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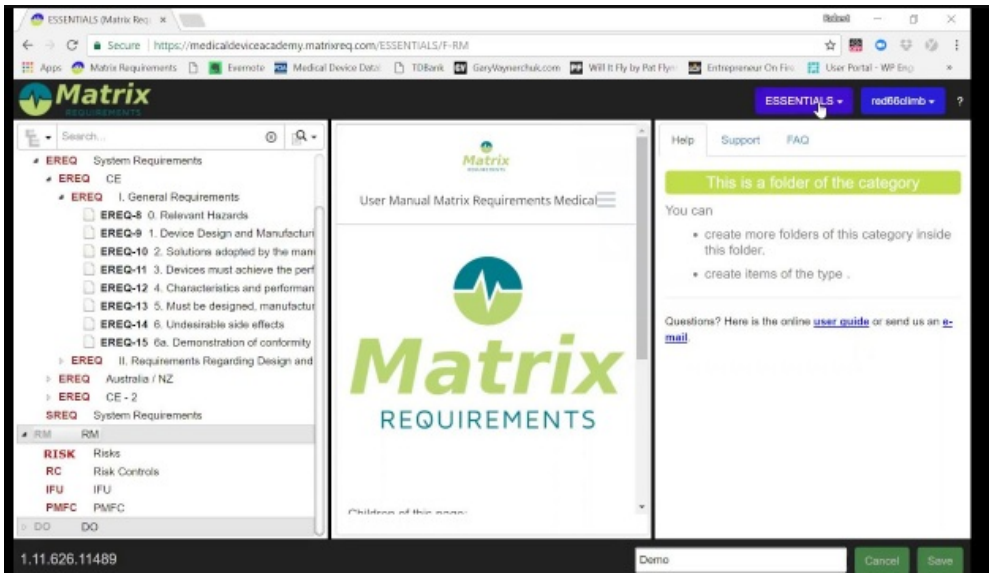
matrix Medical Device Software



Introduction

Matrix Requirements, now part of Matrix One, is a cloud-based Application Lifecycle Management (ALM) and eQMS platform tailored specifically for medical device and SaMD/SiMD development. It streamlines requirements, risk, test, and change

management with full traceability across design history files (DHF), helping teams move faster while staying compliant. The company holds ISO 13485 (medical device QMS) and ISO 27001 (information security) certifications.

Specifications

Feature / Module	Details
Product Suite	MatrixALM (requirements, risk, test, traceability), MatrixQMS (quality system)
Regulatory Support	Supports ISO13485, IEC62304, ISO14971, FDA-QSR, EU M DR
Compliance & Certif ication	ISO13485 & ISO27001 certified
Deployment	Cloud-based SaaS; integrates with GitHub, GitLab, Jira, Slack , etc.
Traceability Engine	End-to-end traceability matrix linking user requirements → tes ts → risks
Risk Management	Built-in support aligned with ISO14971
Audit Logging	Full revision history, electronic signatures, version compare/re store
Validation Deliverab les	Template-based validation plans, execution, reports (FDA CF R-Part11 compliant)

Usage

1. **Install & Onboard**
    - Sign up for cloud deployment. Benefit from free setup/configuration support.
    - Optionally deploy on Windows, Mac, Linux or use via web access.
2. **Define requirements & risks**
    - Enter user/system requirements, tie to risk items, and create traceable design

outputs. Use agile tools like backlog sync with Jira or Git

3. **Execute and document tests**
    - Plan and run test cycles, capture results, and link to requirements for verification
4. **Use QMS tools**
    - Manage CAPAs, audits, suppliers, standard operating procedures, and generate audit-ready documentation.
5. **Validate the tool**
    - Leverage built-in validation templates: System Requirements Spec, Validation Plan, Report. Audit your use and collaborate on versioning

Safety & Compliance

- **Standards-compliant development**
    - Designed specifically to support IEC62304, ISO14971, and ISO13485, ensuring proper risk classification and safe lifecycle processes.
- **Software safety classification**
    - Enables classification per IEC 62304 safety classes A–C based on potential hazard severity.
- **Audit traceability**
    - All actions leave a timestamped log, user metadata, and version comparison—critical for regulatory audits.
- **Tool validation support**
    - Preconfigured validation artifacts (requirements, risk, test, reports) aid regulatory compliance and reduce validation burden.

