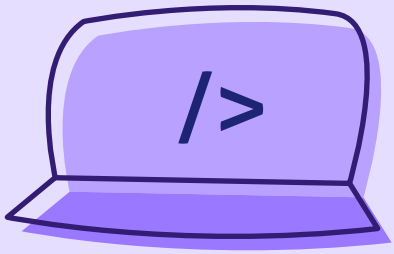
Qualio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Design controls management software

How Qualio drives concerted, compliant medical device product development

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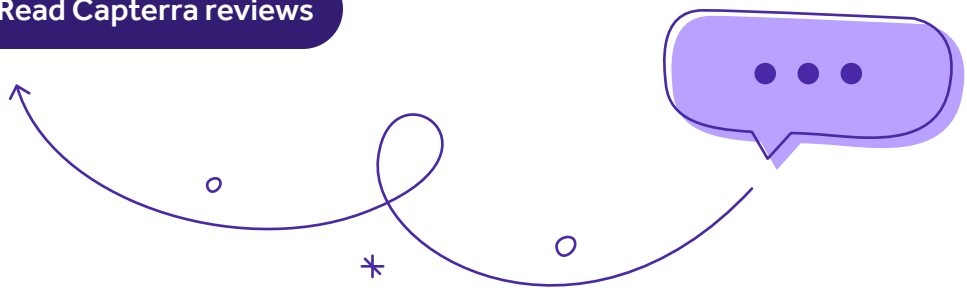
Qualio was founded in 2012 with a simple but important mission: to help life science organizations bring their vital products to market with a faster, stronger, more quality-centric approach.

Over 500 life science and healthcare businesses across the globe use Qualio to centralize, optimize and automate their quality management systems.

Qualio is a scalable and flexible cloud-based system that grows with your business and makes meeting your quality requirements truly simple, from ISO 13485 and ISO 17025 accreditation to FDA and GxP compliance.

Read G2 reviews

Read Capterra reviews



Medable

imbio

CENTOGENE
THE RARE DISEASE COMPANY

Lunaphore
technologies

AVECTAS

Biofidelity.

Cardiaccs

PROSCIA

Bringing quality and development into harmony.

In a perfect world, quality professionals would have quick and painless access to the product development information they need for design controls management. But it isn't always like that.

Your development and engineering teams use other tools for their day-to-day work and don't want to duplicate effort for your quality system. By the time you gather and centralize design control data yourself, it's already made out-of-date by new activities.

Fragmented workflows, information gaps and siloed platforms frustrate your colleagues and interested parties, block your route to market and make it difficult to show your auditor holistic design control management.

At Qualio, we believe quality should be an empowering — not an opposing — force for your product development velocity. So our Design Controls functionality has been developed for medical device hardware, SaMD and SiMD manufacturers who want to bring their quality and development teams permanently into lockstep.

From centralizing product information to removing departmental friction and generating deep and accurate real-time data, Qualio Design Controls arms your business with a coordinated and directed pathway to market that doesn't slow you down.

Kelly Stanton
Director of Quality, Qualio

Effortless design controls

Qualio Design Controls is used by hundreds of medical device companies to structure, strengthen and centralize their product development and quality activity. Use Design Controls to embed effortless and concerted design control management:

1. **Centralize by product**

   Categorize your development activity in a single source of truth from user requirements to test data — all arranged logically by product.

   Drag and drop drawing and design PDFs to attach them to your user requirements, test cases and results.

2. **Connect your data**

   Automatically pull design elements straight from the source systems your development and engineering teams use, like Jira, TestRail and Azure DevOps, or manually add requirements yourself.

3. **Integrate your risk management**

   Record, categorize and treat your product risks with built-in FMEA and ISO 14971 methodology frameworks, including 3x3 or 5x5 risk matrices.

4. **Prove compliance**

   Gather all your product development documentation in real time, from inputs to V&V, and view and export at the touch of a button to demonstrate compliance with ISO 13485 Clause 7.3 and FDA 21 CFR Part 820.

