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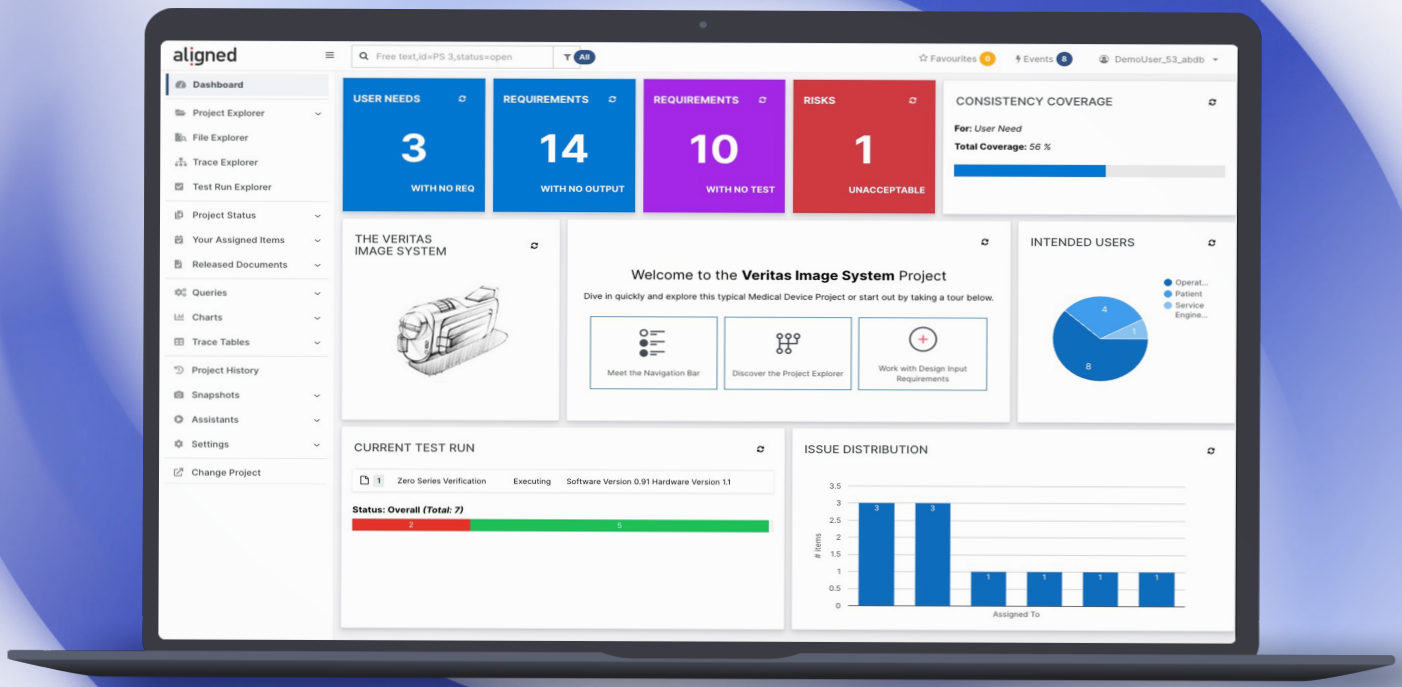
MDR/FDA Compliance & ALM: How Medical Device Manufacturers Build Regulatory Readiness

A Practical Guide for Quality, Regulatory, and Engineering Leaders in MedTech



Introduction

The growing complexity of the global regulatory landscape has significantly increased the technical documentation effort in medical device development. Documented compliance with EU MDR, FDA 21 CFR Part 820, and ISO 13485 can make out as much as 50% of the total development effort, diverting critical engineering resources from innovation to documentation work.

The stakes are high. Incomplete, inconsistent, or incorrect documentation can result in delayed market access, costly Notified Body re-reviews, or triggered recalls.

This paper explains how Medical Device Manufacturers can achieve regulatory readiness using dedicated **Application Lifecycle Management (ALM)** software to transform compliance work from a reactive burden in Word and Excel to a strategic, data-driven, competitive asset.

Context: Why MDR/FDA Compliance Demands a Systematic Approach

The global trend is clear: the technical documentation burden will increase rather than decrease in the future. Medical device manufacturers operate in an environment where regulatory expectations continuously evolve, product portfolios grow, and development cycles accelerate.

In this context, sporadic, last-minute documentation scrambles or audit-driven clean up phases are not sufficient for staying compliant. Regulatory readiness must be built into the daily development work rather than being enforced retrospectively.

Companies that resolutely address this challenge with appropriate software and processes stand to gain strategic competitive advantages, including faster submissions, earlier revenue flows, and the possibility to bring innovation to the market faster than their competitors.

Application Lifecycle Management software provides a structural approach to embed regulatory requirements, traceability, and design control into engineering processes, enabling organizations to maintain compliance in a continuous state of regulatory readiness with minimal effort.

