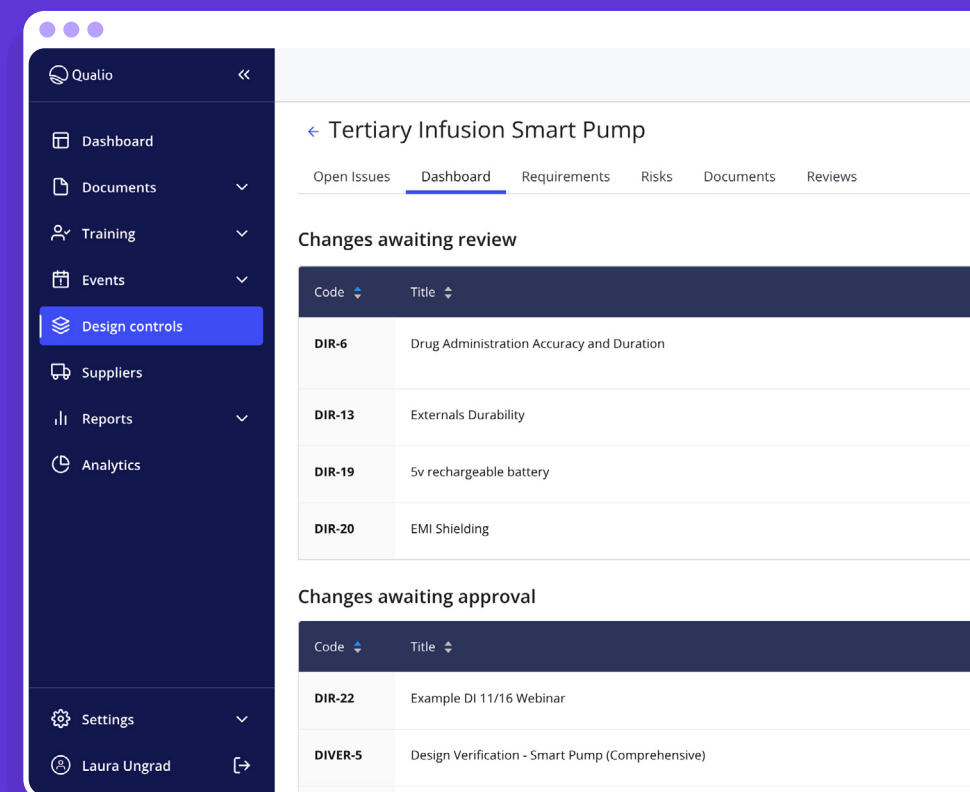


Qualio Design Controls

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.

KAREN HUE

Head of Quality & GxP Compliance
30 Technology



Watch interview snippet



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.

LOWELL HOFFMAN

Director of Quality Assurance
Restech



Watch interview snippet

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.

