



# *Supplier management software*

How Qualio embeds compliance and control into your supplier relationships

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

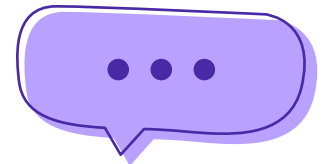
Qualio is a scalable and flexible cloud-based system that grows with your business and makes meeting your quality requirements truly simple, from ISO 13485 and ISO 17025 accreditation to FDA and GxP compliance.



Read G2 reviews



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“

*Modern quality management no longer stops with the four walls of your company. The life science world is now so connected, interwoven and interactive that the quality failure of a supplier can be as costly as the failure of your own quality system.*

*But traditional ways of assessing, qualifying and managing suppliers are burdensome and time-consuming, and distract from your own quality objectives and demands.*

*Lengthy qualification processes, prolonged reviews and scattered auditing delay supplier engagement, damage relationships and prevent fruitful collaboration. In turn, your product quality, delivery schedules, processing efficiency, customer satisfaction and product cost can all be impacted.*

*Qualio Suppliers was designed to eliminate this problem.*

*By centralizing your supplier information in a digital repository connected to the rest of your eQMS, Qualio Suppliers empowers your business with a consistent and quality-centric approach to supplier management that doesn't demand time-heavy manual data administration.*

*Use this datasheet to explore the core features and functionality of Qualio Suppliers, and learn how our software makes good supplier management natural, automatic and intuitive.*



**Meg Sinclair**

Manager, Quality and Customer Support

# Effortless supplier management

We launched Suppliers to let our customers structure, strengthen and centralize their supplier management activity within their broader eQMS.

Use Suppliers to:

## **1. Put your supplier base at your fingertips**

Ditch spreadsheets and duplicated effort by harmonizing all supplier compliance information in a single source of truth

## **2. Build and enforce policies**

Configure bespoke policies for manufacturers, service providers, distributors, consultants and more – then use them to enforce supplier requirements and ensure compliance

## **3. Attach documents**

Link key documentation like quality agreements, SLAs, GDPR statements and SOC 2 reports to suppliers. Mandate document sets for specific supplier categories

## **4. Manage risk**

Build bespoke risk levels, then assess and categorize suppliers accordingly for a full picture of your third-party risk environment

## **5. Audit with accuracy**

Link a targeted and appropriate auditing program to your supplier base for consistent review and quality assurance

# Key modular features

## Policy matrix

*I like the policy configuration part of Suppliers. It supports a more risk-based approach. Before, we required an audit, an agreement, a questionnaire for every single supplier regardless of what they did.*

— Steve F.

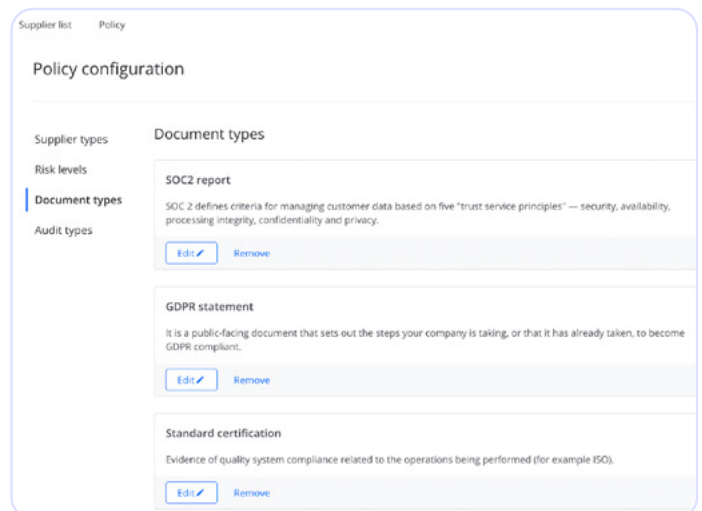
VP Quality Assurance, Capstone Development

Your business needs a consistent framework for categorizing, managing and controlling your supplier relationships.

