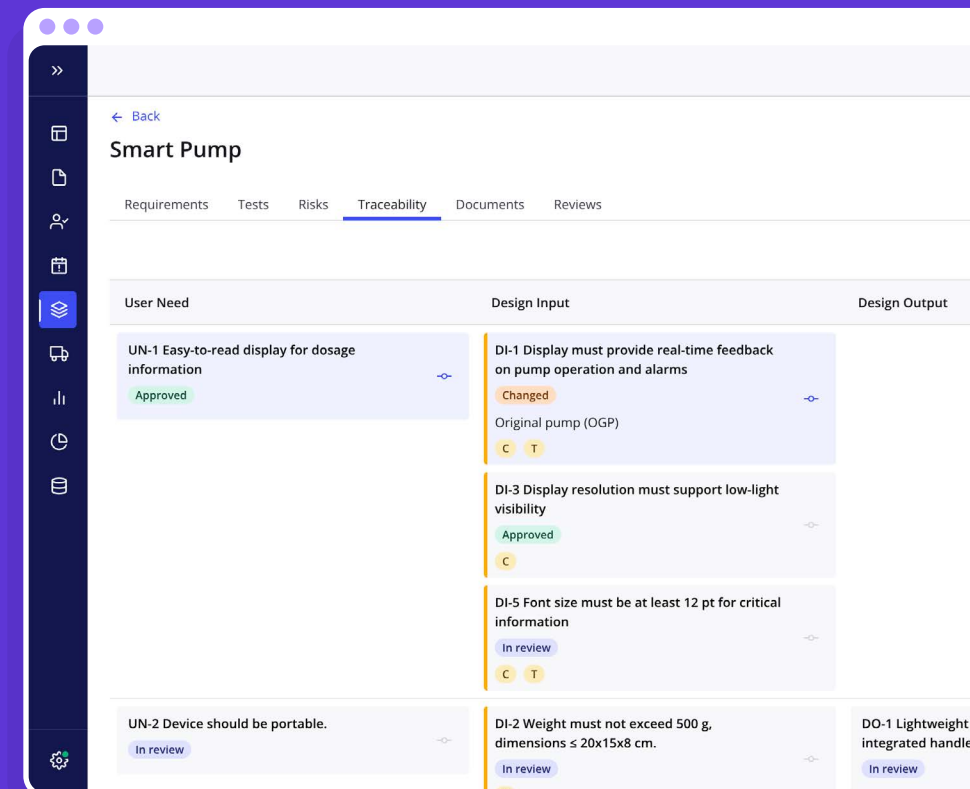


Qualio Design Controls

Ensure compliance and
streamline collaboration





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](#)