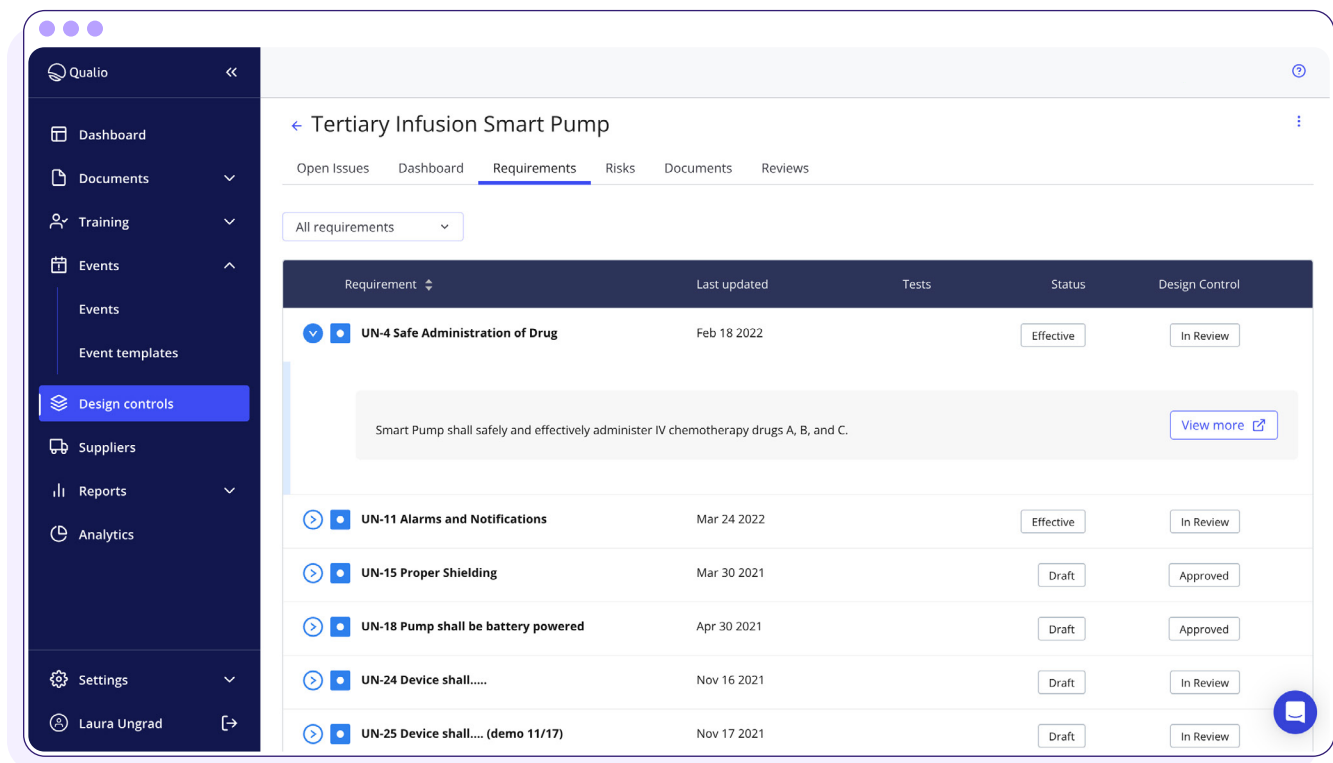
The screenshot shows the Qualio Design Controls interface for a product named 'Tertiary Infusion Smart Pump'. The left sidebar contains a navigation menu with options: Dashboard, Documents, Training, Events, Design controls (highlighted), Suppliers, Reports, and Analytics. The main content area has tabs for Open Issues, Dashboard, Requirements, Risks, Documents, and Reviews. Below the tabs, there are filters for 'All', 'Orphaned 11', and 'Missing links 15'. A table displays a list of design elements with columns for Code, Title, Last updated, Status, and Design Control. The table contains 12 rows of data, including items like 'Drug Administration Accuracy and Duration', 'Externals Durability', '5v rechargeable battery', 'EMI Shielding', 'Example DI 11/16 Webinar', 'Alarms and Notifications', 'Smart Pump Peristaltic Motor Assy', and 'Webinar example 11/16'. Each row has a 'Design Control' button with status indicators like 'CHANGED', 'In Review', or 'Approved'.

Code	Title	Last updated	Status	Design Control
DIR-6	Drug Administration Accuracy and Duration	Jul 16 2021	For approval	CHANGED
DIR-13	Externals Durability	Aug 9 2021	Draft	CHANGED
DIR-19	5v rechargeable battery	Apr 30 2021	Draft	CHANGED
DIR-20	EMI Shielding	Jul 1 2021	Draft	CHANGED
DIR-22	Example DI 11/16 Webinar	Nov 16 2021	Draft	In Review
DIVER-11	Alarms and Notifications	Jul 2 2021	Draft	Approved
DOR-1	Smart Pump Peristaltic Motor Assy	Nov 29 2021	Draft	In Review
DOR-12	Webinar example 11/16	Nov 16 2021	Draft	In Review

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.

