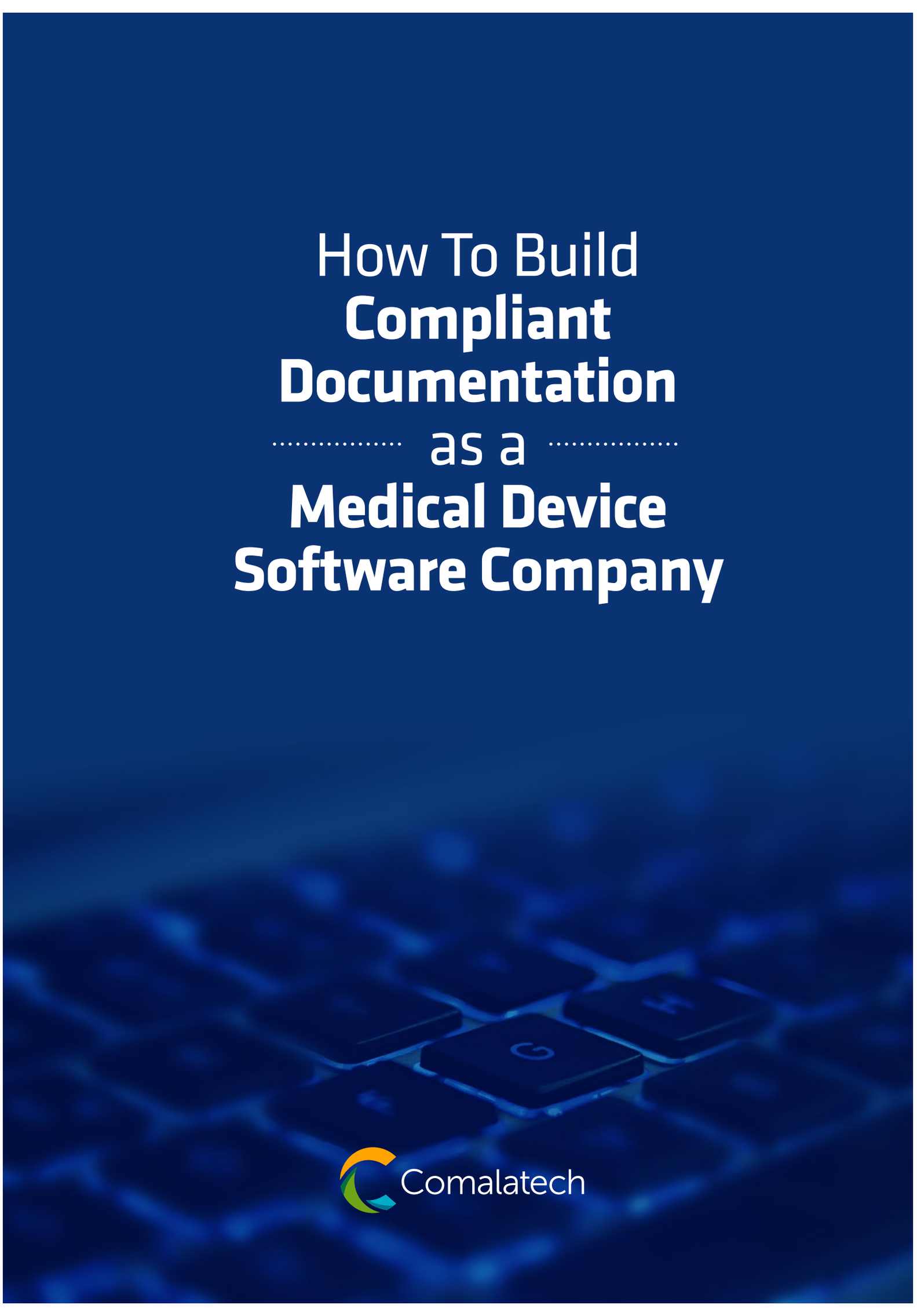
How To Build **Compliant Documentation** as a **Medical Device Software Company**



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How To Build Compliant Documentation as a Medical Device Software Company

The Medical Device industry is rapidly becoming more and more software-driven. Manufacturers of medical device hardware are keen to pair with talented software developers, but they are looking for firms who understand the complexities of complying with documentation standards.