Software made to overcome your compliance challenges in life sciences



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



Software made to overcome your compliance challenges in life sciences



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

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

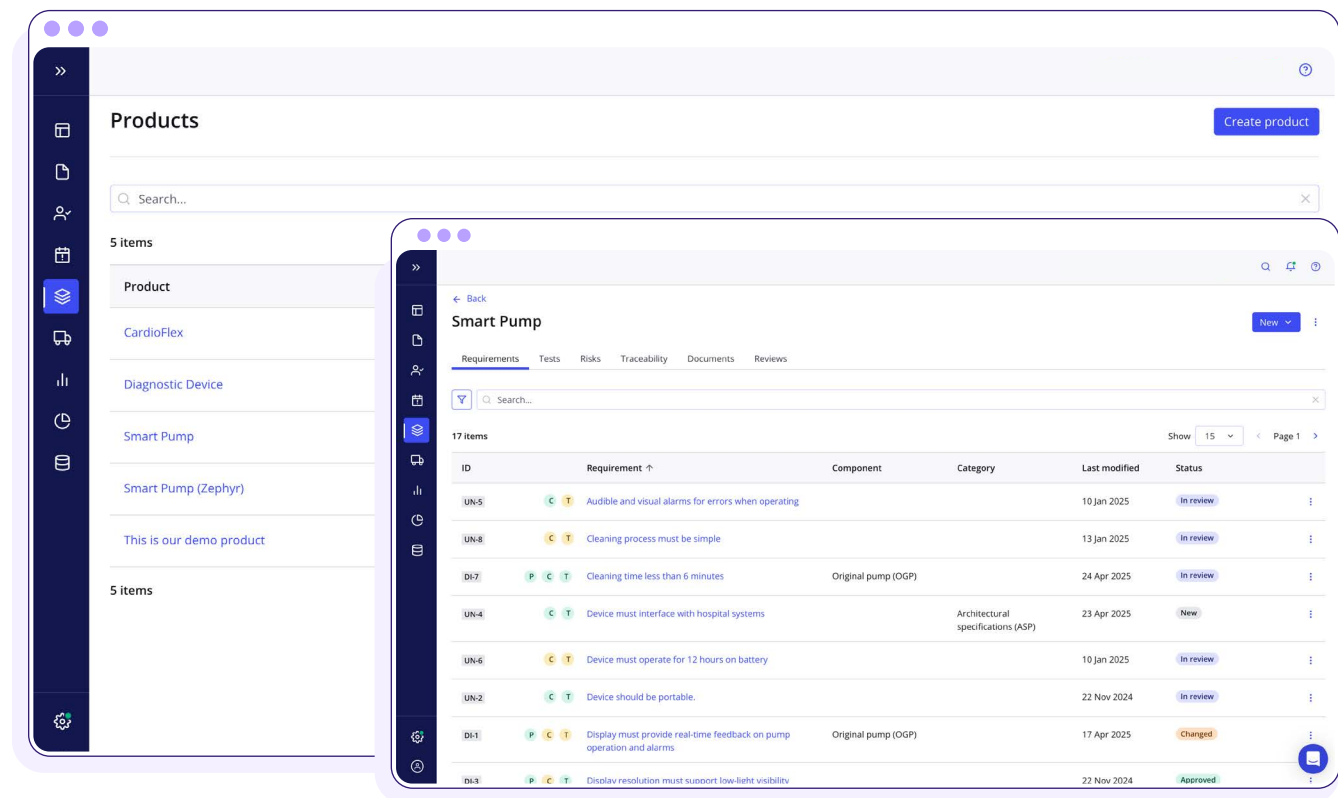
1. Stay organized and compliant with an integrated view
2. Traceability and instant gap analysis to focus efforts
3. Automatic documentation for a controlled route to market
4. Robust risk management for maximum safety
5. Interconnected data for holistic quality management

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 Stay organized and compliant with an integrated view

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

- › Requirements
- › Tests
- › Risks
- › Documents
- › Reviews



1 Stay organized and compliant with an integrated view



Top Tip!

You can add fresh requirements, tests or risks at any point, with configurations set at the product level!

The screenshot shows a web application interface titled "Configure product". On the left is a dark sidebar with a vertical list of icons: a double arrow, a folder, a document, a person, a calendar, a stack of papers (highlighted in blue), a magnifying glass, a list, a clock, and a book. The main panel has a header "Configure product" and a sub-header "Requirements". Below the sub-header is a paragraph: "You can create and manage components and categories in the [Resource Library](#) to further organize your requirements." The main panel contains four sections for configuring requirements:

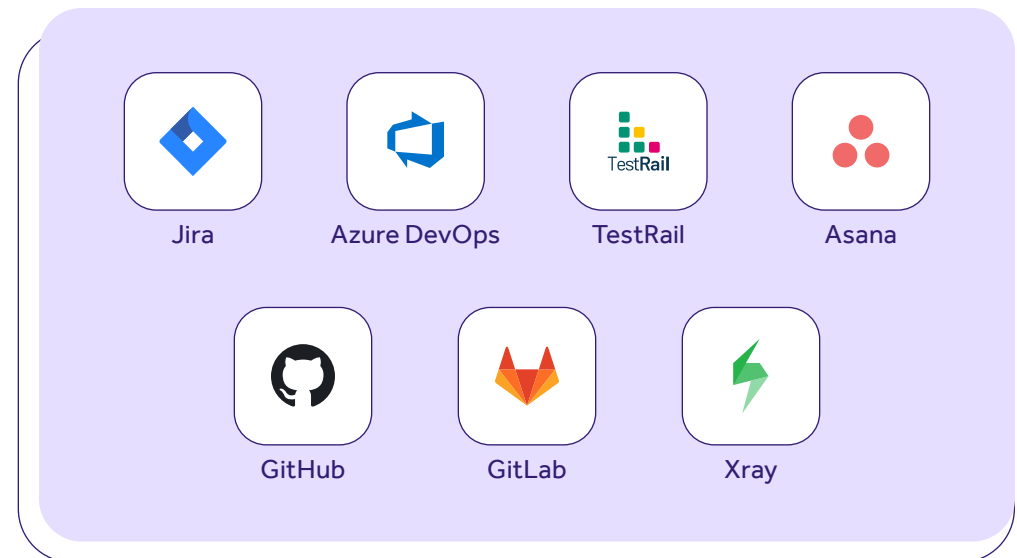
- Level 1**: A form with two input fields. The first is labeled "Prefix" and contains the text "UN". The second is labeled "Name" and contains the text "User Need".
- Level 2**: A form with two input fields. The first is labeled "Prefix" and contains the text "DI". The second is labeled "Name" and contains the text "Design Input". Below the form is a button labeled "Delete" with a trash icon.
- Level 3**: A section with a "Disabled" status indicator and an "Enable" button.
- Level 4**: A section with a "Disabled" status indicator and an "Enable" button.

