**Document functionality** 

# Qualio

- Specialized, cloud-based quality management software designed specifically for life science businesses
- Validated with the latest best practice laid out in FDA CSA guidelines: riskbased and 'least burdensome' approach with complete validation document pack provided
- Cloud-based library for storing and managing documentation, specially built to support quality and compliance demands like GDocP and ALCOA+
- Flexible hybrid approach gives you control of how you manage your documents. Upload and store static documents in their original file formats. Convert them into editable Qualio documents at any time to make updates, or build fresh documents within the system – all with full in-app editing and collaboration features
- Document action workflows, tags, bespoke templates, automatic audit trails and integrated version and access control streamline your document activity while giving you the oversight and visibility you need for robust compliance
- FDA- and EU-compliant, legally binding e-signatures as standard
- Al functionality automates document tasks like rewrites and summarizing changes

# **SharePoint**

- Not a life science tool, no dedicated functionality for regulated businesses
- You're responsible for validating and revalidating every time there's an update to SharePoint, or to the other third-party software you'll need to integrate with your SharePoint system
- Additional consultancy strongly recommended if you plan to apply in a regulated industry
- Cloud-based access point for storing documentation, with some basic permission controls and collaboration
- No core life science compliance functionality like version control, audit trailing and change histories
- Storage only: no workflow functionality for managing documents, no template options for consistent records
- No built-in functionality to provide the e-signature capability required in modern electronic record regulations. Further investment in third-party software required to fulfill this requirement, bringing extra cost, time and validation work
- No Al functionality

### **Benefits of Qualio**

- Designed with quality management in mind to help you bring life-saving products to market
- No workarounds or additions needed for use in a regulated sector
- Quick and painless validation handled by us, not you
- No additional consultancy or support spend required
- Purpose-built quality document management system means no extra investment required: full toolset available in a single system
- Gain rapid access to controlled, standardized information
- Control how documents are routed, controlled, reviewed and accessed within your business
- Build and launch documents with onestop-shop native collaboration, from inline commenting and suggestions to review and approval workflows
- Be confident in total compliance and traceability with version histories, audit trails and configurable access controls
- Compliant and binding e-signatures underpin your document activities for automatic compliance with FDA 21 CFR Part 11 and EU Annex 11
- Al supercharges your document work

- · Documents and training united in a single connected environment
- Assign training on documents based on roles and responsibilities, build workflows to manage training, generate **Qualio Analytics** reports on individuals, departments and your company, and ensure training is always completed with automated prompts and reminders
- No built-in functionality to train employees on QMS documents, or prove understanding and competence when your auditor comes knocking
- No visibility of organizational training statuses or gaps
- Train staff on documents quickly and easily
- Assign the right training to the right person based on their role, with all functionality required to maintain quality and compliance integrity
- Use Qualio Analytics to pinpoint and plug training gaps



### Qualio

# Customer suppor

- Commits to a long-term partnership with customers, backed by decades of collective life science industry expertise
- 86% of customers self-serve support they need with Knowledge Base and Help Center - round-the-clock support team with rapid response times also provided
- Pre-built eQMS content and life science industry-specific content pathways provided for customers to populate their Qualio systems

### **SharePoint**

- Some <u>online training</u> and access to
   Microsoft customer support. Wait
   times can be substantial due to the
   high volume of worldwide Microsoft
   users
- No pre-built quality content provided, no in-house life science industry expertise

### **Benefits of Qualio**

- Enjoy close partnership with a specialized vendor, with a range of support options whenever you need them
- Work with our team of seasoned life science quality success experts to ensure you meet and exceed your goals
- Access a wealth of pre-built life science content templates to feed into your system for accelerated quality and compliance maturity

# **20**

- Annual SaaS subscription model
- All costs visible upfront for your longterm planning
- Purpose-built scalable tool for embedding long-term, airtight and efficient quality and compliance: accelerates your route to profitability while slicing the risk of regulatory punishment
- Free with Office 365 subscription, but brings a slew of hidden costs: separate system investments and workarounds unavoidable for operation in a regulated life science environment
- Basic, inflexible set-up doesn't scale
  with you, meaning a ceiling will
  eventually be hit as you grow forcing
  eventual migration to other tools
- Compliance gaps, manual upkeep,
   validation work and associated admin
   all add time and money drag, while
   slowing your time to market and
   inviting the risk of regulatory fines and
   costly mistakes
- Higher up-front costs pay for themselves in a matter of months with lean, sharp, automated and scalable processes
- Be confident you have everything you need for robust compliance in a single dedicated system that doesn't need add-ons later
- Holistic eQMS optimizes your document and training activity, as well as your quality event, design control and supplier management

"Our company used to keep all our quality documents on SharePoint. It was a headache to find anything you needed. The layout of Qualio is easy to understand. Qualio has improved our control processes and our management systems."

Jesse Woodring
 Fulfilment & Logistics Specialist, Emsere

"I usually hate dealing with documents. But every time I have to log into Qualio, it's a very pleasant interaction. Man, I really love Qualio!"

— Dmitry FedorovChief Technology Officer, ViQi

"It's almost impossible to quantify how much time Qualio has saved us because it's impossible to know how much we were wasting before when we were using SharePoint and spreadsheets."

— Kate Nicholson

Head of Business & Portfolio Optimization, Enara Bio

"We had SharePoint. But the fact that Qualio offered everything all in one – events, CAPAs, complaints, documents – and getting in on that sooner before we grew much larger, made sense for us."

— Hanna FanousQuality Assurance Supervisor, Kazmira

# A quality director explains why you should *never* use SharePoint for your quality docs

Watch the video ▶

# Compare Qualio and SharePoint in more detail

View the comparison webpage ▶