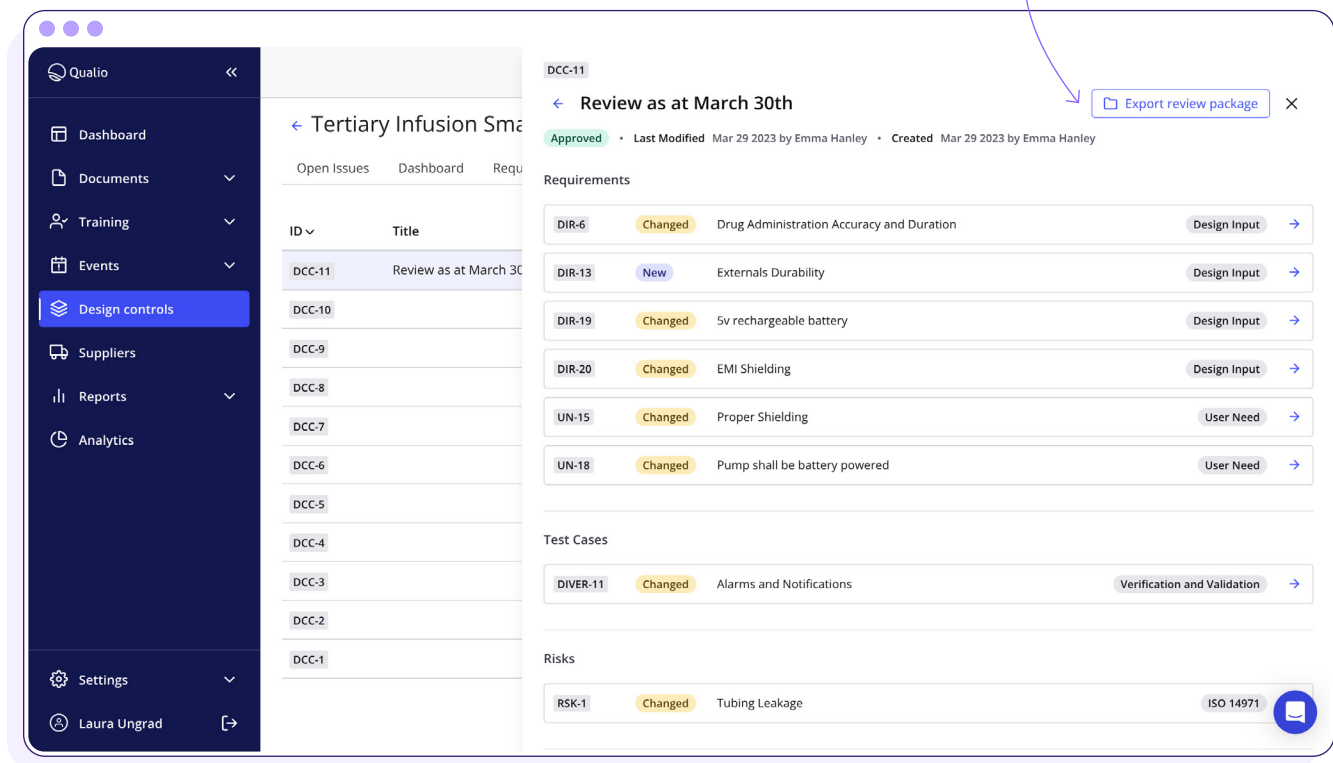


1 Centralized design information for a controlled pathway to market

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!

