



How Qualio does it

Validation

Qualio is a specialized quality management software system provided specifically for life science businesses by a dedicated cloud vendor. Qualio has embraced the latest validation best practice laid out in the [FDA's 2022 computerized system assurance \(CSA\) guidelines](#). We take responsibility for the bulk of the validation process to provide a sensible, risk-based and 'least burdensome' experience for our customers. At the end of our industry-leading implementation timeframe, Qualio customers are provided with a complete validation document pack demonstrating how Qualio is validated, fit for purpose and compliant for operation in a regulated GxP environment. Plus, every time Qualio updates, you're provided with an updated document stack to keep you compliant. [Learn more about our validation approach](#) ›

How SharePoint does it

Since SharePoint is not a dedicated life science tool with in-house expertise, you're responsible for validating your SharePoint system and revalidating it every time there's an update to it, or to any other third-party software integrated with your SharePoint system.

We strongly recommend additional consultancy support on the validation needs of any system if you plan to handle internally.

Benefits for your business

- Quick and painless validation handled by us, not you
- More time for you to focus on getting to work with your new eQMS
- No need to carry out detailed validation work yourself (though you always have the option to perform any additional validation testing you wish to)
- No additional consultancy or support spend required

E-signatures

Qualio provides FDA- and EU-compliant, legally binding e-signatures as standard.

SharePoint has no built-in functionality to provide the e-signature capability required in modern electronic record regulations like FDA 21 CFR Part 11 or EU Annex 11. Further investment in third-party software is required to fulfill this requirement, bringing extra cost, time and (as discussed above!) validation work.

- Compliant and binding e-signatures underpinning your eQMS activities
- Automatic compliance with FDA 21 CFR Part 11 and EU Annex 11
- No more chasing employees for signatures to shore up compliance
- No need for extra software investment

Document management

Qualio also offers a cloud-based library for storing documentation, then builds on it with a framework that embeds quality and compliance and ensures your organization meets the requirements of benchmarks like GDocP and ALCOA+ easily and automatically.

A built-in web editor, document tagging for rapid search, bespoke templates and integrated version and access control streamline your document management activity while giving you the oversight and visibility you need for robust compliance.

SharePoint offers a digital access point for storing your company documentation. But since it isn't a dedicated quality tool, core compliance functionality like version control and change histories are missing or limited.

- Bespoke templates provide consistency and standardization
- Library-wide search using document tags simplifies access to information
- Web editor allows fresh documents like new SOPs and policies to be built on the fly from within the system
- Workflows control how documents are routed, controlled and approved
- Version histories and defined access controls embed compliance and traceability
- Entire quality management system linked in a single source of truth



How Qualio does it

Training management

Qualio unites documents and training in a single connected environment. Assign training on documents based on roles and responsibilities, build workflows to manage training, generate reports on individuals, departments and the business, and ensure training is always completed with automated prompts and reminders.

How SharePoint does it

SharePoint offers no built-in functionality to train employees on QMS documents, or prove understanding and competence when your auditor comes knocking.

Benefits for your business

- Help new employees onboard faster with a streamlined approach
- Assign the right training to the right person based on their role
- Notify the correct person when training is required for new procedures
- Underpin all training activity with FDA- and EU-compliant e-signatures and complete audit trails
- Maintain quality standards and compliance with training assessments
- Use system reports to pinpoint and plug training gaps

Audit trailing

All Qualio activity is underpinned by automatic audit trailing, allowing you to quickly and easily:

- Provide requested data for audits
- Trace the histories of document versions, individual training, quality events, device design artifacts and more
- Prove compliance
- Demonstrate continuous improvement
- Report on system activity

SharePoint does not provide audit trail functionality to demonstrate control, visibility and compliance to a regulatory auditor.

- Demonstrate control and traceability to your auditor and answer questions with ease
- Proactively identify gaps and predict quality performance with our connected ecosystem
- Drill into any activity and action performed within Qualio

Customer support

Qualio commits to a long-term partnership with customers and offers three levels of support:

- Dedicated customer success and onboarding managers to support your set-up process, train your teams and guide you to your North Star eQMS objective
- Help Center and live chat with rapid response time, supported by frequent thought leadership and best practice webinars
- Qualio+ add-on support: expert consultancy from the Qualio quality team

SharePoint offers customers some [online training](#) and access to Microsoft customer support. Wait times can be substantial due to the high volume of worldwide Microsoft users requiring help and support.

- Enjoy close support and partnership for as long as you're a Qualio customer
- Access live chat and a help and support library at any time
- Work with our team of seasoned quality experts to ensure you meet and exceed your QA goals
- Access ISO/FDA strategy sessions, QA support, eQMS training and market intelligence sessions
- Be audited by the Qualio+ team to get your quality system airtight and optimized