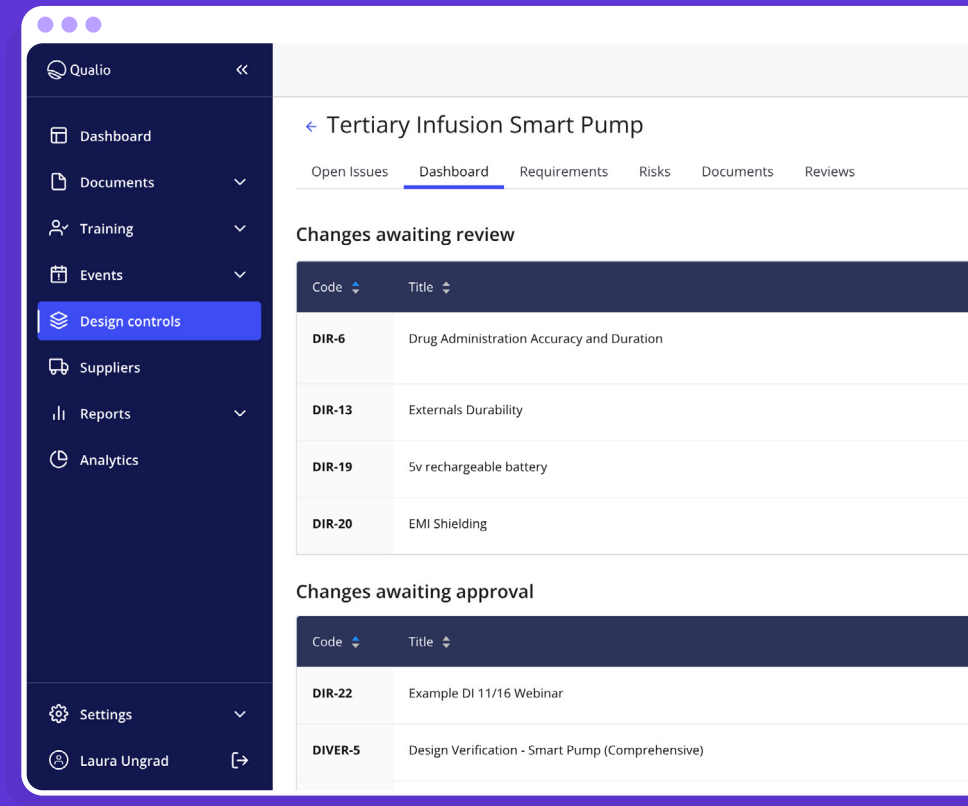
Qualio

QUALIO PRODUCT GUIDE

Qualio Design Controls

For safe, effective and compliant medical devices



Qualio's eQMS software empowers growing life science organizations to do their vital work with a stronger, faster, more quality-centric approach. Our software is built and continuously improved with three key objectives at the core:

To be the easiest, most intuitive eQMS on the market

To seamlessly connect your internal and external stakeholders to your quality work

To empower your growth with flexible, collaborative quality content management

Over 650 life science businesses across the globe now use Qualio to optimize and automate their quality management systems.

Request a demo

Design control management software for modern medical device challenges

We were trying to do our design controls in Excel, and the team was screaming at each other. When we saw Qualio, we realized what we were missing. The whole process was a lot smoother after that. It was a big win for us.

Watch interview snippet

MICHAEL HALLOCK

VP of IT
SimBioSys

We can go into Design Controls, select a project and see all the documents linked and interconnected. Having everything in one place is an excellent option to have.

Watch interview snippet

DIVYA MAVALLI

Director of Regulatory & Quality
ProSomnus Sleep Technologies

Design control management software for modern medical device challenges

I contacted Qualio in November. We went live mid-December. We had all users in by January. And we had our ISO 13485 certification by July. Without Qualio, we'd never have done that.

Watch interview snippet

KAREN HUE

Head of Quality & GxP Compliance
30 Technology

It wasn't just a sales pitch with Qualio. They told us what was going to happen and they executed exactly. When I didn't know how to do something, Casey made a video to show me. To me, that's where the value is. We're a partner, and Qualio treats us like partners. That's probably the rarest of all when you're dealing with software companies in this area.

Watch interview snippet

LOWELL HOFFMAN

Director of Quality Assurance
Restech

Two-thirds of our customers bring new products to market using our software.

They report...

>90% reduction in quality admin time

25% faster design control processes

1-3 FTE spends mitigated

140% increase in device marketization speed

5x faster external audits

More collaborative quality cultures built on controlled information

Simplified compliance with FDA 21 CFR Part 820, ISO 13485, ISO 14971, EU MDR/IVDR, and more

5 software features to optimize your design control processes

This datasheet is designed to give you and your colleagues an introduction into how the Design Controls area of Qualio helps your business get robust, best-in-class design control management in place.

We've picked out the 5 top things we think you should see.