Qualio Suppliers empowers your business with that framework by allowing you to build a bespoke supplier policy using our matrix functionality. Configure your overarching policy then use it to govern and structure all your supplier management activity, including:

1. Types of suppliers
2. Supplier documentation
3. Audit types and cadence
4. Risk categories

Each component is completely configurable to match your supplier management preferences. For instance, you may wish to add 'consultant' and 'software provider' as supplier types, add an SLA and quality agreement as document formats to be captured, assess supplier risk criticality as 'low', 'medium' and 'high', and assign annual and biannual audits for different ISO standards. The choice is yours.



Configure a bespoke supplier policy framework within Qualio Suppliers

# Supplier list

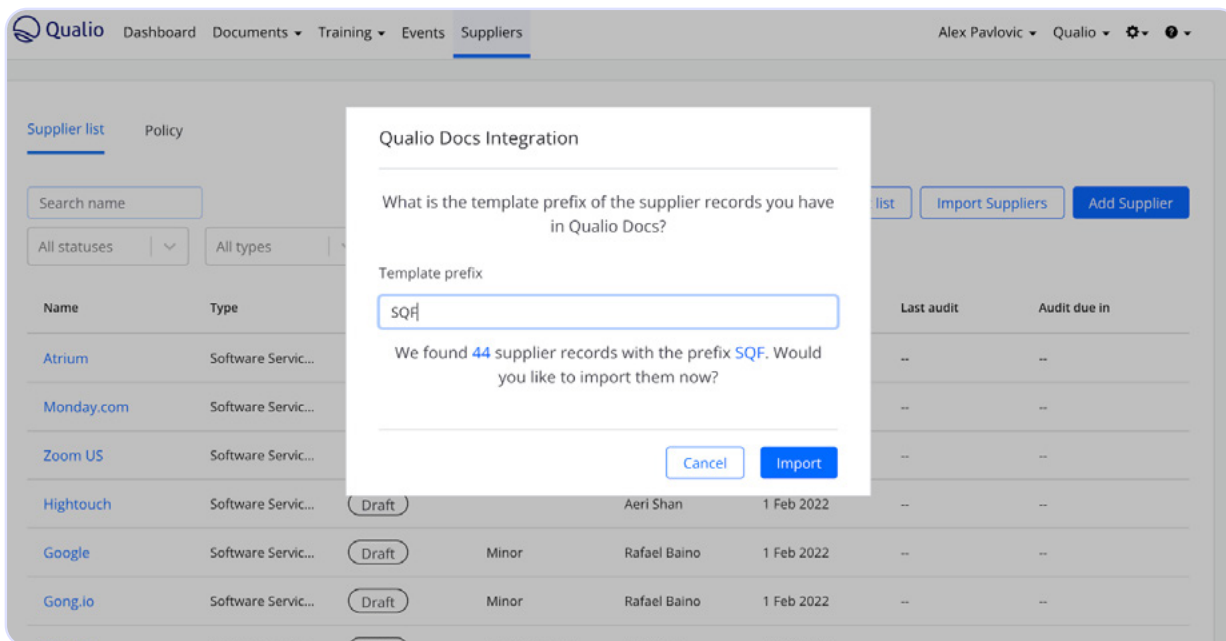
*Qualio stood out for us because it was cloud-based and optimized for medical device companies. Qualio was the right investment.*

— **Andy L.**  
CEO, ArcScan

Too many businesses rely on clunky, uncontrolled spreadsheets to list their suppliers.

Qualio Suppliers provides a clean, intuitive and easy-to-use interface list of your entire supplier base. Categorize suppliers as draft, pending, rejected or approved. Filter by type, risk level and status, add new suppliers on the fly, and export supplier information such as an Approved Supplier List (ASL).

Best of all, Suppliers integrates with Qualio Documents. Existing supplier records already in your document management system? Simply enter the template prefix and automatically import any connected supplier straight into your database.



