



7 Signs of an Outdated Medical Device QMS

A hand is shown typing on a laptop keyboard. The background is a blurred image of a document with technical drawings or diagrams. The overall color palette is light blue and white, with a prominent teal accent on the left side.

Focus on Documents Instead of Data

Most software provides some level of cloud capability. But a digitally mature solution is built to deliver a real-time view and analysis of your quality data via a robust SaaS platform, not just let you view your documents online.

Outdated Quality Processes

Outstanding quality and compliance management depends on in-depth knowledge of quality workflows such as complaints, nonconformances, and CAPAs for medical device manufacturers. Unless your QMS provides proven, pre-validated processes — developed around Medical Device best practices — you are not maximizing its potential to increase efficiency and effectiveness.

Limited Accessibility

Quality events rarely occur when it's convenient. You need the ability to support a "see something, say something" culture and allow users to view, log, and manage quality events at any time, from anywhere. A QMS that doesn't provide 24/7/365 access from any location doesn't give you the mobility you need.



Performance Issues

Change is inevitable, be it M&A-driven expansion or an increase in quality data. A QMS that isn't built to rapidly scale in terms of concurrent users or volume of data could mean a slowdown in performance—the last thing you need.



Lack of Real-time Supply Chain Visibility

End-to-end medical device lifecycle visibility demands real-time collaboration, so you can maintain quality standards throughout your extended supplier network. That can't happen unless both your quality teams and your suppliers can connect to the same platform for audits, changes, corrective actions, and more.



Rigid, Proprietary Technology

Hosted QMS platforms built on proprietary technology can limit your ability to manage rapid change, balance IT resources, take advantage of emerging technology, and integrate with the rest of your operational infrastructure.

Unfriendly User interface

A quality system is only useful when fully adopted.

A QMS with an unfamiliar or difficult-to-navigate interface, unintuitive navigation, or a steep learning curve can alienate users and reduce quality process compliance.