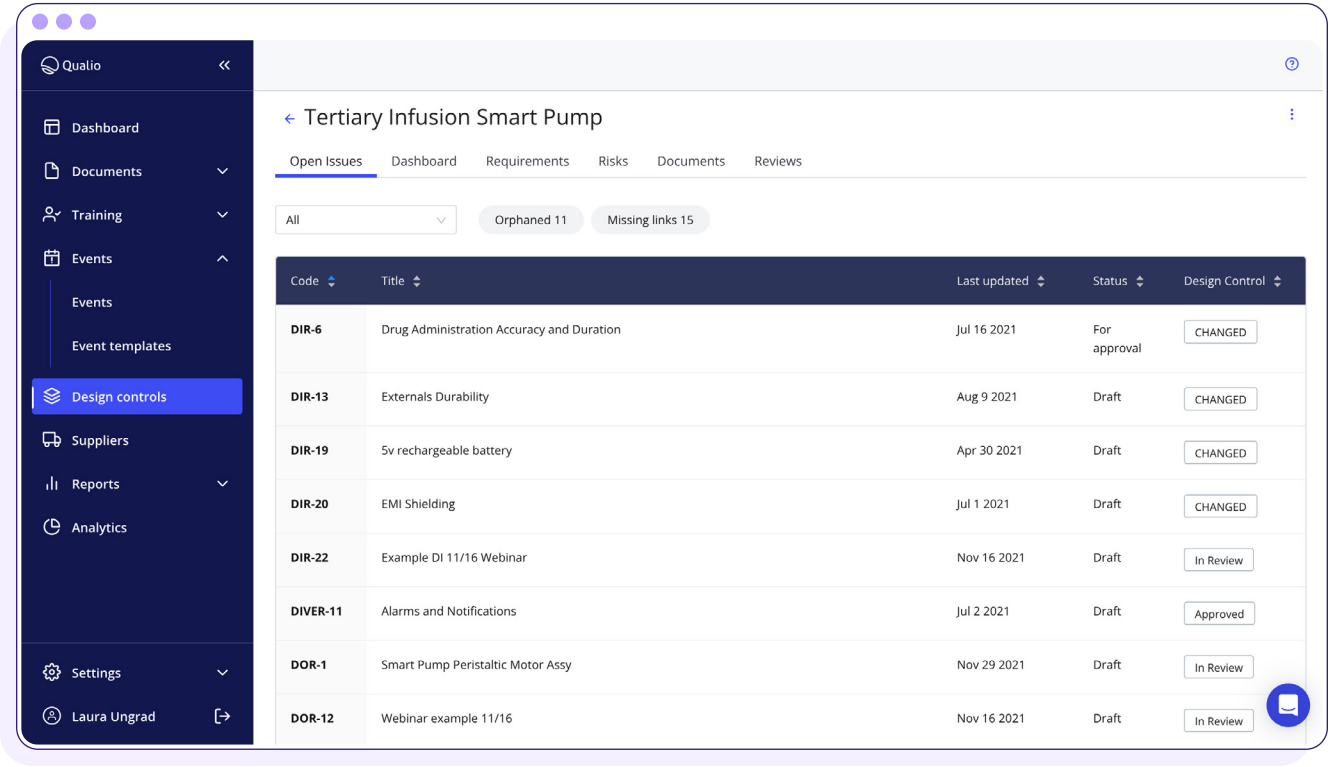
Want to see more, including a walkthrough of Qualio in action? Visit the last page to book a demonstration at a time that suits you.

1 Centralized design information for a controlled pathway to market

Qualio Design Controls lets you organize and manage all of your design control information by product as follows:

- Requirements
- Risks
- Open issues
- Documents
- Reviews

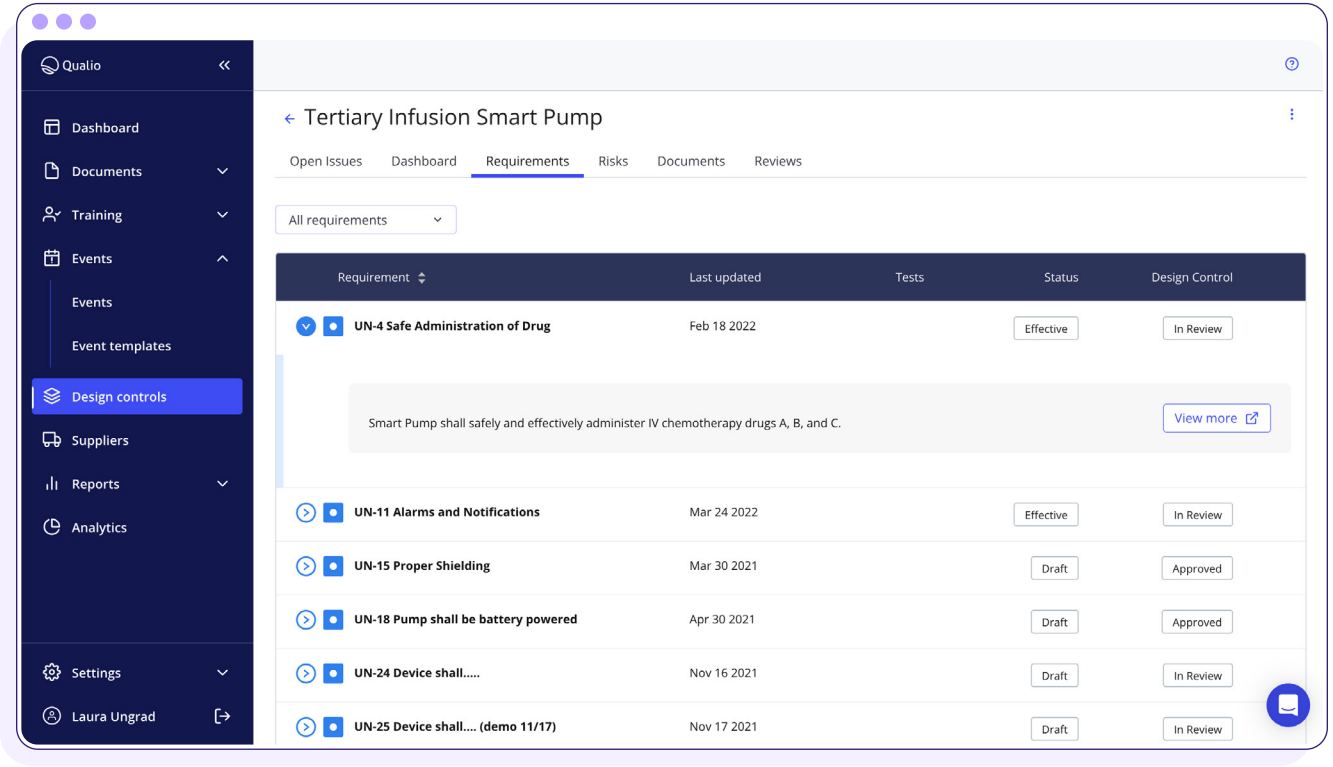
Product-specific action dashboards provide at-a-glance visibility of product changes awaiting review and approval, giving the quality team a synchronized picture of your design elements as they mature and evolve.