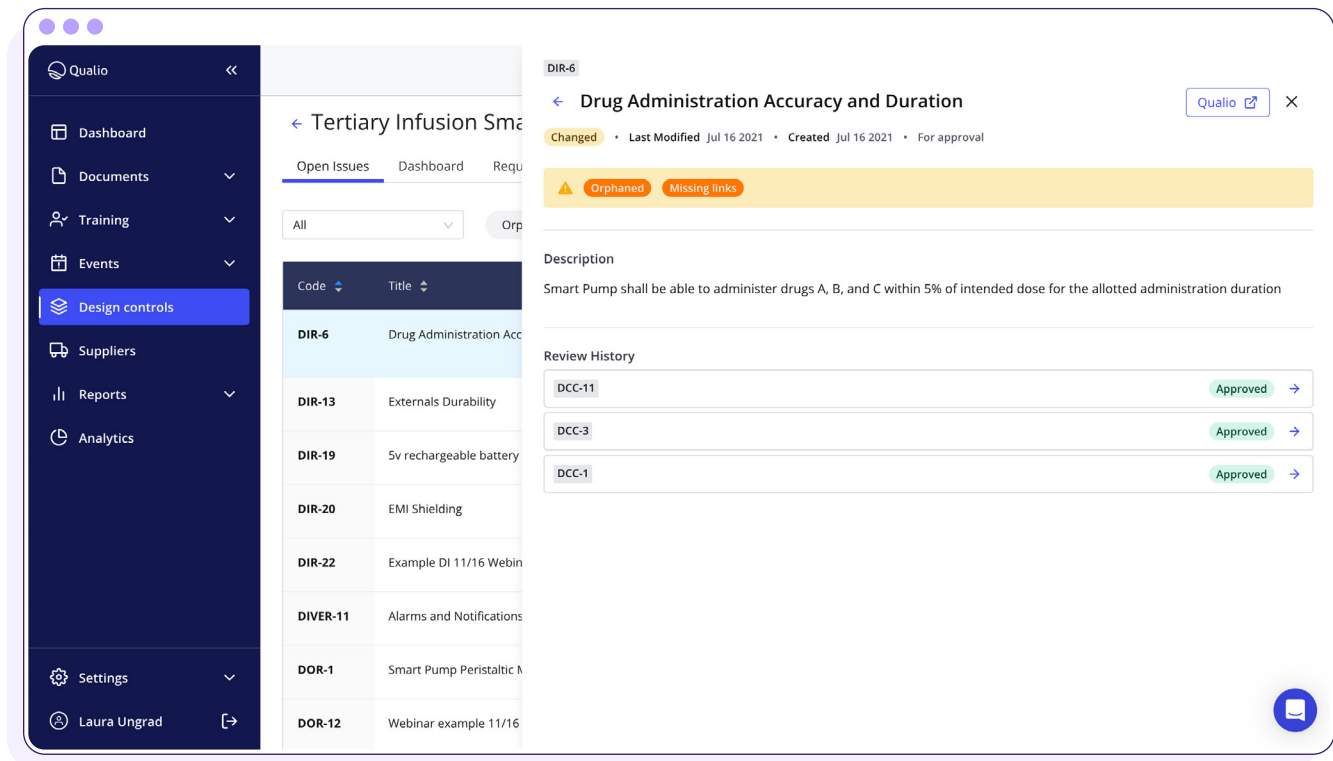


2 Flexible integrations for harmonizing quality and product teams

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.

The screenshot displays the Qualio web application interface. On the left is a dark blue sidebar with a navigation menu including: Dashboard, Documents, Training, Events, Design controls (highlighted), Suppliers, Reports, Analytics, Settings, and a user profile for Laura Ungrad. The main content area is titled 'Tertiary Infusion Smart Pump' and has tabs for Open Issues, Dashboard (selected), Requirements, Risks, Documents, and Reviews. Below the tabs, there are two sections: 'Changes awaiting review' and 'Changes awaiting approval'. Each section contains a table with columns for Code, Title, Last updated, Status, and Design Control. In the 'Changes awaiting review' section, four items are listed: DIR-6 (Drug Administration Accuracy and Duration, For approval, CHANGED), DIR-13 (Externals Durability, Draft, CHANGED), DIR-19 (5v rechargeable battery, Draft, CHANGED), and DIR-20 (EMI Shielding, Draft, CHANGED). In the 'Changes awaiting approval' section, two items are listed: DIR-22 (Example DI 11/16 Webinar, Draft, In Review) and DIVER-5 (Design Verification - Smart Pump (Comprehensive), Effective, In Review). A 'Create review' button is located in the top right of the 'Changes awaiting review' section. A chat icon is visible in the bottom right corner of the interface.