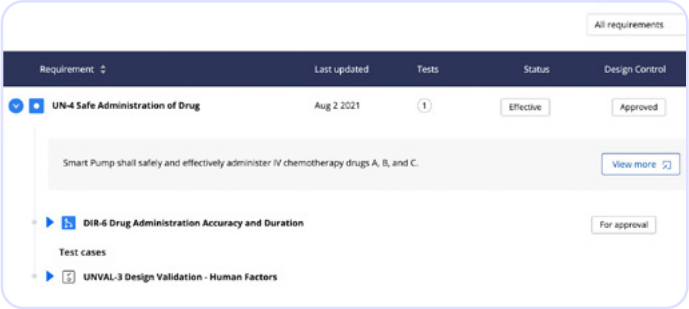
5. **Automatically create what you need**

   Automatically generate trace matrices, requirements documents and more as change controls are managed and completed with end-to-end visibility.

Key modular features

Powerful integration

> ***Qualio stood out for us because it was cloud-based and optimized for medical device companies. Qualio was the right investment.***
>
> **— Andy Levien**
> CEO, ArcScan



View integrated documents from Jira, TestRail and more within Qualio Design Controls

Your colleagues already know and love product development tools like Jira, Azure DevOps and TestRail. This can hinder collaboration with the quality department, particularly if you ask them to start using a new eQMS.

Qualio Design Controls allows you to work with this familiarity, not against it, by automatically pulling data from these source systems into Qualio with always-on API synchronization.

Absorb and centralize business-wide product development activity, from inputs to verification and validation, into a product-based design control repository.

View activity updates, trace your product development lifecycle from end to end, and access and export key documentation like test plans and trace matrices, all without ever leaving Qualio.

Your engineering teams get to stick with familiar and embedded tools. Your quality team gets to jettison time-heavy manual searches through multiple systems to get the information you need. Enjoy end-to-end design control traceability, irrespective of where product development activity occurs in your business.

Qualio Design Controls integrates with:

Jira

Azure DevOps

TestRail

Asana

Top Tip! *You can always manually add fresh device and user requirements into your system at any point too!*

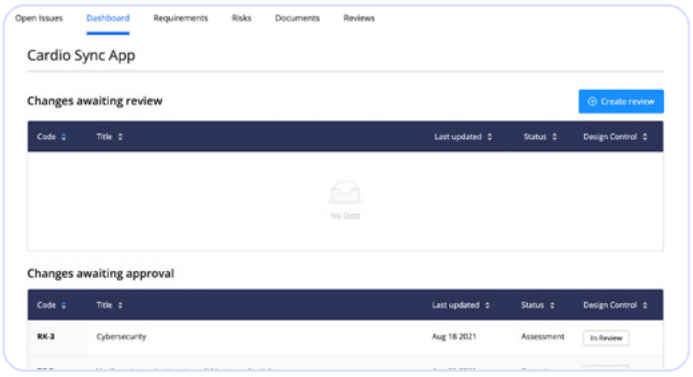
Centralized design information at your fingertips

> *Qualio enabled us to seamlessly work through our ISO 13485:2016 requirements and design errors out of our quality management system.*
>
> **— David Hughes**
> CEO, Surfatek

Qualio Design Controls arranges your design control information by product as follows:

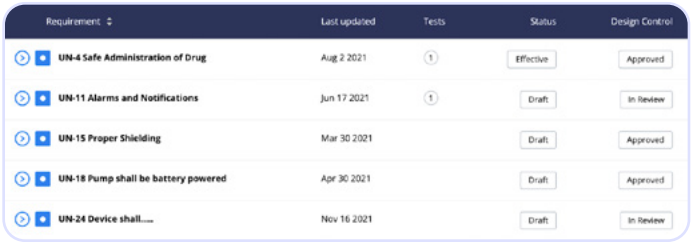
- Requirements
- Risks
- Open issues
- Documents
- Reviews

Product-specific action dashboards provide at-a-glance visibility of product changes awaiting review and approval, giving the quality team a synchronized picture of your design elements as they mature and evolve.



View your design control activity and outstanding tasks in a clear, intuitive framework

Dive into the Requirements tab to access user requirements information from top—level user needs through to design inputs, outputs, verification and validation.



Access organized user requirements quickly and easily, with associated tests and status

Drill into product design changes to access critical decision-making information, like connected hazards and review histories.

Attach design and drawing documents to your requirements and test elements to centralize your information - then export them as a ZIP at the touch of a button.

And generate formal change controls straight from your product dashboard, closing them out with FDA 21 CFR Part 11-compliant e-signatures.