Get your Medical Device software in market on any budget

Staying ahead of regulatory requirements, managing risks, and ensuring product quality can feel like an uphill battle. Every day, resource strained development teams grapple with mountains of paperwork, fragmented tools, and the constant pressure to innovate while maintaining compliance. What's right for some companies, isn't always the right path for other companies. Choosing the right toolset depends on your organization's specific needs, budget, size, complexity, and growth stage. Read on to see a progression trend commonly seen in the Medical Device software industry.

What are your options?

Paper-Based Systems

- A paper-based system is exactly what it sounds like: a method of managing information, documentation, and processes using physical paper. In the context of SxMD development, this might include printed design history files (DHFs), regulatory documents, risk management plans, and test reports. These documents are manually created, updated, and stored in physical files or binders.
- A new or small Medical Device software company with a limited budget might rely on paper records when the cost of digital tools prohibitive might rely on paper records. Paper-based systems are a great start for businesses who have straightforward processes and the volume of documentation is manageable and simple. However, as each document change requires manual updates, approvals, and filing, which not only takes time but increases the risk of misplaced or incorrectly updated documents, it quickly becomes infeasible. When auditors come knocking, finding the right paperwork

can become a frantic and stressful endeavor. Paper-based might be a good approach in early stages, but in the long run isn't scalable.

Pros

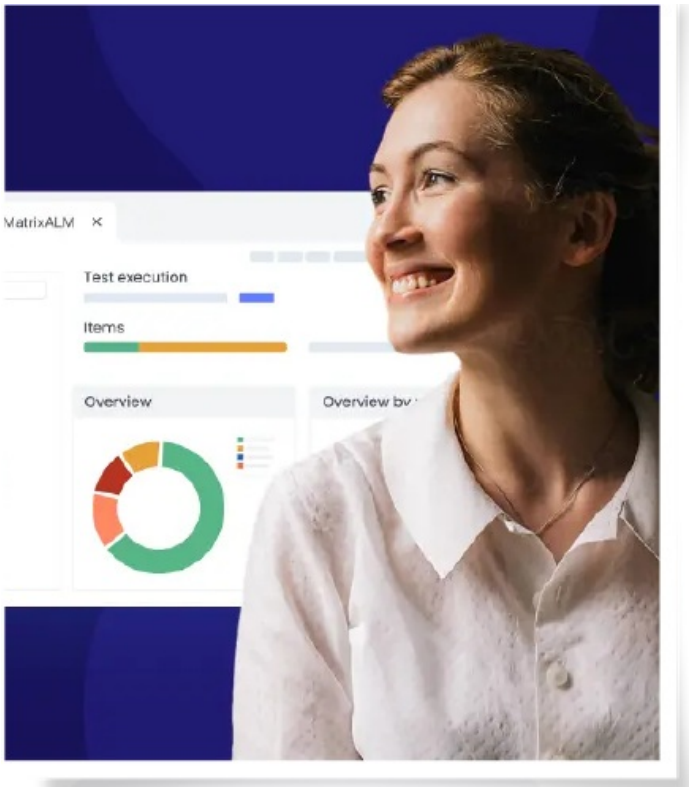
- Simplicity: easy to start, no complex software to learn.
- Accessibility: anyone can access and understand paper documents.

Cons

- Manual errors: prone to human error, which can lead to compliance issues.
- Inefficiency: time-consuming to manage, update, and retrieve documents.
- Scalability: difficult to scale as the company grows.

Indicators that it's time to move on from paper-based systems

- Documentation becomes overwhelming and hard to manage.
- Frequent errors and inconsistencies in manual records. More stringent regulatory requirements that are difficult to comply with manually.
- Expansion of team or product lines necessitates better organization and efficiency.



Project management tools

- Many companies use project management tools in their day-to-day to track tasks and collaborate. It's a logical progression to try and outfit them to fit their needs for regulatory documentation and risk assessment in the Medical Device space since they are generally already using them to manage projects and there are often plug-ins and integrations that can offer a lot of ALM like functionalities.
- Medical Device companies who have minimal integration needs with their other systems but need better team communication and task tracking will find these tools valuable and budget-friendly. While these tools offer more structure than paper-based systems, they still lack the specific features and compliance support needed for the Medical Device industry, making them less suitable for comprehensive SaMD development.