Even development teams designing hardware-independent software, like medical apps, need to be aware of the demands imposed by regulatory bodies in North America and the European Union. This document should provide a solid foundation for companies looking to build compliant documentation for their medical device software

Unique Documentation Challenges for Medical Device Software

There are three major documentation challenges facing medical device software developers:

CHALLENGE 1

Implementing a Compliant Quality Management

CHALLENGE 2

Implementing Digital Document Control for Fully Electronic QMS

CHALLENGE 3

Implementing a Compliant Risk Management Plan

CHALLENGE 1

Implementing a Compliant Quality Management System (QMS)

Companies operating in safety-critical industries like automotive, aerospace, or medical devices, face complex regulatory requirements to which they need to comply.

Medical device companies must acquire a CE mark to sell their products in the EU, or FDA approval for the US market. These regulatory tests include the presentation of rigorous planning and execution documentation. For medical device companies it means assembling a Design Technical File, and providing evidence that the company operates within a ISO13485-compliant Quality Management System.

CHALLENGE 2

Implementing Digital Document Control for Fully Electronic QMS

Safety-critical products can be very complex, and so they are often developed by distributed teams, or in a partnership of several companies working together. A manual process for document management isn't feasible at this scale, so a digital solution that integrates with the QMS is a necessity.

CHALLENGE 3

Implementing a Compliant Risk Management Plan

These same safety-critical software systems are developed within a risk-based framework; the regulatory framework requires the assessment and mitigation of all reasonably foreseeable risks prior to releasing the products on the market. The medical device risk management process has to be documented in a Risk Management Plan, while all the risks, mitigation actions, and verifications need to be reported in a Risk Report.

Navigating the Complex World of ISO & FDA Requirements

In order for a medical device to be certified with a CE mark in the EU or approved by the FDA in the United States it must show that the documentation tracking its software development is ISO 13485 (Medical Devices) compliant. There are a few sections of ISO 13485 that pertain to document control, including §4.2.4 and §4.2.5.

SO 13845 isn't the only standard that medical device software needs to meet in order to marketing in the USA, they also need to be compliant with the FDA's 21 CFR 820 (Quality System (QS) Regulation/Medical Device Good Manufacturing Practices). In addition, the ISO 14971 compliant risk management process is in practice a core part of the Quality Management System. Each of these standards must be met in order for medical devices to be compliant. Although this process can be extremely complicated and interconnected in big teams, the standard requirements for Document Control are actually quite simple. These requirements, described in ISO 13485:2016 §4.2.4 and §4.2.5, and 21 CFR 820.40, are summarized below:

Documents must be reviewed and approved, i.e. have signatures (electronic or handwritten) and date;

If reviewed or modified, they must be re-approved;

Each document must have a revision and the revision must be clearly displayed on it;

Each document should be clearly identified as draft (not released), released or obsolete (other states are possible, these are the minimum requirements);

Documents must be available for people who need and use them;

Documents must remain legible;

The company must prevent documents from being lost or damaged;

Obsolete documents cannot and should be prevented from being used,

External document (e.g. standards, regulations) must be controlled;

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Changes must be approved by the same function(s) (e.g. R&D) as the initial approval, or equivalent; record of changes shall be kept.

Documents must be retained for the life of the device, but not less than records generated by these documents; (e.g.: SOP-AA-bbb gives guidance on how to fill in FORM-cccc; FORM-cccc was used to document the test of product X; thus SOP-AA-bbb cannot be destroyed until the end of life of product X (but it can be Retired / Obsolete)). Note: specific jurisdictions and devices may have higher or different requirements.

Records (e.g. completed forms, results, etc.) follow the same principles;

Records must be retained for the life of the device, but not less than 2 years; Note: specific jurisdictions and devices may have higher or different requirements.

There must be procedures that control the document management process.

Obviously all of this can be done manually, but with distributed teams and large projects digital document control systems with e-signatures is the most convenient solution.

It's possible to meet these standards with a manual paper-based quality management system, or one built in a program like Microsoft Excel, but the reality is that these solutions simply don't scale. A manual process runs the risk of human error. In the medical field, there is simply no room for errors.

The Necessity of Combining Quality Management Systems and Digital Document Control

If an outmoded QMS doesn't scale, then developers and device manufacturers need to find a modern option. There are a wide variety of documentation solutions on the market, offered with different price points and feature sets. What should a team look for in their solution? Of critical importance is the integration of Digital Document Control with the QMS.

Both the FDA and ISO 13485 require a document control system that demonstrates product safety and reliability. Automated systems drive processes that integrate workflow and data capture with applications, databases, notifications and tracking. Getting rid of paper and investing in the right electronic solution not only enhances organizations' digital document handling but also increases the likelihood of regulatory compliance.

