one environment and stop switching between platforms. A strong ALM integrates natively with development tools such as code repositories and issue trackers, and supports building your own integrations through an API, REST API or SDK so your core applications stay connected.

Regulatory adherence

Compliance with regulatory standards is crucial when you develop SxMD, and an ALM's ability to enforce those standards is vital, not just helpful. Requirements traceability, complete audit trails, effective risk management and document generation are the features that help every phase of development meet the standards regulators expect, protecting both the product and the organisation.

> [Matrix Req] has excellent off-the-shelf capabilities for risk management, which help make a complex process much more manageable. In the past, this process could take up to eight hours, but with [Matrix Req], we can output complete and accurate documentation in just 15 minutes.
>
> **Sven Büttner, Head of Quality and Regulatory, ViViRA**

Requirements traceability. Traceability gives you a structured way to make sure every requirement is addressed and documented throughout the lifecycle, which is central to compliance and safety. A strong ALM offers a fully configurable traceability matrix with multiple levels of depth, supports many-to-many relationships, automatically detects missing or suspect traces, and gives end-to-end traceability between levels of requirements, risks, standards, tests and design.

Audit trails and full audit log. Audit trails give a secure, tamper-evident record of all activity and a verifiable history of the whole development process. A strong ALM logs every change, decision and action, offers easily exportable document audit trails, supports full audit trails you can navigate, and makes it quick to find and correct deviations from planned processes or regulatory requirements.

Risk management aligned with ISO 14971. Systematically identifying, assessing and mitigating risk is a key part of compliance in SxMD. A strong ALM integrates risk management with change control, supports custom risk matrices and evaluation criteria with configurable templates and formulas, and links risks to products, components, suppliers and customers in one place.

Flexible document generation. The robustness and adaptability of document generation should be a top priority. Flexible document generation keeps your compliance documentation aligned with regulatory requirements that vary widely, and makes complex information such as traceability matrices clear and complete.

Product quality

In SxMD, product quality is not just a measure of customer satisfaction. It is a matter of safety and reliability. Rigorous test and change management and robust version control give developers what they need to meet the stringent requirements of the medical device industry.

> If we didn't have [Matrix Req], it would be extremely difficult and time-consuming to work on multiple versions of our solution in parallel, but now, we take this ability for granted. [Matrix Req] has truly unleashed our developers, and we're looking forward to building on our partnership in the future.
>
> **Pierre Grandet, QARA Specialist, Diabeloop**

> Without question, [Matrix Req] has helped us to shift our attitude to development: we're now very test-driven. Our commitment to quality doesn't come at the expense of agility.
>
> **Jeff Miller, VP of Engineering, Cognoa**

Test management and quality assurance. Test management makes testing systematic and complete, which is how you verify quality and functionality. A strong ALM supports creating, running and managing automated tests, traces requirements to test cases, lets you write detailed test cases that cover every part of the software, and helps you hold to predefined quality standards.

Change management. Change is inevitable in SxMD. You need tools that support continuous improvement and let you manage change quickly and accurately without losing quality. A strong ALM makes sure every modification is made in a controlled, systematic way, documents and traces each change, and lets you assess the impact of a change so you can mitigate the risk.

Version control. When several developers work on the same product, version control manages concurrent changes, avoids conflicts and lets teams roll back when a change causes problems. A strong ALM supports separate versions for parallel development and merging changes between branches, so teams can experiment and integrate features without disrupting the main line.

Conclusion

Choosing the right ALM software has several dimensions. You need to stay within budget while securing a tool with the features to meet your current and future needs. The ideal solution scales with your company and fits your processes and the fast-moving SxMD market. A thorough evaluation means you invest in an ALM that streamlines your processes, so you can move fast without sacrificing quality.

See Matrix Req on your own requirements

Matrix Req is the requirements, design control and risk management platform for medical device and regulated product teams. Book a demo and we will walk through traceability, risk and document generation using a workflow like yours.

Book a demo

About Matrix One. Matrix One builds software for life science companies. Matrix Req is certified to ISO 13485:2016 and ISO/IEC 27001:2022. Learn more at matrixone.health/products/matrix-req.

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