MediCompli
SOLUTION

HOW MEDICAL DEVICE SOFTWARE TEAMS CAN BUILD COMPLIANT, AFFORDABLE QUALITY DOCUMENTATION

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HOW MEDICAL DEVICE SOFTWARE COMPANIES CAN BUILD COMPLIANT, AFFORDABLE, QUALITY DOCUMENTATION

A primary challenge facing Medical Device Software teams, is building quality system documentation. A good Quality Management System (QMS) provides the necessary foundation for software innovation, but teams striving for a CE mark in the EU, or FDA approval in the United States, must also meet stringent compliance requirements. The high cost of standalone compliance systems, is a significant barrier to entry for start-ups and smaller teams. What does it take to build a compliant QMS, and are there affordable options?

What is a Compliant QMS?

At its core, the purpose of a QMS is to guarantee that the product developed by the company is "safe and effective", meaning that it will satisfy the needs of the user with an acceptable level of risk. As such, the Quality System documents describe in detail the planning, design and development of a medical device, as outlined in the requirements of ISO 13485, ISO 14971, IEC 62304 and FDA 21 CFR 820.

These documents must show designated reviews and approvals, must be accessible and persistent, and be audit-able by a third party. There's nothing that mandates a QMS must be electronic, but in practice, most teams will find a paper QMS to be too cumbersome and problematic.

The majority of teams opt for an electronic QMS, however, examining a few of the standards makes it clear that digital document control has very specific requirements. While there are a number of standards relevant to the medical device software industry, including ISO 13485, ISO 14971, and IEC 62304, the examples below come from FDA 21

STANDARD
11.10 (b) Documents must be made available for auditors in human-readable and electronic formats.
11.10 (d) System access must be limited to authorized indiviuals.
11.10 (g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.
11.10 (k)(1) Use of appropriate controls over systems documentation including: 1. Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance. 2. Revision and change control procedures to maintain an audit trail that documents time-sequenced development, and modification of systems documentation.
11.200 (a)(1) Electronic signatures shall employ at least two distinct identification components, such as an identification code and password.

It's clear that the standards above necessitate products more capable than Microsoft Word or Google Documents. Digital document control software, needs to include advanced features to be viable for medical device software development:

Document Approval

- 11.10 (k)(1) specifies that there must be control over the revision and change of documents inside the QMS. The only feasible way to add that control, is with a formal approval process that prevents documents from being published unless they've been signed off.

E-Signatures

- FDA 21 CFR 11 clearly states that electronic records systems must employ electronic signatures in approvals. The 11.200 (a)(1) standard clarifies even further that the e-signatures must utilize two distinct identification components, such as a user name and password. Therefore, it is not enough to simply have team members write "approved" on the quality documents, they must formally be electronically signed to be compliant.

Access Control

- The document control system doesn't offer very much control if anyone can access it. That's why access control is a critical piece of compliant digital QMS repositories. By limiting the users that can interact with and publish documents, the finished content is more trustworthy.

Each of these features help meet a critical component of FDA 21 CFR 11 compliance, but they aren't a part of common software tools, like Word. That's why MediCompli was developed; to meet these exact needs, without the expensive price tag of its standalone competitors

BUILDING AN AFFORDABLE, COMPLIANT QMS WITH THE MEDICOMPLI SOLUTION

MediCompli is a turnkey electronic Quality Management System solution, compliant with medical device regulatory requirements. It includes pre-configured QMS content based on ISO 13485, ISO 14971, IEC 62304 and FDA 21 CFR 8203, as well as FDA 21 CFR 11-compliant document approval workflows, packaged together with access management.

The solution is built on the world's premier document collaboration platform, Atlassian Confluence. Confluence is used by teams around the globe to build great documentation, and its sterling reputation for quality, means it's trustworthy enough to meet stringent compliance standards for document accessibility and retention. It is easy and intuitive to use, and integrates directly with Jira, something that is beneficial for software teams utilizing the full Atlassian stack.

Confluence alone approaches compliance, but MediCompli brings together some additional important components that create an entire compliance solution. With MediCompli, Confluence comes pre-loaded with a number of documents and document templates that are configured for a compliant QMS. These documents are augmented with configurable and customizable approval workflows. The workflows let teams add customized approval processes to their pages, and includes the necessary electronic signatures component.

Confluence, the document templates, and the approval workflows, come together to provide everything a team needs to reach compliance.

All of this comes pre-installed on a managed AWS server. Set up, configured, and supported by fully trained and certified cloud engineers, MediCompli's dependable and reliable hosting allows staff to focus on more important things.

WHAT MAKES MEDICOMPLI THE RIGHT CHOICE?

The power of Confluence, combined with the features a software team needs to reach compliance with ISO standards or FDA guidelines, all on a managed AWS server — no other solution puts this kind of package in the hands of medical device software teams. Compared to competitor's systems, MediCompli is fully customizable, more flexible, scales better, and is much more affordable. The cost is start-up friendly while maintaining a premium feature set.

More than just price, MediCompi offers peace of mind.

Compliance audits are stressful undertakings, but a trustworthy QMS can mitigate many of the usual concerns. Confluence's publishing and reporting capabilities streamline the auditing process, and the built-in approval workflows automatically record electronically-signed approvals in the logs. MediCompli also lightens some of the IT load. Managed servers and pre-scheduled updates take the burden off of internal IT teams, so they can focus on other tasks. MediCompli's reputation is already growing among medical device software teams. There are several companies who have successfully built compliant QMS repositories by combing Confluence, built-in QMS templates, and approval workflows.

GETTING STARTED WITH MEDICOMPLI

Teams who need a compliant QMS can get started with MediCompli right away. For more information visit *medicompli.com*, where a recorded demo of the solution can also be found.