

Successfully Implementing EQMS

Your step-by-step guide to the best practice implementation process



teach us, provide training and establish the system as we jointly designed, but their professionalism, excellent customer service, openness and flexibility really impresses me..."

- Ellen Boone, BT Global Services

EQMS reduces the compliance burden associated with various Standards and Regulations. Including:









Welcome -Our Mission



Mike Pound MD Qualsys mike.pound@qualsys.co.uk Thank you for choosing EQMS. I am delighted to welcome you on board and look forward to working together in the years to come.

This document highlights our 'Best Practice Implementation Process'. It is written to give each member of your Project Team an overview of the services and support provided as part of your EQMS Implementation:

- a) Learn more about a typical implementation journey
- b) User engagement and customer success
- c) Answer your frequently asked questions

At the start of our partnership I want to share our corporate mission. EQMS will make a real impact in your organisation, something we can all be proud of. I'm sure the project will be a big success.

EQMS by Qualsys. Better people, process and product.

Our mission is to transform the role and impact of compliance in your organisation.

How?

EQMS embeds compliance into the fabric of your organisation. Acting as an 'operational excellence portal', it delivers increased capacity for Quality Teams to drive continuous improvement and culture.

1.1

Your EQMS – Integrated, agile management solution





EQMS is an award winning GRC solution with advanced, yet easy-to-use functionality. Fully integrated EQMS modules are available to manage documentation, training, audits, equipment, complaints, suppliers, workflow and more.

Simply choose the functionality you need and our experienced and proactive team will work to ensure a successful implementation and rollout.

EQMS will:

- ✓ Reduce your operating costs.
- ✓ Improve traceability and accountability.
- ✓ Embed a culture of compliance.
- ✓ Accelerate time to market.
- ✓ Mitigate risk from a business and IT perspective.

DOCUMENT CONTROL

RISK
MANAGER

WEDENATION

CONTROL

AUDIT

MANAGER

MANAGER

MANAGER

CHANGE

MANAGER

Wheel of Integrated EQMS Modules http://www.eqms.co.uk/qrc



Services -

Global experience, optimised for your needs



Isabelle Pound Services Director Qualsys isabelle.pound@qualsys.co.uk

Best Practice Implementation Process

The Qualsys Team has successfully implemented over 500 EQMS systems in complex, highly regulated organisations in diverse sectors such as FMCG, Life Sciences, Manufacturing and Outsourcing.

Despite the regulatory differences, the challenges faced are remarkably similar whether you are a global manufacturer or a growing medical device organisation; it's all about keeping things simple to minimise training need and ensure widespread adoption.

Our Customer Success Team are PRINCE2 trained and use repeatable methodologies to provide a scalable, cost-effective delivery model.

In this section, we provide more information about the services available to you.

2.1

Success Criteria -

What is the desired outcome or business impact?

The first step is to agree the 'Aims & Objectives' of the project. We engage with your key stakeholders to identify and agree how EQMS will meet your project success criteria:

- a) What does success look like to you?
- b) What are your objectives?
- c) How will we measure success?

Qualsys find this delivers better results for our customers as everyone understands the context of our EQMS project and, crucially, how its impact will be measured and communicated:

Typical services include:

- ✓ Project Scoping Workshop
- Consultation Questionnaire (benchmarking pre/current culture)
- ✓ Webinars and Videos
- ✓ Awareness Assessments
- ✓ CEO Video





Strategy and Planning

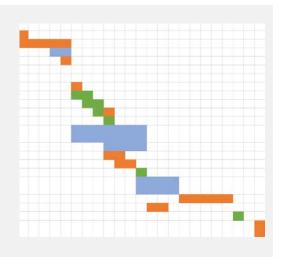
Tailored Implementation Plan

After the success criteria have been defined, we agree a project plan which provides a comprehensive overview of the end-to-end process. This means working backwards from your required go-live dates to ensure there is enough capacity and time to deliver.