1 Centralized design information for a controlled pathway to market

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

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

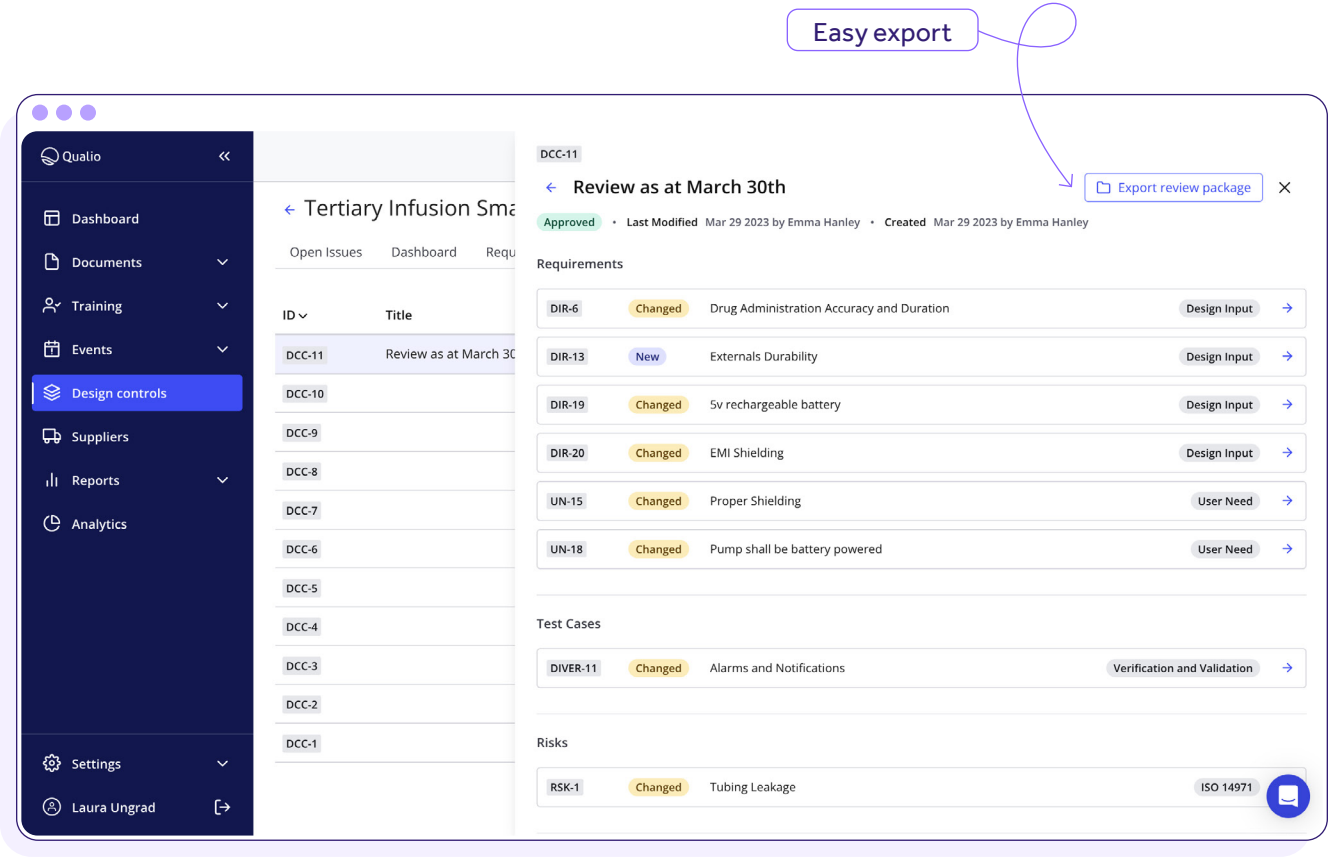


1 Centralized design information for a controlled pathway to market

> 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!

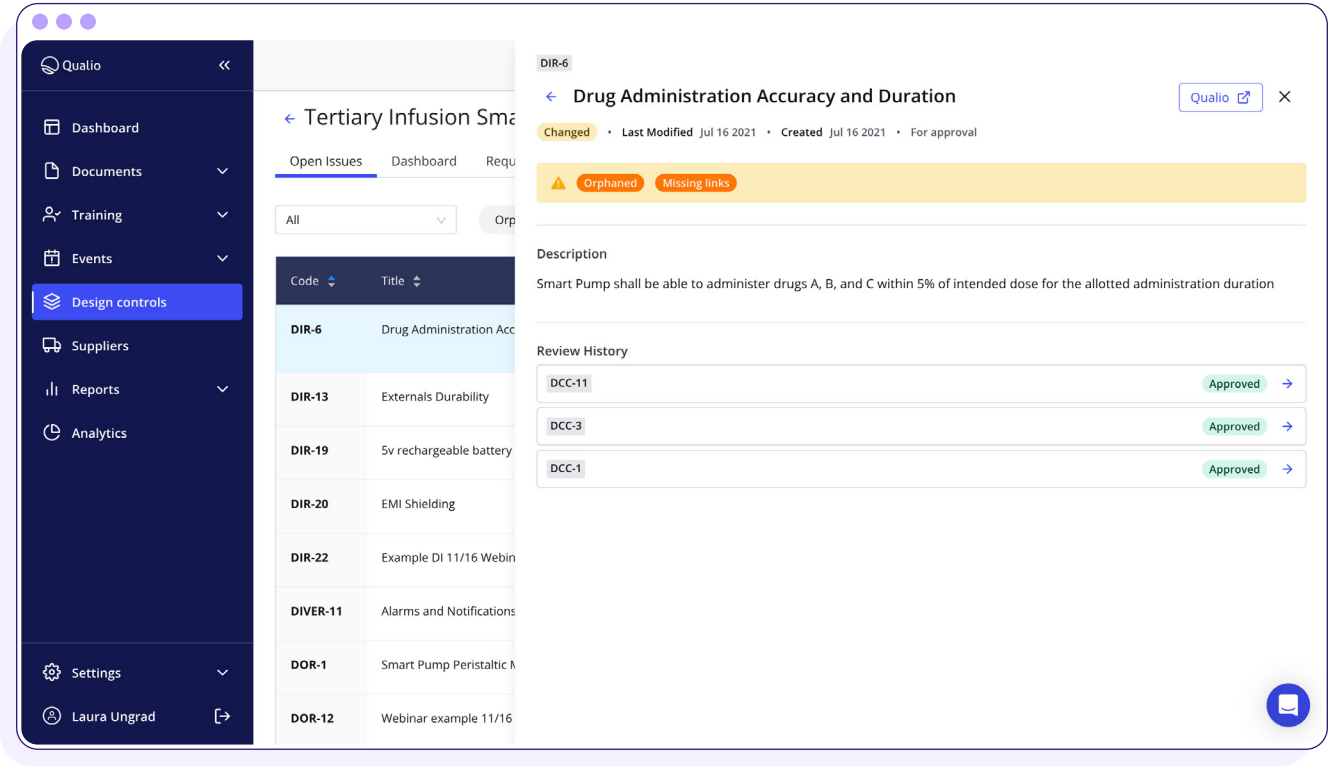


2 Flexible integrations for harmonizing quality and product teams

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.