Seeing the Finish Line: Real-Time Regulatory Readiness

The ultimate ALM regulatory readiness is made possible by making the ALM system aware of the desired final compliance state as defined in the medical device manufacturers QMS. This means the expected regulatory outcome, such as the required document structure of the Technical File, the design control elements, and the traceability links expected by regulators, must be clearly defined from the start and made available to the system.

When this end goal defined, the ALM system can be set up to manage all design control elements in a structured way. Requirements, risks, verification activities, and results are not just stored but connected according to the expected regulatory logic. The system understands how these elements should relate to each other inside the Technical File. Instead of discovering problems during audits or reviews, teams see them in real-time, allowing them to be fixed immediately, allowing them to be fixed proactively.

The ALM software can now continuously compare the current state with the target state. It can quickly identify missing links, incomplete reviews, or inconsistencies and make users aware of these gaps early. This permits an agile work approach as the system is now less dependent on the order in which work as done, since the ALM guarantees that the work is complete at the end.

These automated consistency checks reduce compliance uncertainty, regulatory risk and pre-audit cleanup efforts. Reviews take less time because the information is already complete and consistent. Teams spend less time searching for compliance issues and more time resolving them. As a result, regulatory readiness becomes predictable and repeatable rather than stressful and reactive.

From Document to Design Controls and back again

Efficient technical documentation begins with separating the design controls from the documents in which they reside. Documents made up by interdependent design controls such as requirements, risks, verifications, and traceability links are inherently unaware of the other documents on which they depend. Update one document and other documents become inconsistent. The result: non-compliance, failed audits and massive review re-work. By focusing on the design controls first, we ensure that the content is correct and complete before it ever reaches a document.

Once the Design Controls are established and have reached a desired maturity, they can be reassembled into update-resilient documents. The ALM system now understands the content inside each document and can automatically check for inconsistencies or missing links. Teams are alerted immediately, making it easy to correct issues before they affect audits, reviews, or regulatory submissions.

Managing design controls independently allows teams to achieve a much higher degree of consistency, resulting in higher compliance with less effort. Each requirement or risk is properly linked and verified, reducing gaps or conflicts across the technical file. This structured approach makes it possible to create documents that accurately reflect the design control data rather than masking inconsistencies.

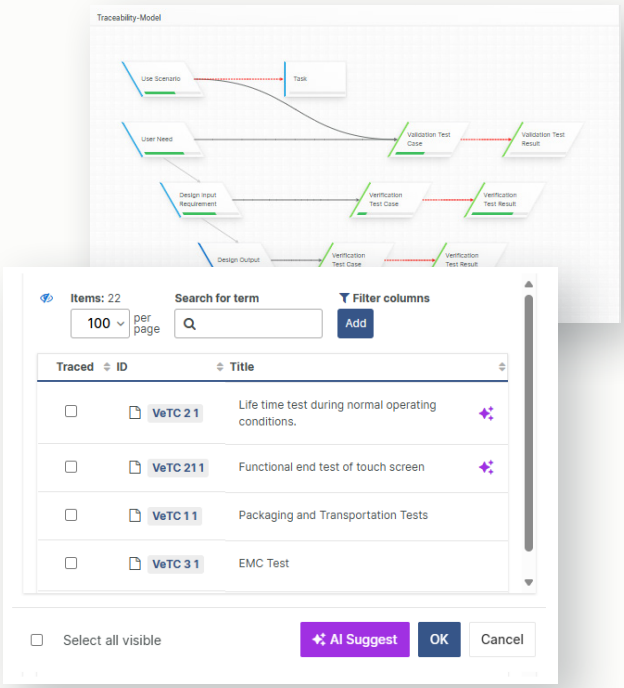
Shifting from a document-centric approach to a design control–driven process transforms documentation from a reactive task into a predictable, rule-based, automated system. Documents become a clear reflection of managed, consistent data, saving time, reducing errors, and ensuring regulatory readiness with confidence.

Key ALM Factors for Medical Device Compliance

Live AI-driven Traceability

Design Control traceability is the glue that holds your Technical File together. With thousands of traces to manage, manual approaches using Excel matrices become unmaintainable.

A designated ALM provides rule-based, AI-driven traceability management with automatic, real-time gap monitoring eliminating manual merging across multiple systems, all set up according to your own QMS rules.

