

# Streamlining & Managing **ACCREDITATION**

For Medical Device Manufacturers  
Who Make Quality the #1 Priority

Quality is very important in today's marketplace and is often what differentiates a good product from a great one. Manufacturers that strive to be industry leaders know that a focus on quality and compliance to industry, customer, and internal standards is essential.

Qualtrax helps medical device manufacturers simplify compliance to regulatory standards with document management and workflow capabilities.

Qualtrax is an all-in-one compliance solution for ISO, FDA, GMP, 21 CFR Part 11, and more.



## Why Qualtrax?

Combining a robust document control engine with automated workflows, standards-based auditing, and employee testing capabilities, Qualtrax is an all-in-one compliance solution for ISO and other quality standards, accreditation requirements, and managing both internal and external audits.

## FEATURES AND BENEFITS

### Document Control

- Keep policies and work instructions up-to-date.
- Ensure only the most current version of any document is available for reference.

*Document control solves the control issues associated with paper-based documentation and improves accessibility to important information.*

### Flexible Workflows

- Automate paper-based processes, such as CAPA.
- Robust escalation management and tracking.
- Easy to create, modify, and run.

*The workflow engine streamlines business processes and eliminates unnecessary paper.*

### Audit Management

- Documents are associated with specific standards.
- Gap analyses can be performed to identify missing documentation.
- Searches and reports can quickly display compliance weaknesses.

*This tool significantly reduces the time needed for internal and external audits*

### Testing, Training & Reporting

- Tests can be "stand-alone" or associated with any document.
- Store training records and test results for employee files.
- Design and run custom reports on the status of documents and workflows for a "snapshot" view of the entire quality system.

*The training function allows supervisors to train employees for specific processes and procedures and maintain records of the results to ensure competency. Reports provide visibility of process issues and a "health check" of the entire quality management system.*

For a demonstration of how Qualtrax can simplify accreditation, call 800.755.1875 or 540.260.9961 or email [requestinfo@qualtrax.com](mailto:requestinfo@qualtrax.com)



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