Code	Title	Last updated	Status	Design Control
DIR-6	Drug Administration Accuracy and Duration	Jul 16 2021	For approval	CHANGED
DIR-13	Externals Durability	Aug 9 2021	Draft	CHANGED
DIR-19	5v rechargeable battery	Apr 30 2021	Draft	CHANGED
DIR-20	EMI Shielding	Jul 1 2021	Draft	CHANGED

Code	Title	Last updated	Status	Design Control
DIR-22	Example DI 11/16 Webinar	Nov 16 2021	Draft	In Review
DIVER-5	Design Verification - Smart Pump (Comprehensive)	Feb 1 2021	Effective	In Review

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

The screenshot displays the Qualio software interface. On the left is a dark sidebar with a menu including: Qualio, Dashboard, Documents, Training, Events, Design controls (highlighted), Suppliers, Reports, Analytics, Settings, and a user profile for Laura Ungrad. The main content area is divided into two panels. The left panel, titled 'Tertiary Infusion Smart Pump', shows a 'Dashboard' tab with a table of 'Changes awaiting review'. The table has columns for Code and Title, with entries: DIR-6 (Drug Administration Acc), DIR-13 (Externals Durability), DIR-19 (5v rechargeable battery), and DIR-20 (EMI Shielding). Below this is a section for 'Changes awaiting approval' with a similar table showing DIR-22 (Example DI 11/16 Webin) and DIVER-5 (Design Verification - Smart Pump). The right panel shows a detailed view for 'Design Verification - Smart Pump (Comprehensive)', marked as 'Deleted'. It includes a description with seven numbered points detailing testing and validation procedures for Product ABC. A 'Review History' section is at the bottom right.

Code	Title
DIR-6	Drug Administration Acc
DIR-13	Externals Durability
DIR-19	5v rechargeable battery
DIR-20	EMI Shielding

Code	Title
DIR-22	Example DI 11/16 Webin
DIVER-5	Design Verification - Smart Pump

Design Verification - Smart Pump (Comprehensive)

Deleted • Last Modified Feb 1 2021 • Created Feb 1 2021 • Effective

Orphaned Missing links

Description

1. Mechanical and physical testing of Product ABC will be completed on both representative coupons as well as finished devices. The coupons will be used in lieu of final devices for testing that does not need to confirm design aspects (i.e. surface thickness of titanium).
2. Biocompatibility testing is being conducted on the Product ABC coating as a stand-alone component. The PEEK and Titanium components used in Product ABC are highly understood biocompatible materials and therefore testing on a finished device was deemed unnecessary.
3. At this time clinical data is not required to support the 510(k). A review of current literature will be completed for internal purposes and can be used to support the 510(k) if requested by the FDA. All regulatory requirements are provided in the attached table but will not have specific testing reports supporting the completion of the activities.
4. Sterilisation activities will be conducted through external contract manufacturing organisations. The sterilisation method for Product ABC is determined to be Gamma Radiation Sterilisation. The full validation activities will be completed during Phase III of the design control process and documented according to the design control procedures.
5. All manufacturing activities will be conducted through external contract manufacturing organisation. The manufacturing process listed in the attached document are high level manufacturing activities. The full details of the manufacturing process will be completed during Phase III of the design process and documented according to the design control procedures.
6. The validation activities are related to the clinical application of the product. The clinical application requires the use of experienced physicians implanting Product ABC under simulated surgery conditions. This study will confirm the validity of the design of the device.
7. Labelling and Packaging Requirements will be documented to be met through the validation process.

Review History

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!

The screenshot shows the Qualio 'Create product' interface. On the left is a dark sidebar with a menu: Dashboard, Documents, Training, Events, Design controls (highlighted), Suppliers, Reports, Analytics, Settings, and a user profile for Laura Ungrad. The main area is titled 'Create product' and contains a progress bar with 'Basic Information' selected. Below the progress bar are sections for 'Requirement Levels', 'Test Case Levels', and 'Risk'. To the right, there is a 'Product name *' text field containing 'Sterile syringe for blood transfusion'. Below this is a 'Type' section with three radio buttons: 'Physical device only' (selected), 'Software only', and 'Combination of physical device and software'. At the bottom right are 'Cancel', 'Previous', and 'Next' buttons. A chat icon is in the bottom right corner.

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.