Qualsys provide a dedicated Project Implementation Manager, a Key Account Manager and Support Team to ensure a smooth and enjoyable experience.

Key items:

- ✓ Strategy and Configuration Planning
- ✓ Project Plan & Work Breakdown Structure
- ✓ Training for all user levels
- ✓ Implementation models: Phased / Pilot / Multi-site deployment
- ✓ Process Mapping and Review
- √ Validation Master Plan (FDA/GxP/MHRA)





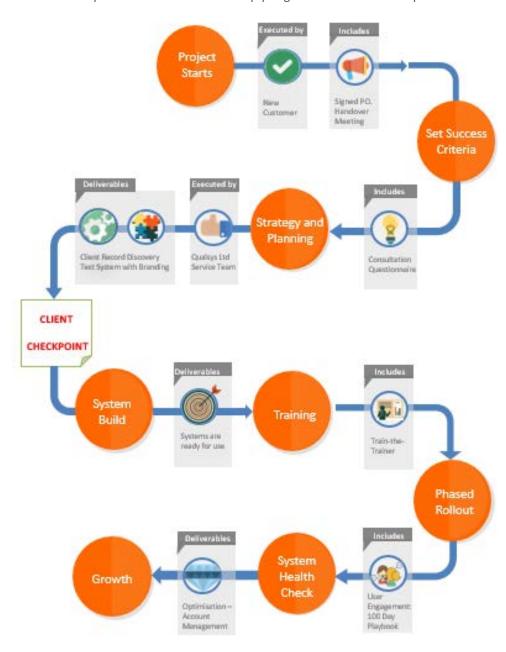


2.2.1

Your EQMS -Typical Implementation Journey

Implementation Journey

The key milestones of the implementation journey are detailed below. The remainder of this document provides more context to help you get best value from the process.



A fully functioning EQMS system will pay for itself in months and deliver ongoing savings for years to come.

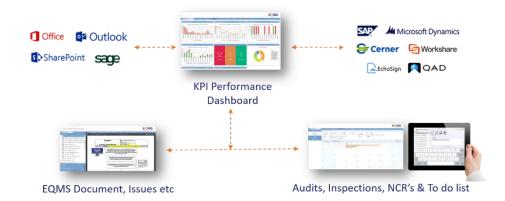


Configuration Planning & Implementation Support

Configuring Your EQMS

Qualsys provide two x EQMS systems as standard – 1x Live and 1x UAT (Test) system. All workflows, custom form-fields and permissions are configured with your Project Implementation Manager.

INTEGRATED EQMS – HOW IT WORKS



Typical services include:

- ✓ Workflow and Document Templates
- ✓ Active Directory / Single Sign On
- ✓ Custom Reports
- √ Validation Process Support
- ✓ Validation Test Scripts
- ✓ Multi-language Translation
- ✓ Integrations with 3rd party Applications such as Microsoft, ERP, Financial, HR.

2.4

Data Services

Data Migration

Qualsys offer qualified and experienced personnel to outsource your time-heavy activities such as batch upload of documents/records and data migration from your legacy systems. e.g. for SharePoint or Lotus Notes.

Typical services include:

- ✓ Design and Load Data Template.
- ✓ Data Extraction.
- ✓ System Migration.
- ✓ Batch upload of documents and records

Speak with your Account Manager for more details



Training Service

Fast, efficientroll-out

Tailored Training - blended, easy, scalable.

EQMS is familiar and simple to use, requiring minimal training for administrators and often no 'formal' training for end users. This is a crucial benefit, in that it lowers the learning curve, training costs and encourages engagement.

EQMS Certified System Administrator / Train the Trainer



From our experience, this engenders wider buy-in, a sense of ownership and delivers a greater return on investment.

End-User Training and Support Resources - Minimal Required

A range of free training and support resources are available to ensure smooth and efficient roll-out.