1 Stay organized and compliant with an integrated view

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.

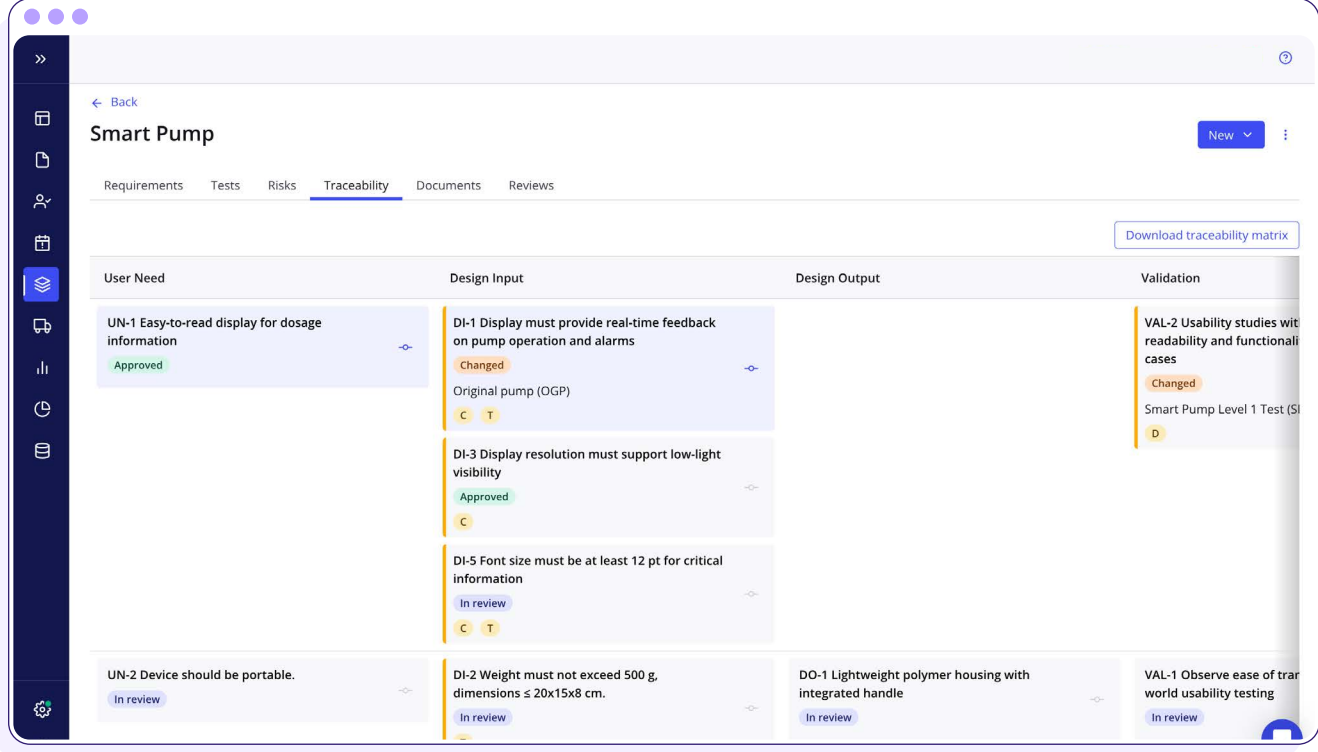
Qualio Design Controls allows you to work with this familiarity, not against it, by automatically pulling data from these source systems into Qualio with always-on API synchronization.