The QMS and digital document control is also important in the risk management process. The medical device risk management process has to be documented in a Risk Management Plan, while all the risks, mitigation actions, and verifications need to be reported in a Risk Report. The goal of such detailed and compliant risk management processes is to ensure that medical devices are **safe**; in the Medical Device world, the word "safety" means "freedom from **unacceptable** risk", which implies that any device is always associated with a level of **residual risk**. Simply put, when dealing with people's lives, teams must exercise extreme caution. The risk assessment includes the determination of key hazards, risks, failure modes, and mitigations.

Digital Document Control is simply the ability for administrators to ensure that documents are reviewed, approved, edited, and accessed only by the right people. This type of system allows teams to collaborate on their documentation, but ensures that management never loses control. The ISO and FDA need to see proper sign-offs and approvals. The right QMS, including Digital Document Control, will keep the ISO and FDA satisfied.

Using Confluence as an ISO/FDA-Complaint QMS

Originally built as a wiki engine, Atlassian Confluence's power as a documentation builder suits it well for QMS applications. Confluence has nearly everything a software team could need for building compliant documentation. Its ability to let teams collaborate is nearly unmatched. Available for both Cloud and Server deployments as well as mobile, Confluence is flexible enough to meet the needs of nearly any team.

Confluence has a great documentation engine, but it also has features that lend itself to a compliance environment. User management, page access permissions, and team tasks are all important elements of what makes the software so valuable for thousands of teams.

Developers that use Jira have even more reason to turn to Confluence, thanks to the integration between the two. Safety-critical systems are increasingly packed with software, and so software developers often prefer to work with open and integrated solutions where different aspects of system development are seamlessly linked to one another. Linking your issue tracking and documentation makes it easier for team members to work together.

The main benefit of integrated solutions is the utilization of existing systems within the organization. Utilizing the existing systems will speed up the process of automation, and preparing for regulatory audits. Moreover, for distributed projects, risks need to be managed in a central system where all stakeholders can contribute to risk identification, evaluation and mitigation. Teams need a solution that is affordable and does not require the company to invest in a brand new set of tools.

However, even with the power of Confluence and Jira, there is still a gulf between it and a full QMS solution. The biggest roadblock for electronic records and electronic signatures is the compliance to 21 CFR 11. Amongst several other requirements, it requires the validation of the electronic document management system and electronic signatures. With the wrong tools this can quickly become a very complicated task. Luckily, using apps available on the Atlassian Marketplace, companies can extend Confluence to become the complete tool they need. Three apps are all that is needed to bridge that gap; Comala Workflows, and SoftComply's pair of apps, eQMS and Risk Manager.

eQMS is a QMS "Short Cut"

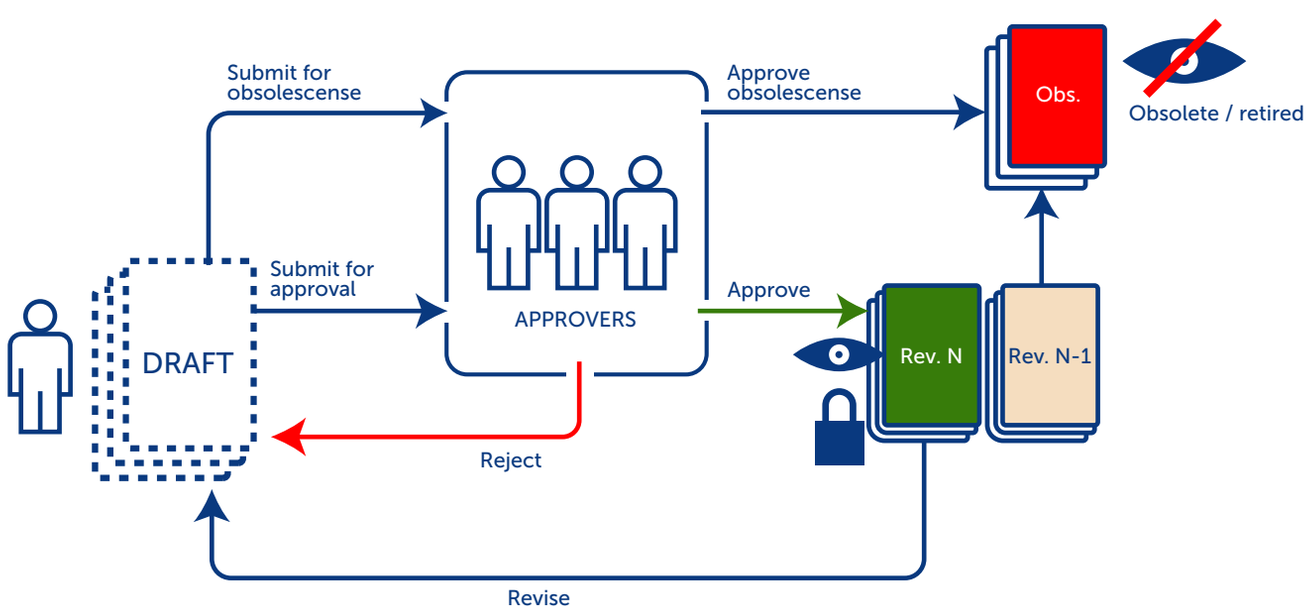
SoftComply analyzed the experiences of emerging software companies to find the ideal method for a new medical device software provider to achieve compliance. The lessons learnt from medical device companies formed the underlying concepts of SoftComply eQMS:

Simple. Maintain a limited number of procedures and templates, to ensure compliance without excessive paperwork overburdening a company. The FDA refers to this as the “least burdensome approach”; quality instead of quantity.

Usable. Procedures are written to be understood by the average user, not an expert in the regulations. The documents in the SoftComply eQMS were created with day-to-day use in mind. Unlike other pre-packaged QMSs, there is little need to consult the parent standards to understand how to use each procedure or template.

Embedded: it is not necessary to install a new software package or revolutionize the IT infrastructure. The SoftComply eQMS is built for Atlassian Confluence, one of the many Atlassian products compatible with Atlassian Jira.

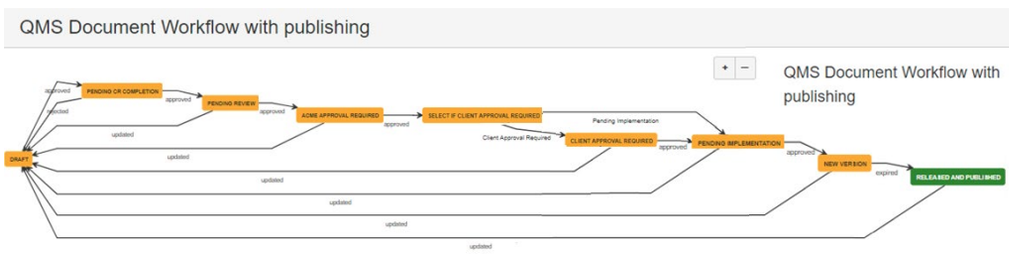
Teams simply establish their Quality System as a space in Confluence (Fig. 1), allowing their users to work with the SOPs and technical documents. Developers can then copy the required templates to any product development project space within Confluence and customize them to whatever the specific project required.



- Figure 1 -

Comala Workflows Provides Digital Document Control

To meet document control needs many companies turn to Comala Workflows, an app available for Confluence. Based on existing document control procedures and the teams' structure, companies can develop their own specific workflows inside the app, defining the required review phases and role-based approvals. Figure 2 shows a real example of one of these workflows:



- Figure 2 -

Teams using digital Quality System documents work more efficiently when those documents are combined with digital document control. To make those systems compliant with FDA and ISO 13485 requirements it is important to configure Comala Workflows and its publishing to Confluence properly.

Setting the document access permissions is critical to achieving compliance, as the hard deletion of documents has to be totally restricted, and the decommissioning of documents has to be handled as part of the document workflow. In addition to those controls, audit trails must be associated with the Quality System documents to keep the archived documents' records as long as needed.

Comala Workflows allows users to view the status of their Quality System documents and know what the next step in the document review process is (Fig. 4):

