Enzyme QMS

Premarket Plan

Enzyme QMS empowers you to conduct key premarket activities like building your design history file, analyzing risks/hazards, and monitoring supplier performance to help improve the quality, safety, and effectiveness of your products. And because we offer postmarket modules too, after your product launch, we'll continue to help keep you compliant, which means you'll never have to migrate to another QMS, ever.

Design Control

Manage your design data granularly so you can manage design history and traceability with ease. With Enzyme QMS, you can focus on your data, not your documents.

- Enable your QMS to be a true system of record by connecting systems like Jira, GitHub, Google Drive, and Zephyr so you never have to do anything twice
- Stay audit-ready with a design history file that can be exported at the click of a button, customized to your input
- Identify missing traces to outputs, tests, and risks with our one-click live traceability view
- Demonstrate GxP compliance with easily-accessible revision histories and Part 11 compliant eSignatures

Risk Management

Seamlessly assess, prevent, and control risks across the total product lifecycle to demonstrate compliance and build trust with patients and customers.

- Build ISO 14971 compliance into your design controls
- Employ an exportable risk matrix that details each hazard, hazardous situation, and harm, and calculates both initial and mitigated risk scores
- Demonstrate comprehensive risk control during external audits and show traceability to related controls

Suppliers

Use Enzyme QMS to simplify your supplier management process and ensure compliance to 21 CFR, ISO 13485, and ICH Q10.

- Track and monitor supplier performance from onboarding to discontinuation
- Categorize suppliers by risk, rating, type, and product
- Utilize in-app metrics and reports to understand supplier performance over time
- Automate manual supplier management tasks
- Easily export your approved supplier list (ASL) and approval history to PDF and Excel

Enzyme

Serving teams from 2 to 2,000, premarket to postmarket, startup to enterprise, Enzyme is the only QMS you'll ever need — or want.