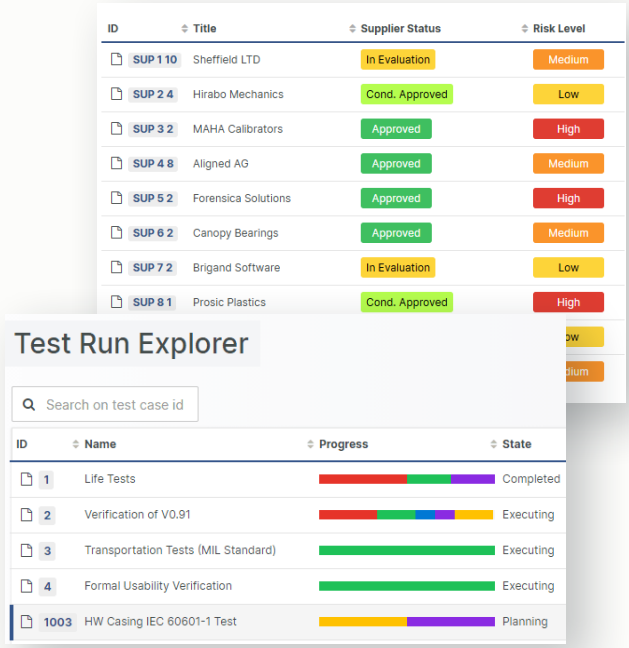


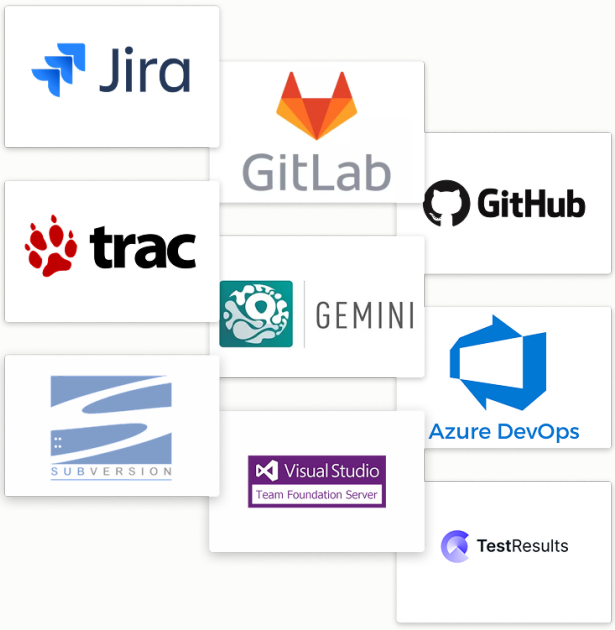
Integrated ISO 14971 Risk Assessment

Risk drives design. Design drives risk. A stand-alone risk assessment approach is therefore doomed to fail. Only with integrated risk assessment capabilities spanning from identification, evaluation, mitigation, implementation to verification within the same platform can real compliance be achieved. No separate risk management tool, no manual synchronization, no version conflicts.

Real-Time Consistency Checks Find Gaps Before Audits

Automated, real-time consistency monitoring finds gaps and errors in seconds. The ALM continuously scans the Technical File for missing risk controls, unreviewed requirements, and broken traceability links. Teams can now achieve regulatory readiness by addressing compliance issues up-front, not during last-minute audit preparation.





Integration With Existing Engineering Tools

No system is an island. The power of an ALM can be multiplied by integrating it with existing engineering tool, expanding the data set on which it can operate and thereby eliminating manual handoffs. Without seamless integration with existing tools, the organization runs the risk of engineers maintaining parallel documentation streams, condemning the documentation to version conflicts and traceability gaps.

Use Case 1: Biotronik Vascular Intervention

From Duplicate Work to Integrated Design Control

Challenge:

The Biotronik Vascular Intervention team struggled to create global technical files due to disconnected software tools and redundant Word reports, making compliance tedious and error-prone. Manual tracking to maintain consistency consumed valuable time, overloading risk management and design control teams leading to user dissatisfaction.

Solution:

A dedicated ALM software to unify design control and risk management, reduce redundancies, and support their entire development lifecycle while remaining adaptable to their specific processes was needed. Selecting Aligned Elements for its configurability and industry-focused design, allowed the team to manage design, test, and risk data in an integrated, consistent way. Tailoring workflows to their needs and leverage interlinked process data lead to greater efficiency and control.

Results:

New users quickly found their way in the new an easy-to-use ALM. The integration of requirements, risks, and tests into a single system eliminated redundancies and improved consistency. The team efficiently migrated legacy data and now leverages linked projects for significant data reuse, achieving high data integrity, automated change control, and a complete, consistent audit record across the entire product lifecycle.

The Aligned Elements UI is perceived as very easy to use. New users are up and running extremely fast.

- Sascha Miskovic, Senior Principal Design Control Engineer,
  Biotronik Vascular Intervention

Use Case 2: Tecan

Reducing Documentation Duplication with 80%

Challenge:

Tecan's modular platform strategy allowed efficient product development and reuse of hardware components, but regulatory documentation had become a growing bottleneck. Each product required a separate Design History File even though the same underlying hardware modules were re-used in multiple products, leading to significant duplication of documentation.