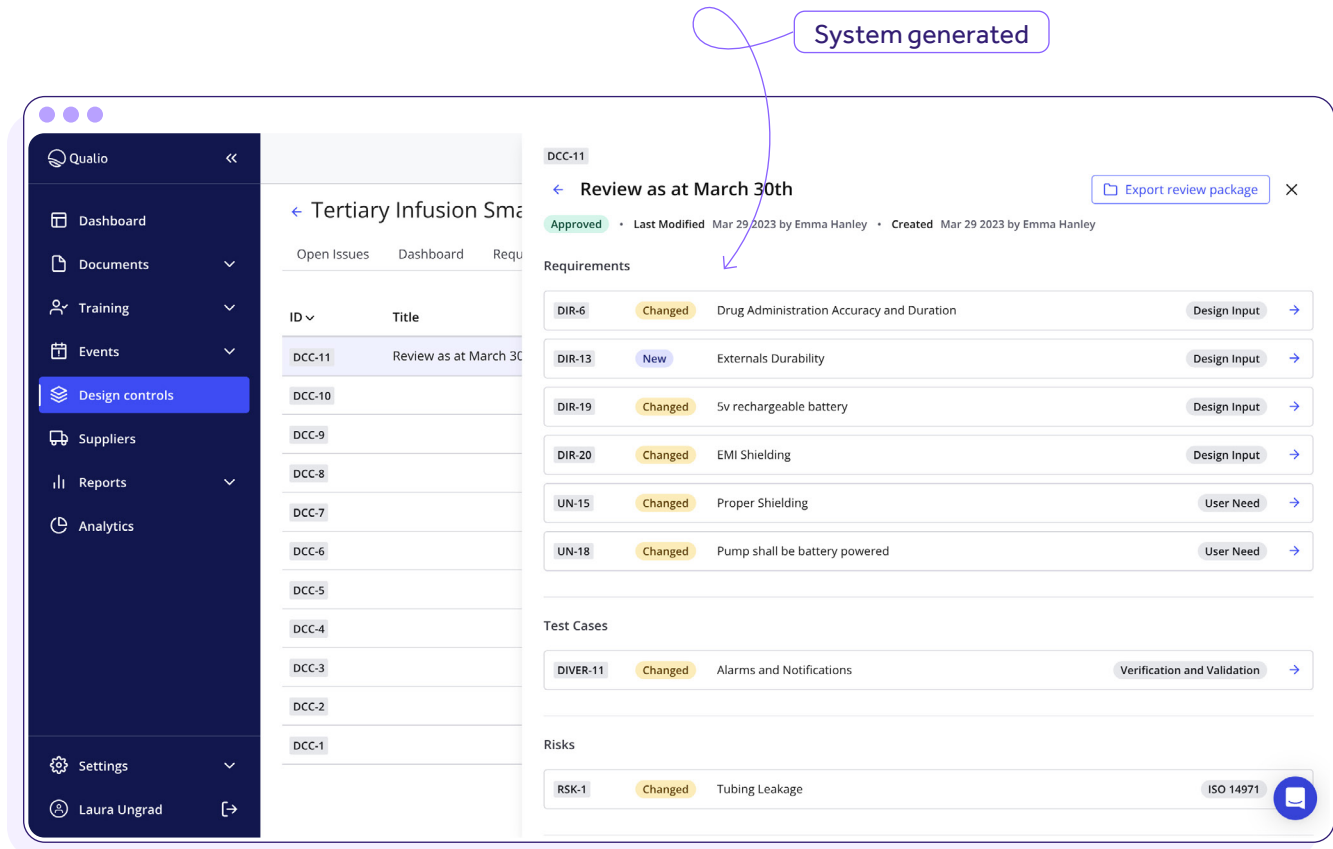
The screenshot displays the Qualio Design Controls interface. On the left is a dark sidebar with navigation options: Dashboard, Documents, Training, Events, Design controls (highlighted), Suppliers, Reports, Analytics, Settings, and a user profile for Laura Ungrad. The main content area is titled 'Tertiary Infusion Smart' and includes tabs for 'Open Issues', 'Dashboard', and 'Requirements'. Below these is a table with columns for 'ISO 14971', 'FMEA', 'ID', 'Hazard', and 'Harm'. The table lists several risks, including RSK-14, RSK-1, RSK-2, RSK-3, RSK-4, RSK-5, and RSK-6, with details on their mechanical, electrical, and cybersecurity aspects. To the right of the table, a detailed view for 'RSK-1 Tubing Leakage' is shown, including an 'Initial Assessment' section with 'Hazard' (Mechanical, Interfacing Components), 'Reasonably Foreseeable Misuse / Use' (Crack in the tubing causing loss of dosage), 'Harm' (Underdose: ineffective therapy), and a 'Mitigation' description (Pumping mechanism surfaces redesigned to minimize probability of damaging tubing). The 'Final Assessment' section shows a 'Risk Level' of 'Medium' with 'Severity' as 'Serious' and 'Probability' as 'Probable'. An 'Edit' button is visible in the top right corner of the risk detail view.