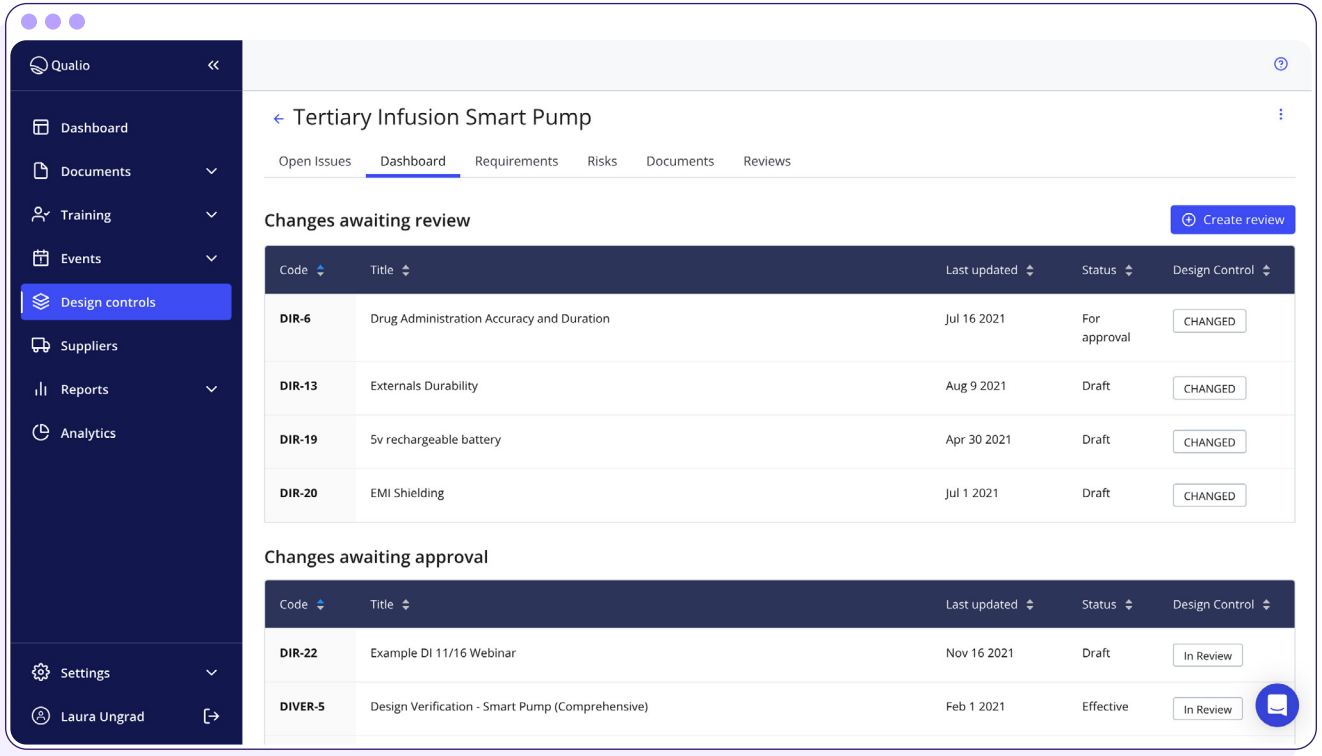
> Qualio Design Controls allows you to work with this familiarity, not against it, by automatically pulling data from these source systems into Qualio with always-on API synchronization.



2 Flexible integrations for harmonizing quality and product teams

> 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.