2 Traceability and instant gap analysis to focus efforts

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 shows the 'Smart Pump' project page in Qualio, specifically the 'Traceability' tab. The interface includes a sidebar with navigation icons, a top navigation bar with tabs for Requirements, Tests, Risks, Traceability (selected), Documents, and Reviews. A 'Download traceability matrix' button is visible in the top right. The main content area displays a table with four columns: User Need, Design Input, Design Output, and Validation. The table lists various requirements and their status.

User Need	Design Input	Design Output	Validation
UN-1 Easy-to-read display for dosage information Approved	DI-1 Display must provide real-time feedback on pump operation and alarms Changed Original pump (OGP) C T DI-3 Display resolution must support low-light visibility Approved C DI-5 Font size must be at least 12 pt for critical information In review C T	DO-1 Lightweight polymer housing with integrated handle In review	VAL-2 Usability studies with readability and functional cases Changed Smart Pump Level 1 Test (S) D VAL-1 Observe ease of transworld usability testing In review
UN-2 Device should be portable. In review	DI-2 Weight must not exceed 500 g, dimensions ≤ 20x15x8 cm. In review		

2 Traceability and instant gap analysis to focus efforts

Instant gap analysis provides at a glance visibility of open issues and changes awaiting review, giving the quality team a synchronized picture of your design elements as they mature and evolve.

Drill into your requirements, tests and risks, with critical decision-making information, like status, open issues, connected hazards and review histories at your fingertips.

The screenshot displays the Qualio software interface for a requirement detail page. The page title is "DI-3 Display resolution must support low-light visibility". It shows the requirement is "Approved", created on "22 Nov 2024", and last modified on "22 Nov 2024". A yellow warning banner indicates a "Missing related requirement" with the message: "You must link at least one Design Output requirement." The "Description" section states "128x64 pixels minimum". Below this is a "Review history" table with one entry: Code "DCC-1", Title "Display resolution must support low-light visibility", Date "22 Nov 2024", and Status "Approved". The "Requirements" section shows a table with one entry: Code "UN-1", Title "Easy-to-read display for dosage information", Component "User Need", and Status "NEW". The "Test cases" section is currently empty.

Code	Title	Date	Status
DCC-1	Display resolution must support low-light visibility	22 Nov 2024	Approved

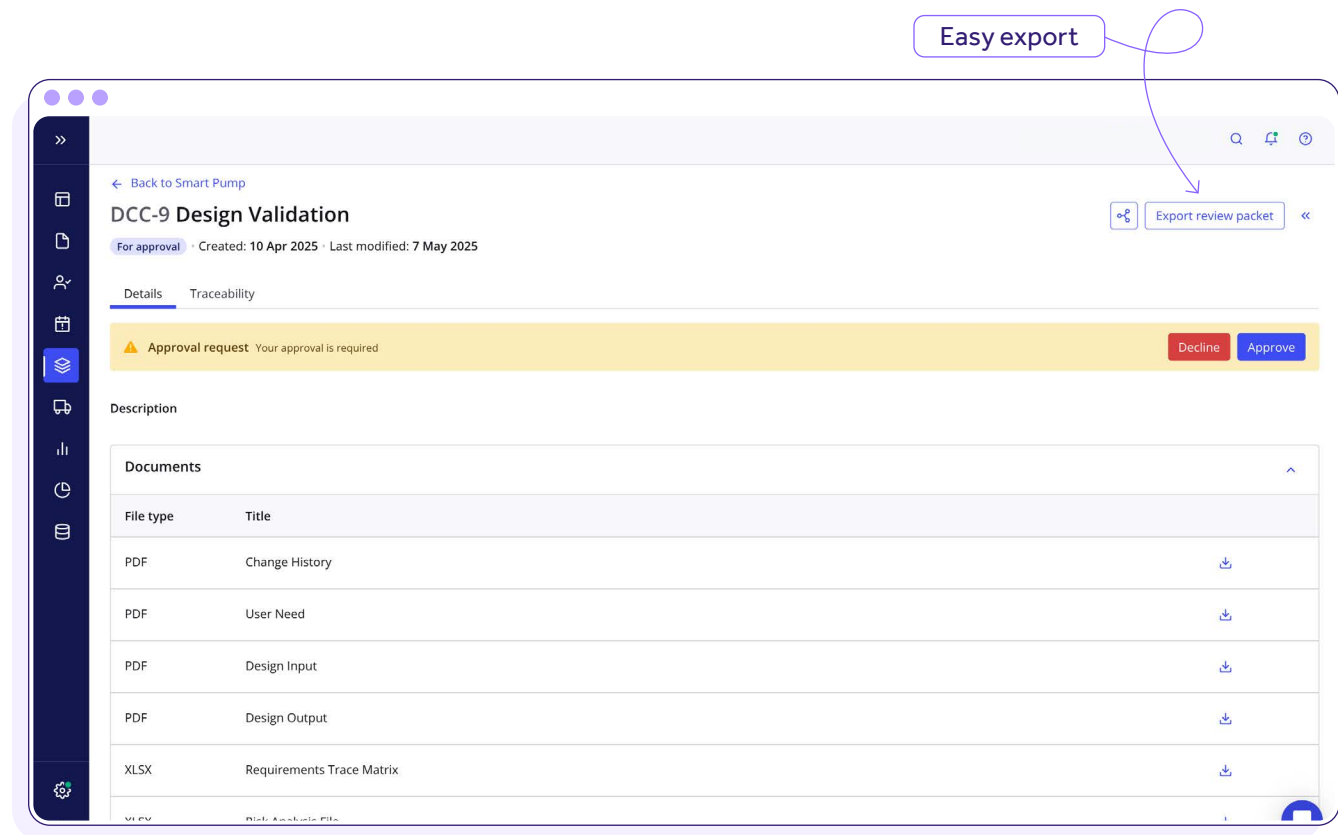
Code	Title	Component	Category	Type	Status
UN-1	Easy-to-read display for dosage information	User Need			NEW