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.

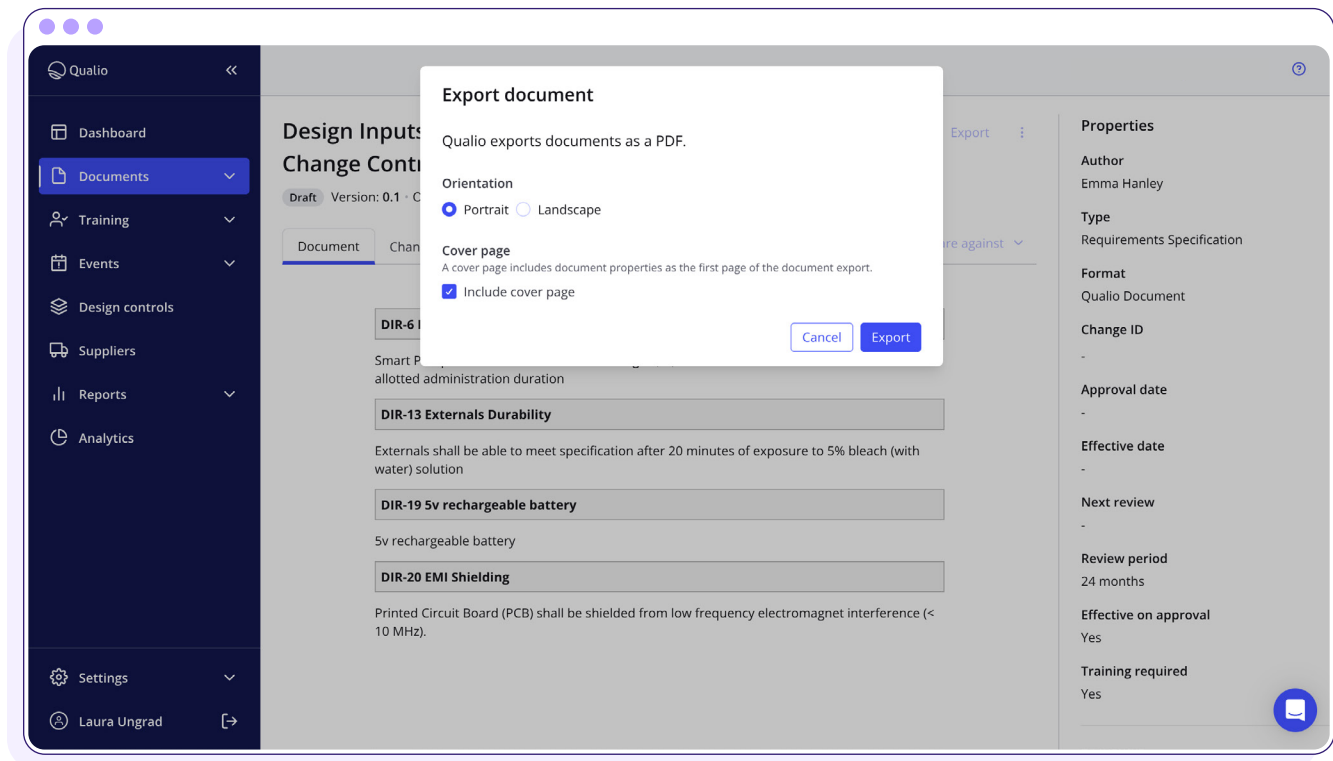


4 Automated compliance to let you focus

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.