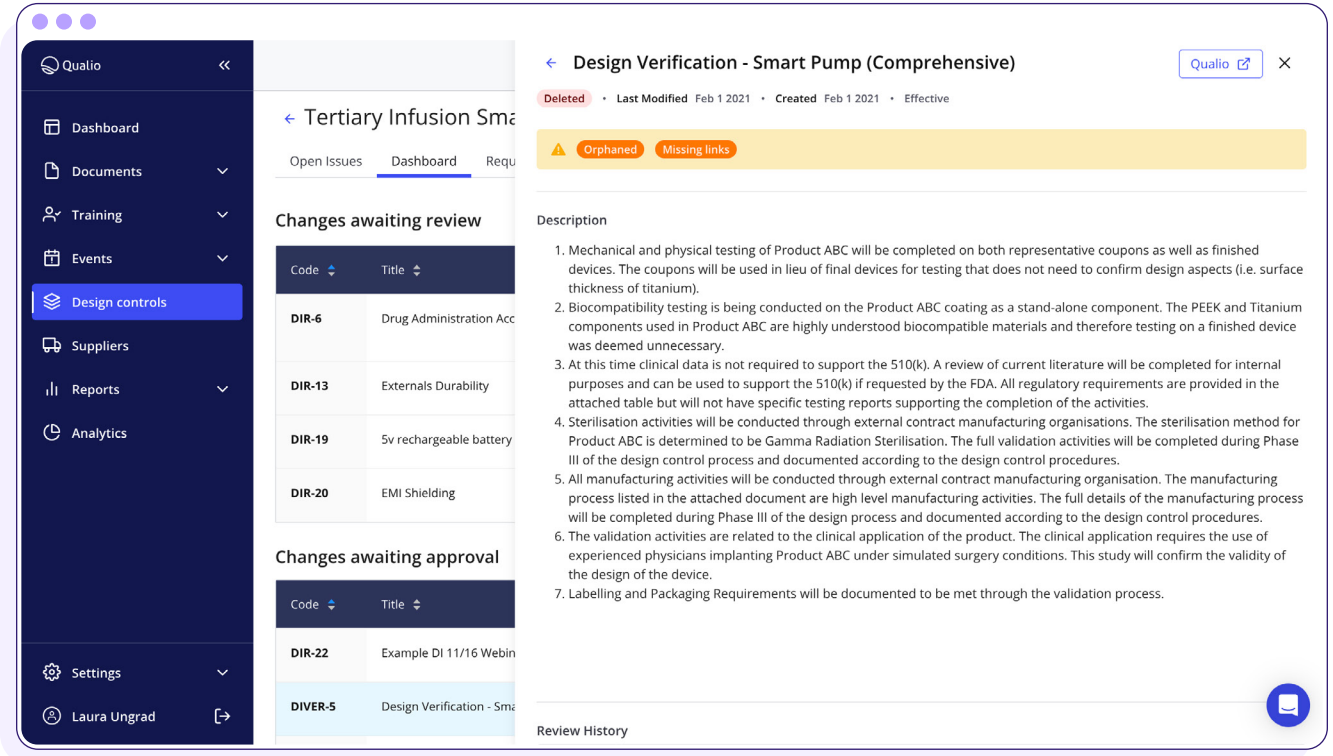


2 Flexible integrations for harmonizing quality and product teams

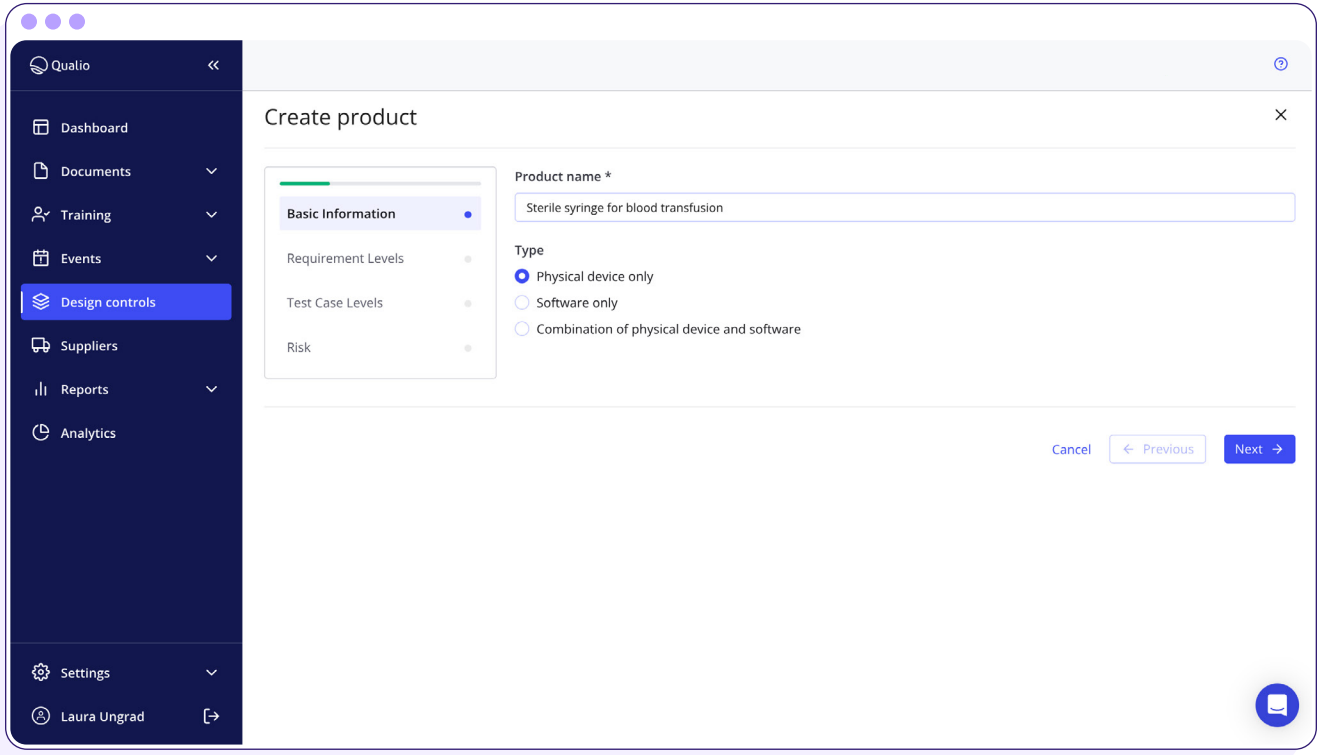
Your engineering teams get to stick with familiar and embedded tools. Your quality team gets to jettison time-heavy manual searches through multiple systems to get the information you need.

Enjoy end-to-end design control traceability, irrespective of where product development activity occurs in your business. Qualio integrates with:

- Jira
- Azure DevOps
- TestRail
- Asana



2 Flexible integrations for harmonizing quality and product teams



Top Tip!