3 Automatic documentation for a controlled route to market

Gaps in documentation lead to FDA citations and complaints.

Ditch your manual data collation and updates by automatically generating key reports, such as trace matrices and requirements documents, as part of the change control review.

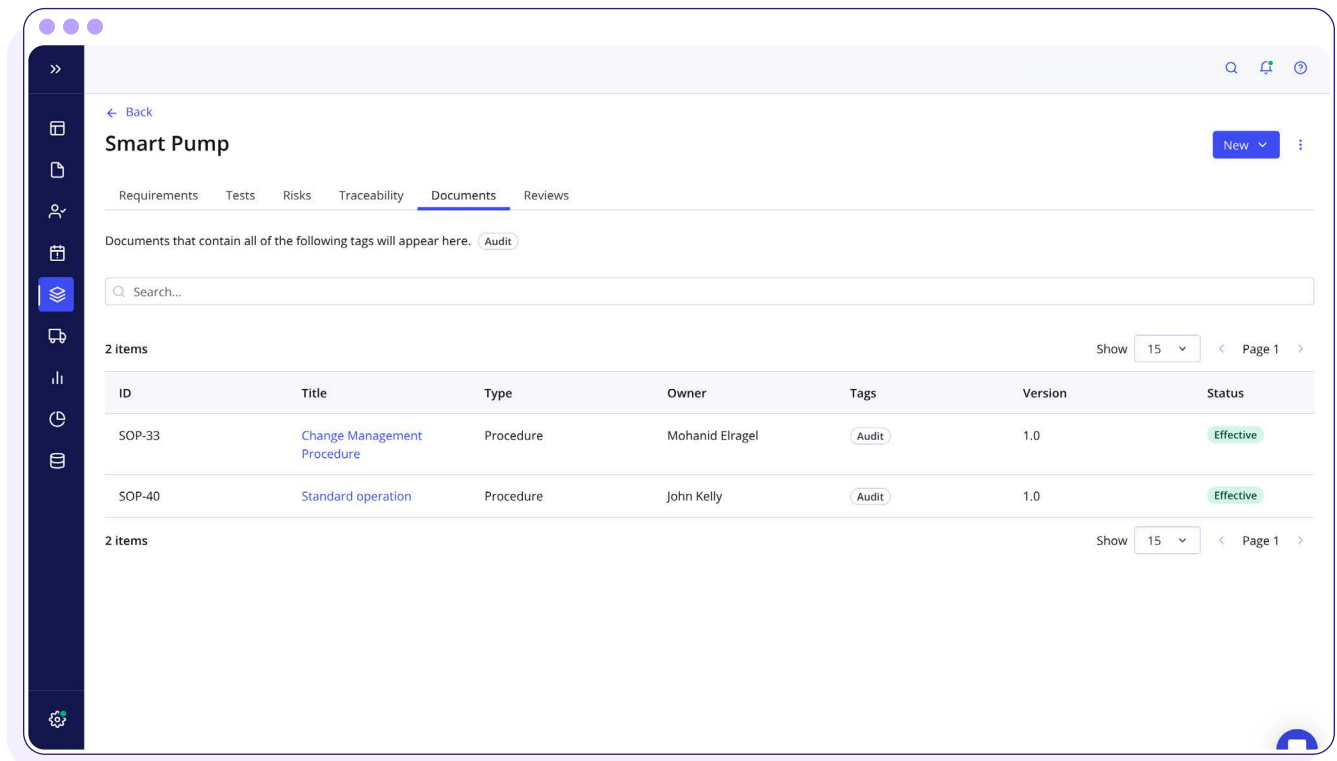
Your formal review approvals are recorded with FDA 21 CFR Part 11-compliant e-signatures.