*View a centralized list of all your suppliers and import new ones straight from Qualio Documents*

# Consistent supplier records

*Qualio enabled us to seamlessly work through our ISO 13485:2016 requirements and design errors out of our quality management system.*

— **David H.**  
CEO, Surfatek

Qualio Suppliers provides a consistent, repeatable framework for adding suppliers into your eQMS.

As you add a supplier, include key information like contact details, supplier type and internal sponsor.

Then, based on your supplier policy, mandate associated documentation depending on the risk profile and type of each supplier in your database. A high-risk manufacturer, for instance, may require a quality agreement and SOW agreement to be attached before the supplier can be fully approved for operation. A software partner, like Qualio, may require the addition of release notes, and so on.

SUPPLIER TYPE	RISK LEVEL		
	Major - Direct ⓘ	Major - Indirect ⓘ	Minor ⓘ
Software Services ⓘ	GDPR statement Release Notes DPIA SQF (Supplier Qualification Form) Major - Direct only	GDPR statement Release Notes DPIA	DPIA
Consultants ⓘ	Other Certifications	Other Certifications	No documents required
Auditing Body ⓘ	No documents required	Other Certifications	No documents required

*Enforce documentation requirements for each supplier for complete compliance*



# Approval and control

*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 Y.**

Senior Quality Manager, Proscia

As your supplier base grows, it requires careful oversight and control. Qualio Suppliers provides automated approval workflows to ensure diligence and consistency as fresh suppliers are onboarded.

Simply choose one or multiple supplier approvers, and an approval task will be generated and distributed to each recipient. Suppliers cannot be confirmed until all approvers have completed their action.

Approval

① Select people who can approve this supplier. Approval will be granted when all of them accept.

Approvers

Paul Harte × Victoria Englund × Sumatha Kondabolu × | × | ▾

Jeff McCarthy

Andrew Bates

Hayley Trace

Rich Taylor

Alan McKenna

David Haberkorn

Quincy Brown

Send for approval

*Route onboarded suppliers to designated approvers*

# 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 G.**

Director of Quality, Ultragenyx

FDA 21 CFR Part 820: Purchasing Controls (Section 820.50) mandates that you develop and maintain procedures to ensure all supplied products and services meet your requirements, while ICH Q10 gives pharmaceutical businesses the responsibility of 'assessing the suitability and competence of the contract acceptor to carry out the work required'. Robust, repeatable and appropriate risk management is therefore a crucial component of your supplier management activities.

Use Qualio Suppliers to assess suppliers by their risk profile and assign them a designated risk category. This risk category, as we've seen, then enforces the required documentation, as well as the required audit cadence for that particular supplier. Automated prompts and reminders ensure supplier audits are never missed. Depending on your bespoke supplier policy, you might, for instance, receive an annual reminder for a medium-risk supplier and a biannual reminder for a high-risk one.

SUPPLIER TYPE	RISK LEVEL		
	Major - Direct	Major - Indirect	Minor
Software Services	Remote - Requirements Re-evaluation (Major - Direct Only) every 12 months Remote - Security/Privacy Reassessment every 12 months	Remote - Security/Privacy Reassessment every 12 months	Remote - Security/Privacy Reassessment every 12 months
Consultants	Remote - Requirements Re-evaluation (Major - Direct Only) every 12 months Remote - Security/Privacy Reassessment every 12 months	Remote - Security/Privacy Reassessment every 12 months	Remote - Security/Privacy Reassessment every 12 months
Auditing Body	No audits required	No audits required	No audits required

*Link an appropriate and targeted audit program to your supplier base based on risk profile and supplier type*

Manage audits from directly within Qualio Suppliers, categorize the audit type, attach associated documentation like an audit report, then drill into audit trails of all activity related to each supplier.