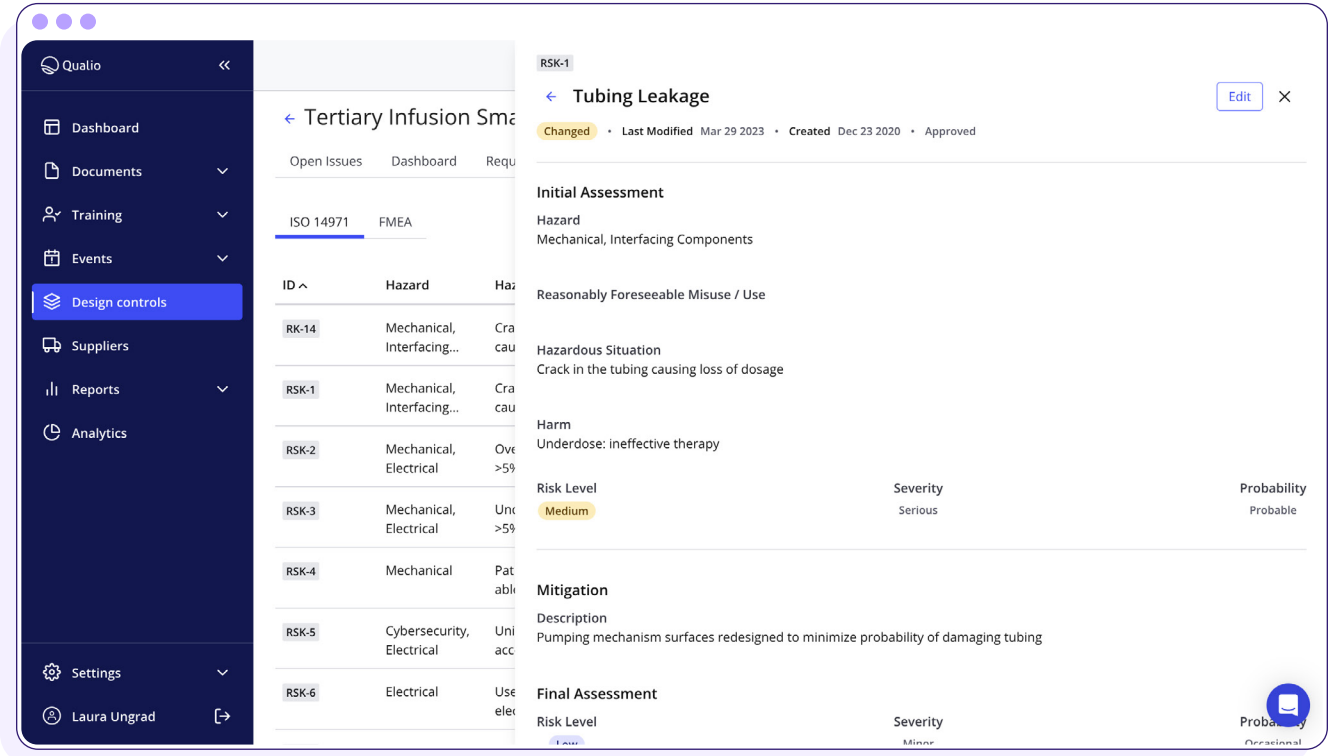
You can always manually add fresh device and user requirements into your system at any point too!

3 Best-in-class risk management for maximum device safety

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.

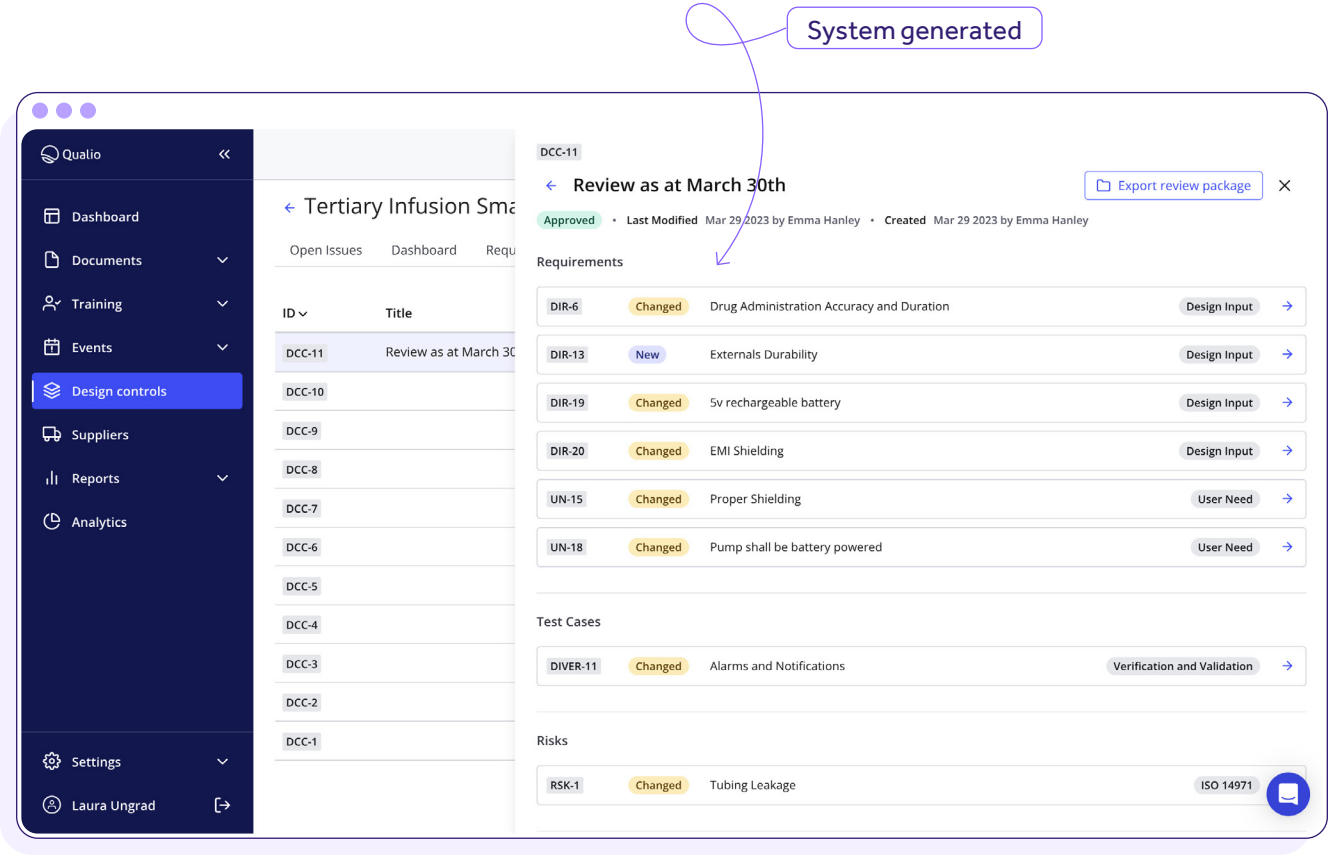


4 Automated compliance to let you focus

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.