3 Automatic documentation for a controlled route to market

Store your generated documents in Qualio Documents, creating a single source of truth for all product development data that you can quickly query.

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



4 Robust risk management for maximum 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 product your business works on:

- › 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 3-5 x 3-5 format to capture, assess and treat risks how you want.

The screenshot displays the Qualio Design Controls web application. The main interface is divided into several sections:

- Header:** Includes a navigation bar with icons and a search bar.
- Left Sidebar:** Contains a list of icons for navigation, including a gear icon for settings.
- Main Content Area:**
 - Back to Smart Pump:** A link to return to the previous view.
 - RSK-1 Misinterpretation of dosage information due to poor visibility, leading to incorrect administration:** The title of the risk entry.
 - Properties:** A section on the right showing the risk profile (ISO 14971) and an edit button.
 - Initial assessment:** A section containing:
 - Hazard:** Inadequate visibility of dosage information on t
 - Risk level:** Medium (highlighted in orange)
 - Probability:** Remote
 - Severity:** Major
 - Reasonable foreseeable misuse/use:** yes, it's possible
 - Hazardous situation:** During a nighttime shift in a dimly lit hospital r
 - Harm:** They misinterpret the dosage setting and admini
 - Review history:** A table with columns for Code and Title.
- Configure product:** A section on the right for configuring the product, including:
 - Risk assessment policies:** A section for creating and managing components and categories in the Resource Library.
 - Risks:** A table with columns for Prefix and Name, showing a risk with prefix RSK and name Risk.
 - ISO 14971:** A section for configuring the risk level and requires risk control, with dropdowns for Risk level (Low, Medium, High) and Requires risk control (No, Yes).
 - Risk matrix:** A section for configuring the risk matrix, with a table showing Rows (5) and Columns (5), and a grid of risk levels (Negligible, Minor, Serious, Major, Critical) with corresponding probability levels (Low, Low, Low, Low, Low).

5 Interconnected data for holistic quality management

Your vital design controls work should never be siloed.

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.

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 screenshot displays the Qualio Design Validation interface. On the left, a sidebar contains navigation icons. The main content area is titled 'DCC-9 Design Validation' and shows a 'Draft' status with creation and modification dates. A warning message states: 'Some design elements under review are outdated'. Below this, a 'Description' section lists requirements with columns for 'Code' and 'Title'. The requirements listed are:

Code	Title
DI-5	Font size must be at least 12 pt for critical information
DI-6	Materials must withstand 10 cycles of disinfection with alcohol or equivalent
DO-1	Lightweight polymer housing with integrated handle
DO-4	new screen
UN-8	Cleaning process must be simple

Below the requirements, a 'Risks' section is partially visible. On the right, a 'Design Validation' panel shows 'Linked records' with a filter dropdown set to 'Select...'. It lists 7 items in a table:

ID	Title	Type	Linked date
UN-8	Smart Pump - UN-8 Cleaning process must be simple	req1	10 Apr 2025
DI-5	Smart Pump - DI-5 Font size must be at least 12 pt for critic...	req2	10 Apr 2025
DI-6	Smart Pump - DI-6 Materials must withstand 10 cycles of...	req2	10 Apr 2025
DO-4	Smart Pump - DO-4 New screen with larger dimensions	req3	10 Apr 2025
DO-1	Smart Pump - DO-1 Lightweight polymer housing with integrat...	req3	10 Apr 2025
RSK-2	Smart Pump - RSK-2 Fluid leakage from connections or...	iso	25 Apr 2025

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](#)