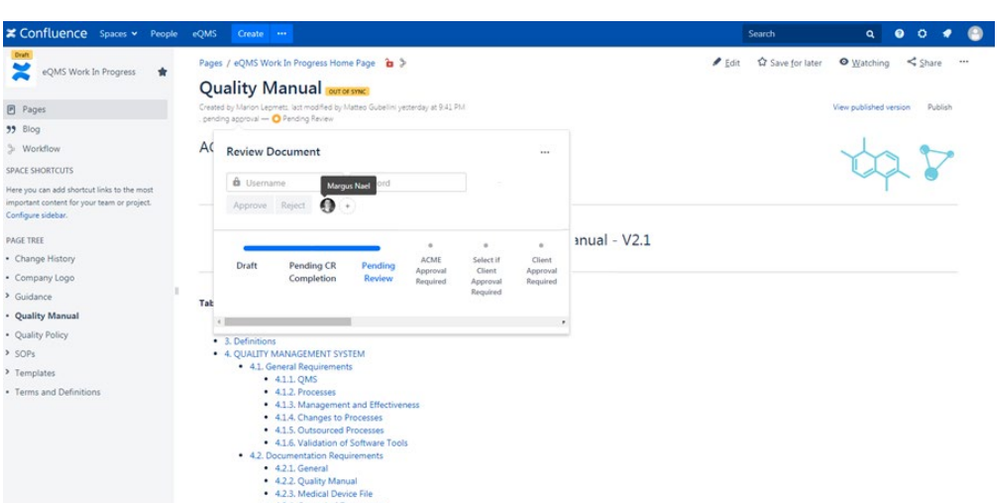


Figure 3 – Checking the status of the Quality Manual

Comala Workflows ensures that all approval steps are conducted in the predefined order verifying that the user has the necessary authority to perform key functions and supports role-based and electronically signed approvals.

Most importantly, all document revision history has to remain attached with the complete audit trail of each Quality System document as shown in Fig. 5 below:

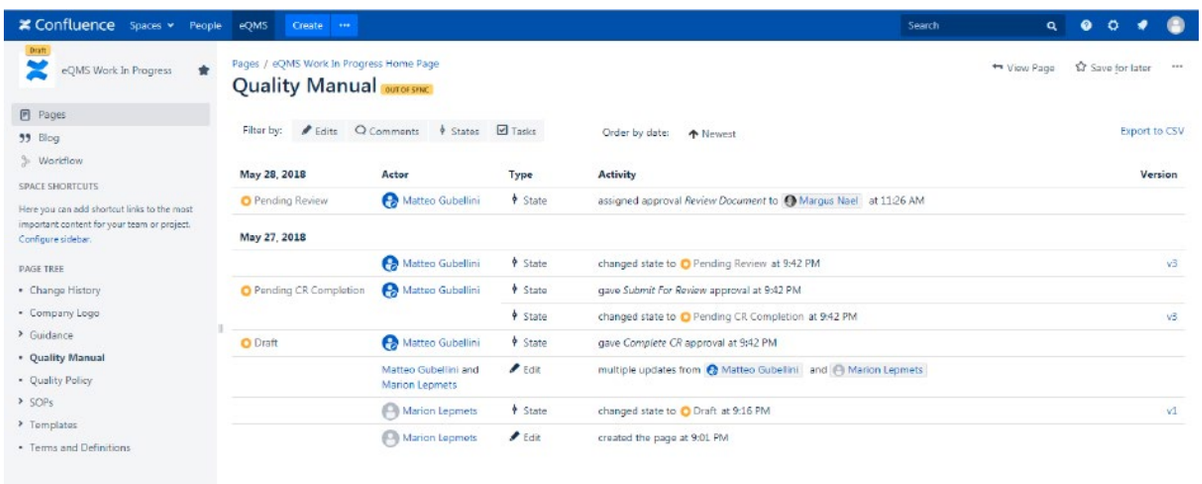


Figure 4 – A full audit trail for each Quality System document, e.g. this Quality Manual

Risk Manager Makes Planning Easier

An integrated risk management solution like SoftComply Risk Manager allows software developers using Jira to utilize their existing Atlassian tools, seamlessly linking software requirements and test cases to risks, as required for compliant risk management. Moreover, the developers existing familiarity with Jira mitigates the need for training, which accelerated the compliance process. The most important benefit of integrated targeted solutions is that the end user of the solution, the Regulatory Affairs Manager, gets exactly the right solution for their problem – there is no additional coding or complex configuration required. SoftComply Risk Manager meets the specific needs of regulated safety-critical system developers while being affordable and integrated to the rest of the development toolset.

Teams who have chosen to automate the risk management process with SoftComply Risk Manager have increased efficiency and reduced costs by a factor of ten, compared to using Excel. The software allows them to complete work ten times faster, while still adhering to regulations, thanks to its full integration with Jira.

Conclusion

As medical devices become more dependent on software, and in some cases are entirely without hardware, the integration of regulatory compliance into the software development platform is not only desirable, but mandatory.

Although there are numerous regulatory compliance software tools, most are conceived from the regulatory perspective, and are not preferred by software developers.

Atlassian tools are the preeminent integration between the rapid software development world, and the world of regulatory compliance. When combined with the apps available inside their Marketplace, it's clear why there software is a popular choice for helping medical device companies stay compliant.

With more affordable regulatory compliance tools the completed devices get to market faster, and with better margins.

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