Solution:

Instead of maintaining a monolithic Technical File per product, Tecan used the Aligned Elements ALM to structure documentation around modular design control packages, each containing specifications, risks, and verifications with full traceability and audit trails. Product specific Design Control content was separated from module data and linked across modules, enabling controlled reuse on a massive scale, cross-module traceability, and a significantly more efficient management of the Technical File.

Results:

Tecan significantly increased efficiency using a new modular documentation approach. It was further optimized with a shared requirement pool, eliminating duplicate requirements across products. The change enabled rapid setup of new product documentation within hours by reusing existing, fully traced technical file content.

> *Thanks to the Linked projects feature, we are able to reduce the duplication of module documentation to a minimum.*
>
> - Christoph Karthaus, R&D Manager, Tecan

Implementation Checklist

Phase 1: Define the Target Design Control Model

Start by clearly defining the desired regulatory end state by analysing the existing QMS and development process. The end state includes the required design control elements, document structures such as the Technical File or Design History File, traceability expectations, and applicable standards and regulations. Agree on what “complete and compliant” means for requirements, risks, verification, and change control.

Phase 2: Validate the approach using a Pilot Project

Run a pilot project using a new and/or small project to allow team members active during difference phases of the product life cycle to gain familiarity with the ALM. Gather and analyse the use experience from all team members. Adapt configurations, workflows, templates and process steps to maximize re-use and minimize manual, repetitive tasks in order for each team member to operate as efficient as possible.

Phase 3: Train and Roll Out

Train users on both the mechanics of the ALM tool and the organization's foreseen use of the tool with focus on the underlying design control concepts. With the result from a tried and tested pilot project, with all kinks ironed out, it is time to roll out broadly. Continuously monitor system usage and compliance indicators to properly integrate the ALM into daily work.

Phase 4: Establish a proactive governance stance

Pay attention to user feedback as new projects, potentially using new technologies, might require a new or adapted definition of the desired compliance end state. Update the ALM if new geographical markets are entered. Keep an eye on global regulatory changes (regulations, standards and guidance) and adapt the ALM as new regulatory requirements emerge.

Success Factors and Common Pitfalls

Anchor ALM ownership in engineering, not in IT or QARA

Successful ALM implementations are driven by engineering roles who understand design control dependencies and use the system as part of their daily work. When systems engineers and project leads shape and own the ALM setup, adoption becomes organic and sustainable. Top-down mandates alone cannot achieve the same level of value, trust, or long-term compliance.

Manage risk with a structured proof-of-concept

A POC is an excellent way to reduce and manage adoption risks. Use a POC with real data representing your typical technical file content (as opposed to data provided by the vendor) to properly evaluate the software and validate your assumptions. Don't forget to establish POC success criteria before starting to maximize the use of your POC effort.

Separate tool training from methodology training

Tool training teaches *how* to use the software functionality. This training can often be done by the vendor. Methodology training teaches *why* the design control work is done a particular way in a particular organization. This can only be taught by the organization itself. Separating tool and methodology training ensures that users understand both the regulatory logic and how to implement it correctly in the ALM.

Avoid big-bang implementations

Phased rollouts allow early feedback and rapid adaptation, giving a selected team the chance to refine configurations before the full organization relies on the system. By starting with a subset of projects or modules, users can learn the ALM tool gradually, build confidence, and provide practical insights on what works and what needs adjustment.

Demand technical depth from your vendor

Medical development is a very specific field requiring a deep understanding of both medical device regulations and design control processes. Experienced vendors who truly understand the regulatory landscape can advise on best practices, anticipate pitfalls, and help adapting the ALM system to meet compliance requirements without overcomplicating workflows. Engaging a vendor with this level of expertise reduces implementation risk and is a prerequisite for accelerated adoption.

Conclusion

Medical device manufacturers have more important things to do than diverting their best people to do menial documentation tasks. Maximum value is instead achieved by letting people do what they do best: innovating. Get the best from your development team by giving them the best software tools money can buy.

Continuous regulatory readiness is within your grasp. A dedicated Application Lifecycle Management software, such as Aligned Elements, lifts a big chunk of the documentation tasks off the shoulder of your team. The technology exists, is implementable in weeks rather than months, and delivers measurable ROI within the first audit cycle.

Start Your Audit Readiness Transformation Today

Book a 20-min demo and see live how Aligned Elements reduces your audit preparation. No generic sales pitches, just a hands-on walkthrough with your actual MDR/FDA workflows.

www.aligned.ch

About Aligned Elements

Aligned Elements is a purpose-built Application Lifecycle Management software for medical device manufacturers. Trusted by leading medical device companies worldwide, Aligned Elements provides live traceability matrices, impact analysis, and real-time consistency analysis, making it easy to demonstrate compliance and design control maturity to auditors and notified bodies.

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