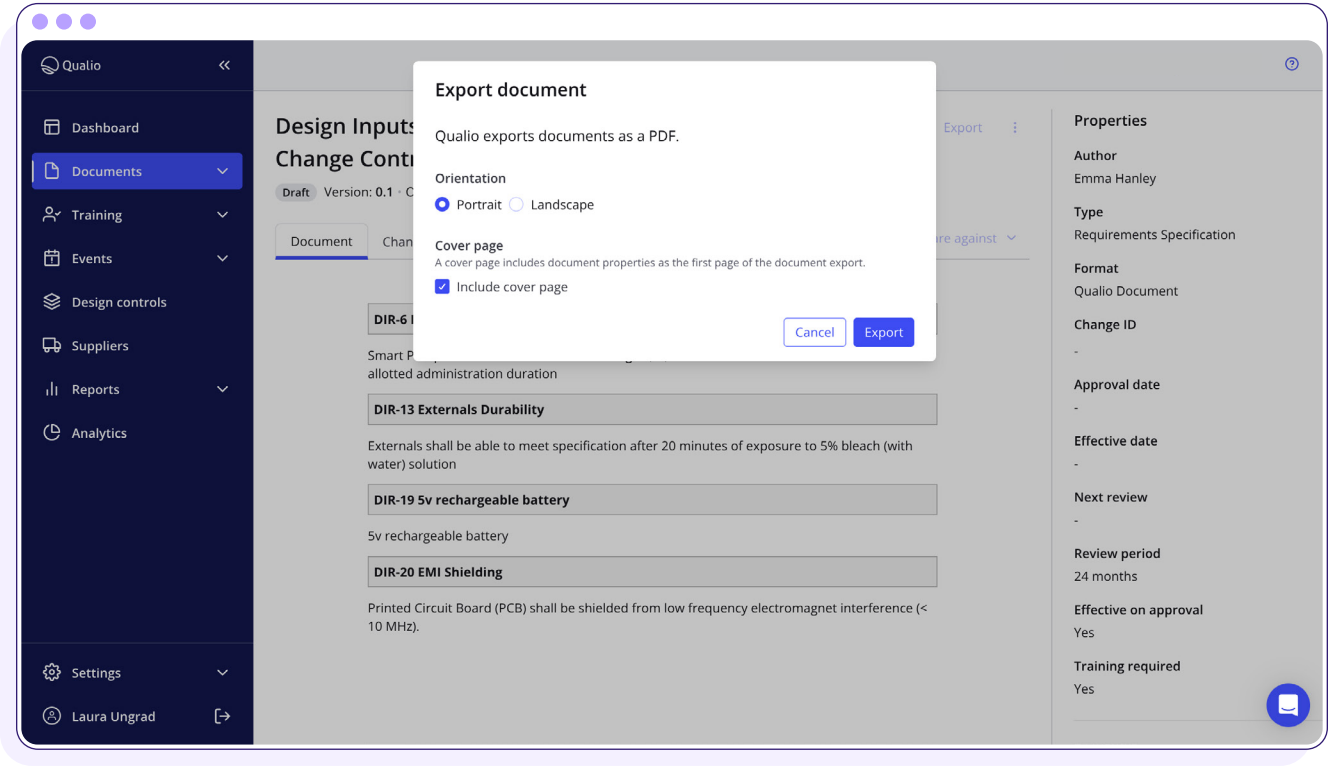


4 Automated compliance to let you focus

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

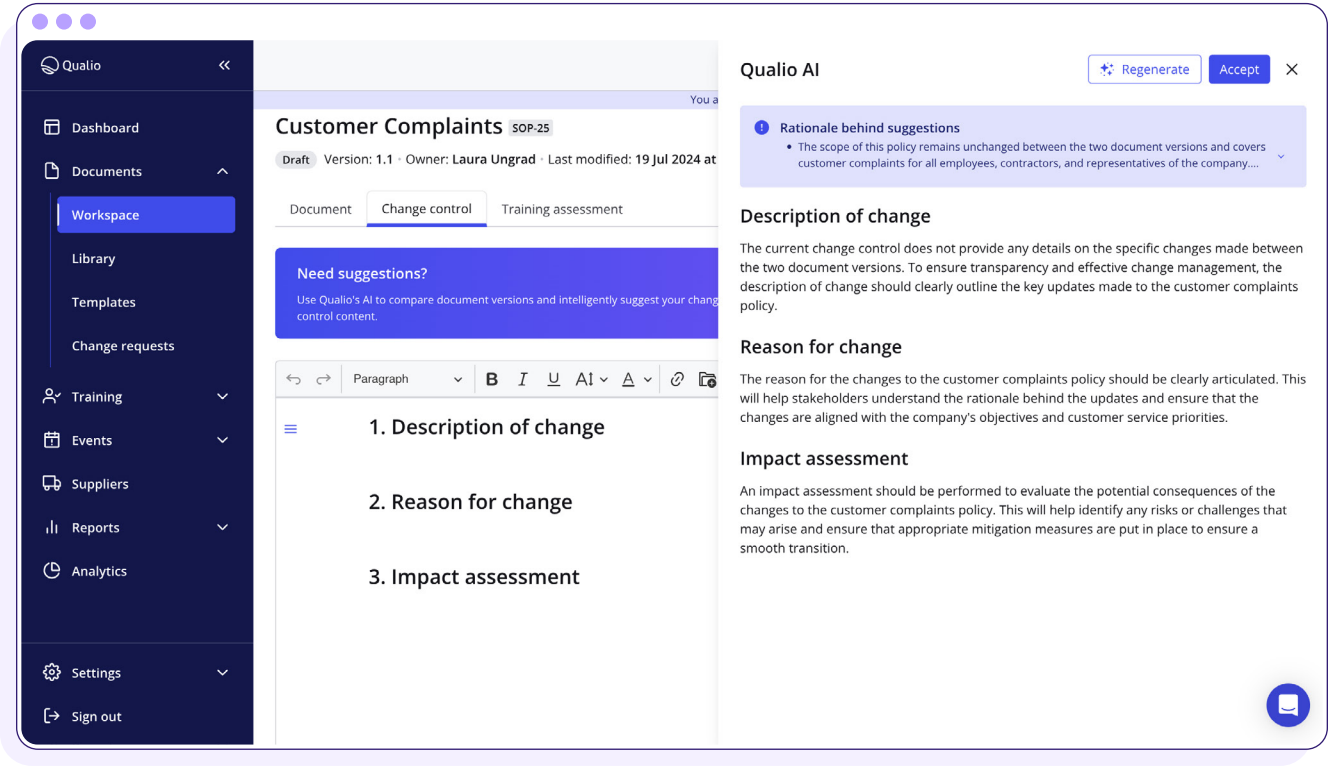


5 Interconnected data for holistic quality management

Your vital design controls work should never be siloed.