Pros

- Ease of use: often user-friendly and designed for general project management.
- Collaboration: facilitates team collaboration and task tracking.
- Affordability: generally more affordable than specialized ALM tools.

Cons

- Limited compliance support: not designed for regulatory compliance in the Medical Device industry.
- Lack of specific features: missing industry specific features like risk management and design history field.
- Integration challenges: may not integrate seamlessly with other specialized tools needed for SxMD development.

Indicators that it's time to move on from project management tools

- Projects are growing in complexity and your current tools start to feel limiting.
- Need integration with development tools, testing frameworks, and other systems.
- Requirements are exceeding the capabilities of generic project management tools.
- Need a more comprehensive management of the entire lifecycle from requirements to deployment.

One size fits all ALM (Application Lifecycle Management) tools

- Companies often choose one-size-fits-all all ALM tools for their versatility, cost-effectiveness, and broad feature sets. These tools integrate well with other enterprise software and can scale with the company's growth. However, they may require significant customization to meet the specific regulatory and compliance needs of the SxMD industry.
- A company developing software for more than one industry not only specific to Medical Device software that has increasing complexity in their software development projects or the need for integrations with various development, testing, and deployment tools might find a one-size-fits-all ALM to meet their needs best. These ALM tools can track changes, issues, and requirements throughout the development lifecycle.

Pros

- Versatility: can be adapted for various industries and use cases.
- Integration: often integrates well with other enterprise tools.

Cons

- Customization needs: requires significant customization to fit the unique needs of SxMD.
- Compliance challenges: not inherently designed for regulatory compliance in the Medical Device industry.
- Complexity: may be too complex or feature-rich for specific needs, leading to underutilization.

Indicators that it's time to move on from generic ALM tools

- Constantly tweaking and customizing the tool to meet FDA and EU MDR requirements.
- Struggle to align the tool's capabilities with the stringent demands of the Medical Device industry, leading to gaps in compliance.
- Need specialized features such as risk management or regulatory documentation.

- Your core focus is Medical Device software making a generic tool overly complex.

Medical Device software ALM

As companies grow, they often outgrow their existing tools or the weaknesses start to outweigh the benefits. An industry-specific tool will include compliance support, streamlined traceability of even the most complex products, and integrated risk management. These tools are designed to meet regulatory requirements and streamline processes specific to the Medical Device industry, despite potentially higher costs and a steeper learning curve.

Pros

- Industry-specific: designed with regulatory requirements in mind.
- Compliance support: helps ensure adherence to standards like ISO 13485 and IEC 62304
- Risk management: integrates risk management features specific to Medical Devices.

Cons

- Cost: often more expensive than generic ALM tools.
- Learning curve: may require specialized training for teams.

Indicators that it’s time to switch to an industry-specific Medical Device software ALM

- Need to meet specific regulatory requirements (FDA, EU MDR) seamlessly.
- Must adhere to industry-specific standards and practices.
- Need for end-to-end lifecycle management tailored to industry needs.

A natural progression

- By recognizing the signs of growing complexity, regulatory demands, and the need for better integration and scalability, you can make informed decisions about when to upgrade your toolset to best meet your organizational needs.
- Switching to an industry-specific solution, like MatrixALM is an investment.

Understanding the return on that investment (ROI) is crucial. That's why we offer a free ROI calculator. This tool helps you quantify the benefits of adopting MatrixALM by taking into account factors like test documentation efficiency, document review efficiency, and document creation and update efficiency.

Benefits of switching to MatrixALM

- MatrixALM is designed specifically for the unique challenges of the SxMD market. It's not a one-size-fits-all solution but a tailored platform that understands and addresses the intricacies of Medical Device software development and bridges the gap across different teams.