Best of all, this information is constantly aligned in real time with the work your development and engineering teams are doing, simplifying communication and making status meetings obsolete.

Smart risk management

> *Qualio keeps us in a constant state of audit readiness. We chose Qualio as we needed our system to be scalable to support our rapid growth.*
>
> **— Deb Glancy**
> Director of Quality, Ultragenyx

For effective design control management, your business needs to demonstrate robust and integrated risk control in tandem with FMEA and ISO 14971 principles. Qualio Design Controls offers a risk repository for every medical device your business works on, collating:

- Risk, hazard and harm information
- Pre- and post-mitigation assessment levels
- Status
- Review histories
- Failure mode and effects analyses

Build ISO 14971 risk matrices in 3x3 or 5x5 formats to capture, assess and treat risks how you want.

Risk	Hazard	Hazardous situation	Harm	Initial	Final	Last updated
RK-14	Mechanical, Interfacing Components	Crack in the tubing causing loss of damage	Underdose: ineffective therapy	High	Medium	Dec 17 2021
RSK-1	Mechanical, Interfacing Components	Crack in the tubing causing loss of dosage	Underdose: ineffective therapy	Medium	Low	Mar 29 2021
RSK-2	Mechanical, Electrical	Over-administration >5% over target	Overdose: serious injury or death	Low		Apr 28 2021
RSK-3	Mechanical, Electrical	Under-administration >5% under target	Underdose: ineffective therapy	Low		May 5 2021

Drill into complete risk registers with associated system information, collated automatically into ISO 14971 and FMEA frameworks

Simplified compliance

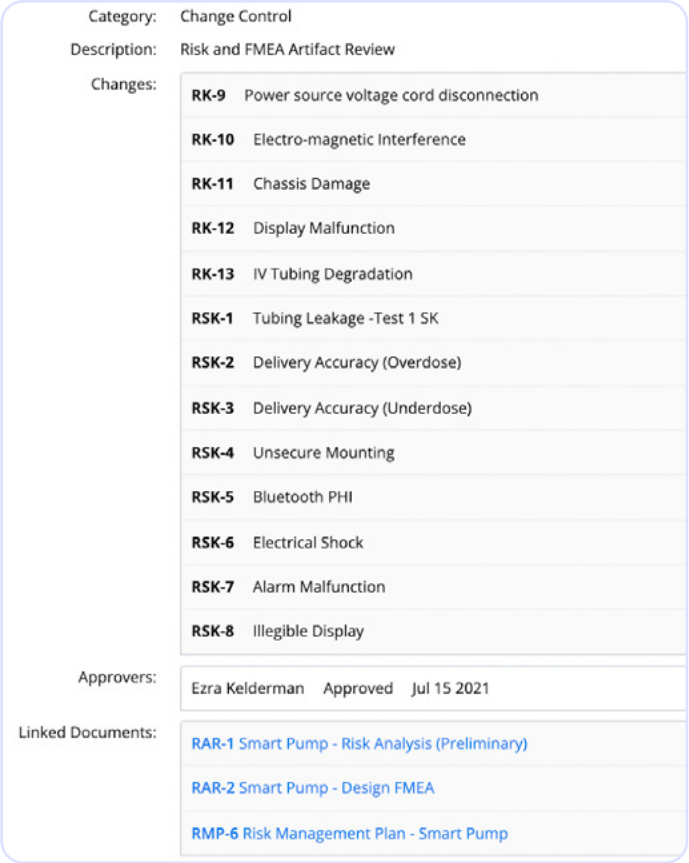
> *Qualio has allowed me to develop a complete medical device quality system for a small company in a way that is Part 11-compliant and provides custom formatting, easy navigability... all without breaking the budget.*
>
> **— Barbara Young**
> Senior Quality Manager, Proscia

Design control management is a key trigger of FDA citations. Common FDA complaints include underdeveloped processes and a failure to adequately document risk analysis and validation activity. Plus, manual design control usually requires unwieldy spreadsheet-based design control processes that take

up your valuable time and weaken your compliance and accuracy.