The screenshot shows the 'Create audit' form in the Qualio interface. The form is titled 'Create audit' and is set for the 'SonarCloud' supplier. It includes the following fields and sections:

- Audit information**
  - Audit name\***: Text input field containing 'SonarCloud annual information security audit'.
  - Audit type\***: Dropdown menu with 'Remote - Security/Privacy Reassessment' selected.
  - Notes**: Text area containing 'Completed by KS on 2/15. Security and privacy remains suitable for purpose. 0 non-conformances discovered.'
  - Date Finished**: Text input field containing '15/02/2022'. A note below it states: 'The completion date determines the next scheduled audit based on the [supplier policy](#)'.
- Audit documents**
  - Radio buttons for 'File from computer' (selected) and 'Qualio doc'.
  - 'Upload file' button.

The background shows a sidebar with 'Supplier List' and 'Supplier details' for 'SonarCloud', and a main area with an 'Add audit' button and a list of existing audits.

*Record audits within Suppliers and attach key documents*

# 10 reasons to manage your suppliers with Qualio

**01.** Embed unshakeable compliance into your supply chain with policy-driven supplier assessments

**02.** Enjoy a single source of truth of all supplier activity, from a list of suppliers to detailed audit histories

**03.** Construct and enforce a supplier policy matrix in line with your risk appetite and internal language

**04.** Slice admin time and duplicated effort with a centralized end-to-end supplier management framework

**05.** Never miss a supplier approval or audit task with system prompts & reminders

**06.** Upload key documents or link them directly from Qualio Documents to supplier records

**07.** Enforce quality and compliance by mandating documentation and audit timelines

**08.** Get to market faster with a more integrated and less burdensome approach to suppliers

**09.** Drill into audit trails to demonstrate complete control and visibility to your regulators

**10.** Drive an integrated audit program to keep your supplier base compliant, healthy & fit for your purposes

# Set-up and services

## Life science quality expertise and commitment to partnership

An excellent life science quality management system can't be achieved with a single tool alone. It requires time, energy, resource and expertise.

Qualio commits to a long-term partnership with our customers, from the exciting infancy days of start-ups to post-market growth and expansion.

Our services include:

- Simple and painless CSA validation to get your platform up and running quickly
- Best practice [onboarding](#) and [support](#)
- Pre-built QMS document templates and pathways
- Migration of your legacy documents

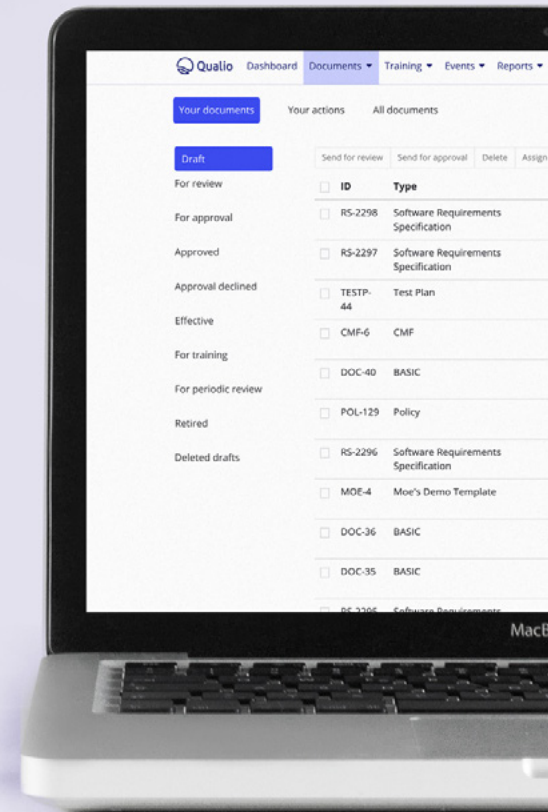


[View our pricing & packaging ›](#)

# Ready for a stronger supplier management strategy?

We'll answer your questions, give you a live private tour of the product and show you how we can meet your supplier management needs.

[Schedule a demo with us](#)



Call us today

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