Centralized source of truth so you can innovate faster

- Centralized systems eliminate duplicate work and data redundancy, freeing up time for more critical tasks, foster a more agile development environment, and support rapid prototyping and testing by providing immediate access to all necessary data and tools so teams can iterate faster on their products, speeding up the innovation cycle.
- In MatrixALM, all your data is centralized and up-to-date, ensuring that every stakeholder can access and share information in a unified way improving collaboration and communication. Teams can see real-time updates, reducing misunderstandings and keeping everybody aligned. When all your project information is stored in one place, it's easier to track changes, responsibilities and progress.
- Matrix Requirements uses a flexible item-based approach to data that makes it easy to build regulatory documentation that remains up-to-date as the product evolves. It's easy to visualize your data in dashboards and reports, and see a clear audit trail of changes and updates, which is essential for regulatory compliance and accountability. By unifying your document management and project tracking systems you can drastically reduce time spent on document retrieval and audit preparation.
- "With MatrixALM, we can easily visualize and report on how Contour, including key metadata on which version we are running. This information is very valuable, as it allows us to demonstrate our compliance to regulators." Jon Giambattista, Director of Software, Limbus AI
- "Crucially, we can generate accurate and complete documentation in the formats our regulators need, showing all the requirements, specifications, risks and test cases."

Chris Freudiger, Co-Founder and CTO, Invenio Imaging

Industry experts are building solutions to evolve with the changing landscape

- Choosing an ALM tool built and evolved by industry experts ensures that it's not only robust and compliant but also adaptable to the changing landscape. These experts bring invaluable insights and best practices to the table, ensuring that the tool remains relevant, secure, and efficient. This alignment with industry standards, proactive adaptation to regulatory changes, and incorporation of the latest technological advancements make MatrixALM a strategic investment for any SaMD, SiMD organization.
- MatrixALM is developed and continuously updated by industry experts who understand the evolving regulatory landscape. This means your ALM tool will adapt alongside changing regulations. Plus, industry expats can anticipate regulatory changes and proactively update the software, keeping you ahead of compliance requirements without constant manual adjustments.
- Industry experts help future-proof your investment by ensuring data integrity with robust security measures to protect sensitive data. They keep up-to-date with trends, ensuring the solution remains relevant and effective overtime and can scale to accommodate growth and increasing complexity without needing a complete overhaul.
- "The Matrix Requirements solution stood out from the crowd in a number of key areas," recalls Milani. "Unlike some of the other platforms we considered, MatrixALM is hosted in a secure data center located in Europe, which helps us to ensure that we meet requirements such as the European Union General Data Protection Regulation [GDPR]." Marco Milani, Project Manager, Tecres
- "From the moment I started, it was clear that MatrixALM 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

Integrated Risk Management

- Risk management is essential for maintaining high standards of quality, compliance, and efficiency. It provides a centralized view of all potential risks across the entire project lifecycle and makes it easier to track and manage them throughout the project. By integrating risk management within the ALM platform, risks can be identified early

in the project allowing teams to address potential issues before they escalate which ultimately reduces the likelihood of project delays, cost overruns or failures.

- The integrated risk management within MatrixALM is aligned with ISO 14971. And, because no two companies operate the same, it's fully configurable to meet the needs of any Medical Device software. You have the flexibility to create unique risk matrices to assess risk at varying levels of granularity, for different projects or different phases of software development for better overall project outcomes. With MatrixALM, you can plan, execute, and track risk mitigation activities with dashboards that show detailed information for your risk matrix and RBM (risk before mitigation) and RAM (risk after mitigation) stats.
- "MatrixALM makes it very straightforward to write requirements and link them to specifications, risks and test cases," explains Sanchez. "Wih the Matrix Requirements solution, we can visualize these relationships from a single point of control, eliminating the need for manual, spreadsheet-based processes." Marvin Sanchez, R&D Engineer, IDMED
- "MatrixALM has excellent off-the-shelf capabilities for risk management, which help make a complex process much more manageable," adds Büttner. "As a class IIa device under the MDR, we will have to create new documentation every time we create a new release. In the past, this process could take up to eight hours—but with the Matrix Requirements solution, we can output complete and accurate documentation in just 15 minutes. We're confident that MatrixALM and MatrixQMS will allow us to keep to an agile release cycle without compromising on quality." Sven Büttner, Head of Quality and Regulatory, ViViRA
- "Our former tool was not designed to address the most important aspects of medical device development: the management and validation of requirements through effective risk analysis. To meet our research and development needs, we looked for a solution that was designed from the ground up with these imperatives in mind." Marco Milani, Project Manager, Tecres

Faster solutions and implementation

- It can be daunting to implement a new solution for your business because it takes time and resources away from your core activities. The quicker the system is up and running, the faster you can see a return on investment.

