MediCompli

SOLUTION

OVERVIEW

MediCompli is a compliance solution for the Medical Devices industry. It is based on Atlassian Confluence and includes a pre-configured Quality Management System, with out-of-the-box FDA 21 CFR 11 compliant document approval workflows and e-signatures. All of these are fully customizable for additional workflows and compliance requirements.

The goal of MediCompli is to simplify and automate compliance processes so that users can focus on what they do best — improving and saving lives through medical innovation.

BUILT ON EXPERIENCE

Brought to you by three Atlassian partners, MediCompli is a combination of SoftComply's regulatory compliance knowledge in the medical devices domain, Comalatech's approval workflows, and Clearvision's Cloud and Atlassian expertise.

FEATURES

MediCompli works to simplify and improve the quality of compliance for related processes. Benefits include:

● A built-in user and access management dashboard feature, based on Atlassian Crowd.

● Customization made possible by Confluence.

● Off-the-shelf and easy to navigate workflows implemented by Comalatech, making linking to appropriate spaces possible.

● Pre-configured hosting on an AWS server managed by Clearvision.

● A complete Quality Management System, developed by SoftComply which includes a Quality Manual, Quality Policy, 17 SOPs and 50 document templates pre-filled to fast-track the development and implementation of a QMS.

● Compliant with the following standards and regulations: ISO 13485, IEC 62304, ISO 14971, FDA 21 CFR 820 and FDA 21 CFR 11.

● An electronic signature for a range of applications.

● Automation of regulatory compliance with pre-configured workflows and full QMS documentation — reducing costs.

Supports FDA and CE-marking i.e. targets the regulations in EU and US markets.

● Full customization capabilities to fit any medical device development project.

BENEFITS

How MediCompli helps your business:

● Security and support - Maintained by fully vetted and certified cloud engineers from Atlassian Platinum Solution partner, Clearvision — Atlassian, AWS and Clearvision are all ISO 27001 certified.

● Focus on your core business - The distractions caused by compliance/admin tasks can really affect organizations. MediCompli removes the hassle, leaving you to focus on what really matters.

● Gain time - It's not just about disruption, it's the time it takes to manage these processes which need to be addressed even if they don't add value to the business.

● Pay as you grow - Low entry point for start-ups of any size who require compliance from the get-go.

● Scalability - Add users, products, processes and regulatory requirements where necessary.

CONTACT

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