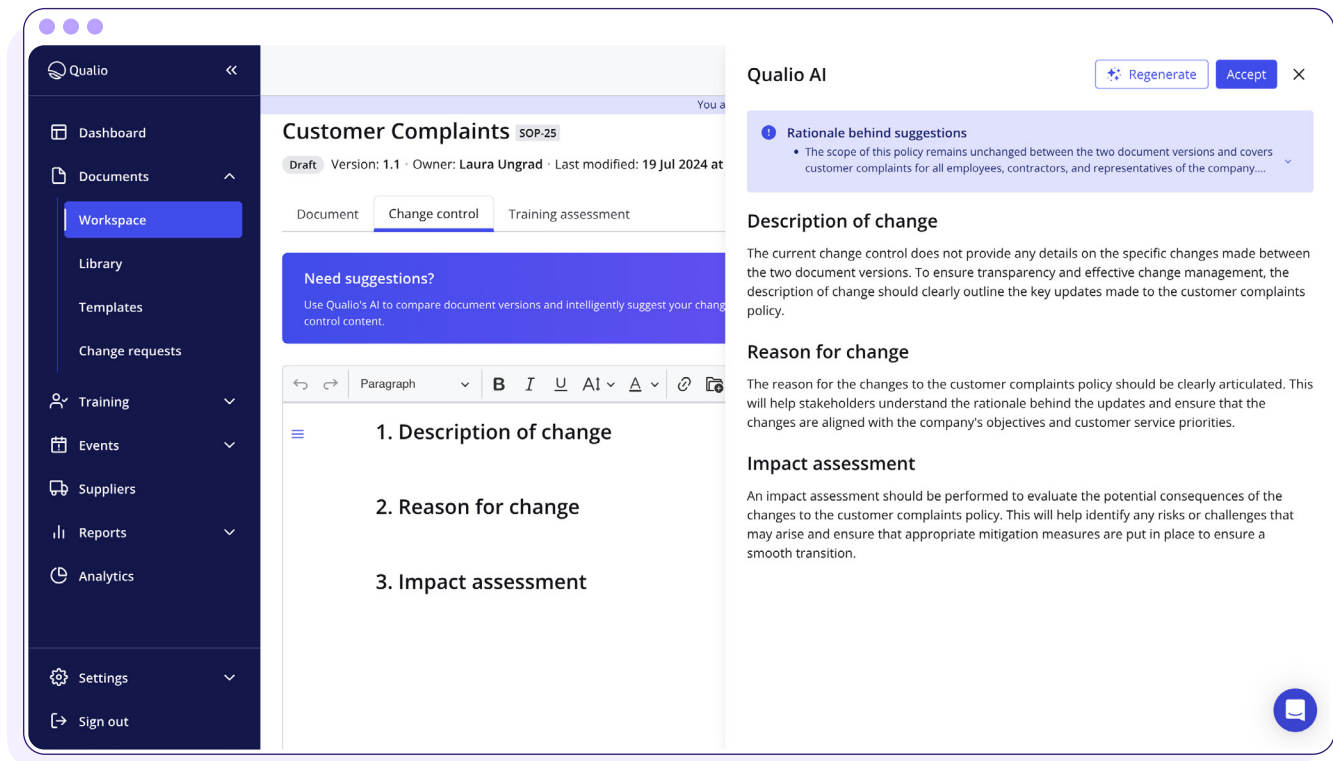


5 Interconnected data for holistic quality management

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.

Qualio

Dashboard
Documents
Training
Events
Design controls
Suppliers
Reports
Analytics

Settings
Sign out

← Back

TA-1

Document Training Assessment

Open · Due April 08, 2024 · Last modified March 11, 2024 at 03:51 PM

Document Training Assessment

Training Assessment View

Content status	Version	Author	Last modified
Draft	0.1	Sumatha Kondabolu	March 11, 2024 03:51 PM

Approvers: Sumatha Kondabolu

Reviewers

Action to complete the Training Complete step

Total	Open	Done	Closed
0	0	0	0

Properties

Status: Open

Due: April 08, 2024 04:50 PM

Last modified: March 11, 2024 03:51 PM

Owner: Sumatha Kondabolu

Created: March 11, 2024 03:50 PM by Sumatha Kondabolu

Related events

Related documents: SOPP-6

Source event

Linked document

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



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](#)