- With MatrixALM, you can leverage existing industry-specific pre-configured templates designed specifically for SaMD and SiMD that include built-in compliance features aligned with regulatory standards such as FDA, EU MDR, and ISO. This ensures that all necessary documentation and processes meet regulatory requirements from the start and streamline audit preparations. They are ready to go out of the box and easily adaptable to your workflows, reducing downtime so you can quickly realize the benefits of an ALM platform.
- For teams who don't have the time or resources to set up their ALM solution, Matrix Requirements offers platinum support services that go beyond the standard application support to ensure seamless operational excellence faster.
- Whether you want support for importing & converting data, audits of your Matrix system, consulting, custom scripts, cyber security guidance, API support and more, our industry experts and support engineers are available to help you configure and utilize your solution and provide best practices guidance.
- Are you switching to an ALM from an existing tool? Download our guide to switching an ALM to make the transition smoother by helping you understand the entire process and avoid common pitfalls. It provides step-by-step instructions, timelines, a best practice checklist, and expert tips to ensure a smooth transition.
- "Their support during the migration and setup process was invaluable, and we successfully switched to the new solution after just two weeks." Michael Strelow, Quality Manager, ViViRA
- "Getting started with MatrixALM was simple; the solution is very well-designed and easy to use. By building on project templates provided by Matrix Requirements, we were able to get up and running within just a couple of weeks. Jon Giambattista, Director of Software, Limbus AI

Connect with your existing ecosystem

- An ALM platform should complement your existing toolkit and not hinder it. Integrations, Software Development Kits (SDKs), and REST APIs are critical components for companies in the SxMD space to support business growth, flexibility, and scalability and ensure long-term viability with new tools and technologies as they emerge.
- MatrixALM offers seamless integration with other tools and platforms in your

development ecosystem with integrations for common developer tools like Jira, GitHub, GitLab, Azure DevOps, and more. Whether it's test automation, or defect tracking, MatrixALM ensures smooth data flow and collaboration across your mission-critical toolkit.

- For companies needing a more custom solution and rapid integration, Matrix provides a robust Software Development Kit (SDK) to help you unlock innovation and efficiency that evolves with your organization. The Matrix updated and enhanced SDK is well-maintained and tested. It includes pre-built libraries, tools, components, and code templates equipped with examples and thorough documentation so you don't have to start from scratch.
- If you want full control over integration and customization with maximum flexibility, Matrix has a REST API that can do everything that the application does.

Conclusion

- Choosing the right toolset for Medical Device software development is essential for maintaining compliance, managing risks, and driving innovation. Whether starting with paper-based systems or advancing to industry-specific ALM solutions, understanding your company's specific needs and growth stage is crucial. MatrixALM offers tailored solutions designed to meet the unique challenges of the SaMD and SiMD markets, ensuring regulatory compliance, enhancing collaboration, and accelerating time-to-market. By leveraging pre-configured templates, integrated risk management, and seamless ecosystem connectivity, MatrixALM helps streamline processes, reduce errors, and support business growth, making it a strategic investment for any Medical Device software organization.
- To learn more, contact us to request a demo with a product expert who can show you how Matrix Requirements can help you get your Medical Device to market faster.

FAQs

Q1: Can I integrate Matrix Requirements with Jira or GitHub for developer collaboration?

A: Yes—Matrix integrates bidirectionally with tools like Jira, GitHub, GitLab, Slack, Rally, ensuring agile teams remain in sync while maintaining compliance traceability.

Q2: Does Matrix support software safety classification per IEC 62304?

A: Yes—it provides risk classification workflows aligned with IEC62304, helping you assign safety classes and manage associated development rigor.

Q3: How does Matrix help with FDA or EU regulatory submissions?

A: It generates audit-ready documentation—including DHFs, trace matrices, QMS records, validation plans/reports—supporting FDA 21 CFR Part 11 and EU MDR compliance workflows.

Documents / Resources

	matrix Medical Device Software [pdf] User Guide DAGdaE7QbNI, BAGLwT-VYsw, Medical Device Software, Software

References

- User Manual

MATRIX

BAGLwT-VYsw, DAGdaE7QbNI, MATRIX, Medical Device Software, Software

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