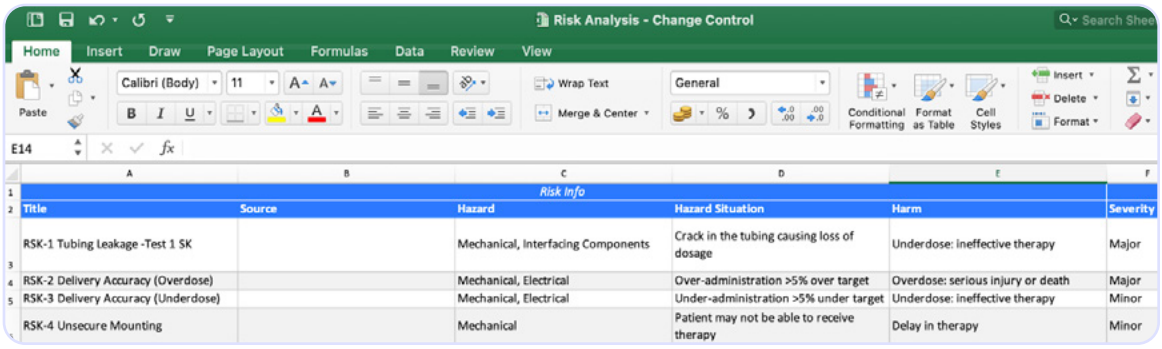
Qualio Design Controls empowers you to ditch your manual data collation by automatically generating key reports, such as trace matrices and requirements documents, with the approval of every change control — ensuring every action your business takes is mirrored instantly in your document stack.

Export key files, like risk matrix XLSXs or design attachment and review document PDFs, at the touch of a button to show your auditor. And store your generated documents in Qualio Documents too, arming you with an integrated single source of truth for all product development data that you can quickly navigate and interrogate. Replace the time you would've spent on laborious document wrangling with what really matters: working your way through design change controls to ensure your finished hardware or software product meets your user requirements from every dimension.



View design element changes, linked documents and automatically generated output documents quickly & simply

And while you work, be confident that your business is completely audit-ready at all times.



A risk analysis XLSX document exported straight from Qualio

10 reasons to manage your design controls with Qualio

01. Break down internal friction by bringing quality and engineering together in a single area

02. Pull design information automatically from your development software systems or add requirements manually as you wish

03. Tackle risks with a FMEA and ISO 14971 approach every time

04. Access a central repository of all design control information, from user requirements and design attachments to testing and validation

05. Save time with automatic document generation

06. Stay compliant with Part 11-compliant e-signature sign-off

07. Keep your documents and data in constant, compliant harmony with your development activity

08. Pinpoint gaps, weaknesses and action points at a glance and be constantly audit-ready

09. Get to market ten times faster (based on a real Qualio customer experience!)

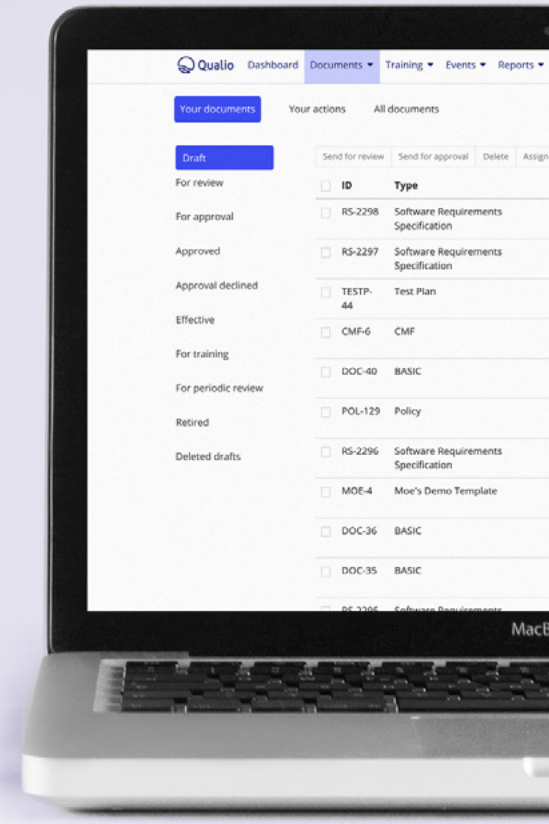
10. Explore open issues, outstanding change controls and review histories quickly and simply

Qualio

Ready for a stronger approach to your design controls?

We'll answer your questions, give you a live private tour of the product and help you determine if we're a good fit for your design control management needs.

Schedule a demo with us



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