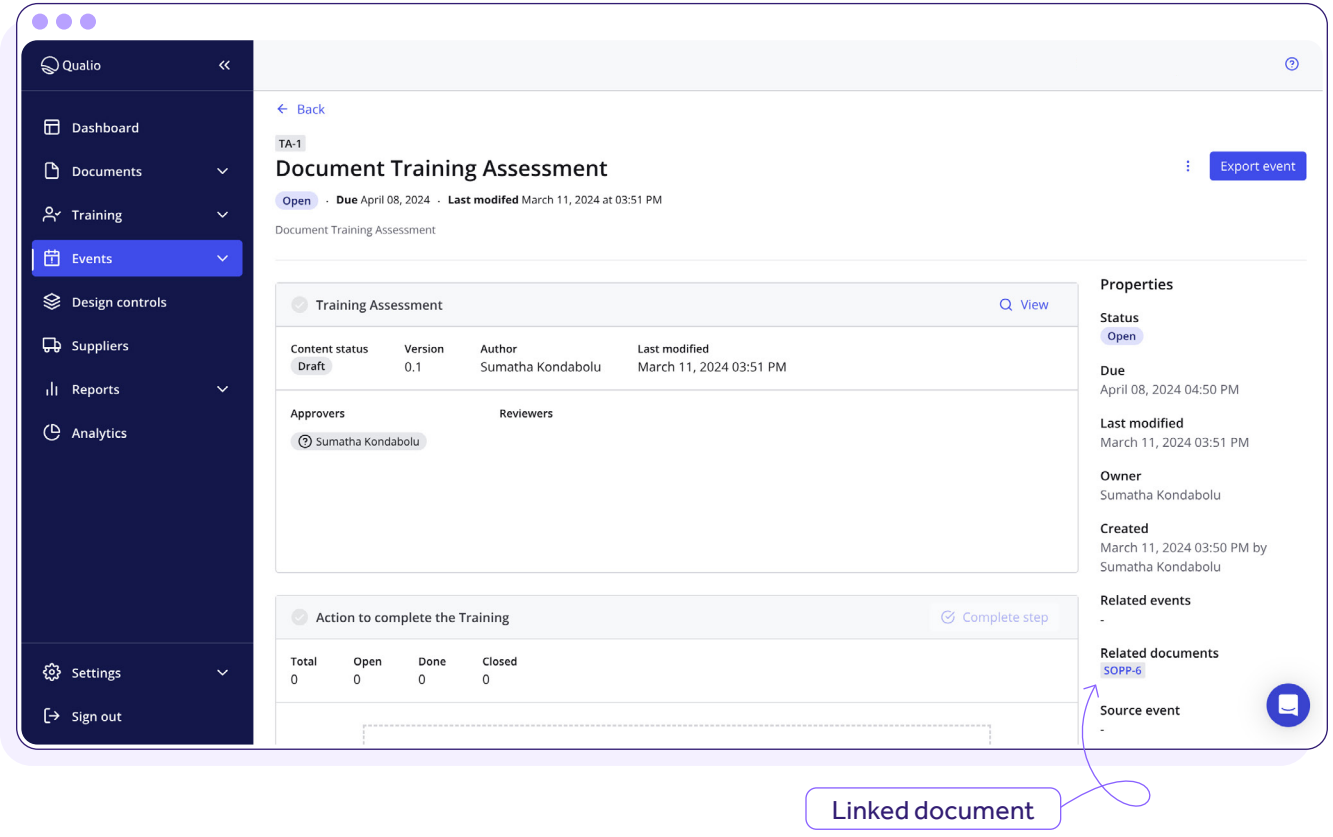
Qualio breaks down internal barriers and ensures your product development work forms part of a holistic, interconnected quality system.

> Use the Qualio Resource Library to build a central, referenceable set of core data objects like products, departments and customers — then apply them as common building blocks across Design Controls, and all other areas of your Qualio platform like Events and Documents.



5 Interconnected data for holistic quality management

And with built-in smartlinking, it's easy to tie design control documents together with other, relevant documents like SOPs, process maps and policies — giving you and your auditors a logical, connected web of quality information to navigate.



The ROI of Qualio

Manual, paper-based quality systems bring a slew of hidden costs to your business, which a Qualio investment completely eliminates.

Get your ROI figure ›

$8m Average cost of a product recall

$400k Average cost of an FDA warning letter

Every day the average life science product is kept from the US market =

$136k in lost revenue

Suboptimal quality processes cost the average med device company:

≈8% of annual revenue

5 FTEs to provide the same level of medical device quality control as Qualio

Watch interview snippet

12 reasons to manage your design controls within Qualio

Hear from our customers!
Explore our successful customer stories ›

1. Dedicated life science eQMS vendor with 650+ regulated customers
2. Keep your documents and data in constant, compliant harmony with your development activity
3. Pull design information automatically from your development software systems or add requirements manually as you wish
4. Stay compliant with Part 11-compliant e-signature sign-off
5. Secure cloud-based access from anywhere
6. Access a central repository of all design control information, from user requirements and design attachments to testing and validation
7. Save time with automatic document generation
8. Pinpoint gaps, weaknesses and action points at a glance and be constantly audit-ready
9. Break down internal friction by bringing quality and engineering together in a single area
10. Tackle risks with a FMEA and ISO 14971 approach every time
11. Double or triple your speed to market (based on a real Qualio customer experience!)
12. Explore open issues, outstanding change controls and review histories quickly and simply

Qualio

Optimize your medical device's quality and compliance

We'll answer your questions, give you a live tour of Qualio and help you determine if we're a good fit for your organization.

Schedule a demo with us