Training and Support Resources

- ✓ EQMS UAT Test System (a test system for users to practice on with no fear of compromising 'live' data)
- ✓ Help & Knowledge Base Step-by-step Guides for Users http://help.eqms.co.uk
- ✓ Many 'How to?' videos available on the Qualsys YouTube Channel.
- ✓ Recordings of EQMS Introduction Webinars
- ✓ User Guides extensive step-by-step guides for each EQMS Module.
- ✓ User Welcome Packs (to include copies of training slides and other Help Guides)
- ✓ Multi-language Translation





End User Roll-out

User Awareness & Engagement - 100-Day Playbook

ISO 9001:2015 demands a focus on culture and managing risk. This means ensuring everyone in the business knows their role, obligations and how they can make an impact.

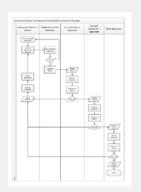
EQMS is free of charge to unlimited end-users. This includes external users such as consultants and supply chain. Our goal is for the system to bring your organisation closer together, enable speedy, better informed decision making and simplify compliance.

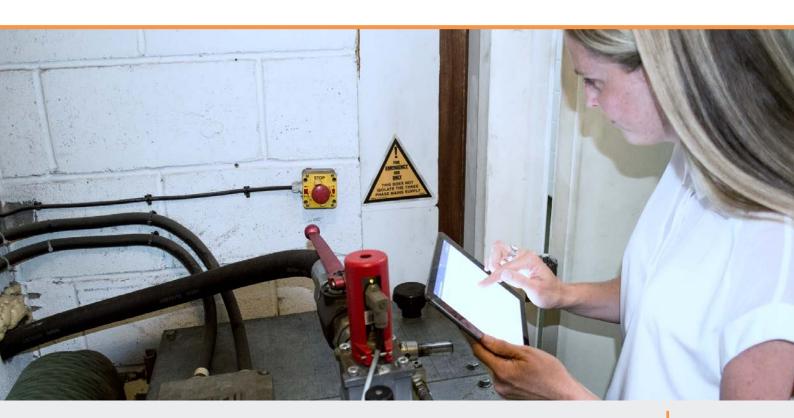
The '100-day Playbook' provides templates, tools and ideas for driving user engagement with EQMS. Wider usage results in greater business benefit.

For more information, email marketing@qualsys.co.uk.

Typical services include:

- ✓ 3-minute video with your CEO / Project Sponsor
- ✓ Tailored landing pages
- ✓ SOP Templates (with Process Flows)
- ✓ Emails
- Brochures
- ✓ Events
- ✓ Webinars
- ✓ Supplier Roadshows







Frequently Asked Questions (FAQ)

When will I start to see a Return on Investment (ROI)?

A fully functioning EQMS will pay for itself in months, and deliver ongoing savings for years to come. Cost efficiencies are typically generated from a) process efficiencies such as automated workflow and reporting and b) risk reduction and lower cost of non-conformity.

Qualsys provides extensive business case support: http://quality.eqms.co.uk/eqms-buying-toolkit

We have an existing, legacy system - can you transfer the data to EQMS?

Yes, it is a standard element of the Implementation Process. Data transfer can be completed programmatically via Qualsys Engineer, via CSV/batch upload and/or dynamically via integration with the 3rd party solution. Speak with your Account Manager for more details.

Can I add extra modules?

Yes, EQMS is a modular system. Simply contact your Account Manager to <u>arrange a demonstration</u>, <u>request pricing</u> and / or discuss the upgrade schedule.

How does the licensing work?

EQMS is **free of charge** for unlimited end-users (internal/external) There is unlimited concurrency and only System Administrator and Manager users impact the license.

The EQMS Portal is highly scalable, opening opportunities for supply chain partnership via self-audit, complaints management, request for proposal and more.

Can we visit Qualsys to meet the team / conduct a Supplier Audit?

Qualsys have an open door policy. You are more than welcome to visit our headquarters in Sheffield either informally to meet the team and/or more formally to conduct a supplier audit (for validation purposes). Arrange your visit: info@qualsys.co.uk

Can you explain Big Bang vs Phased roll-out?

The choice of 'Big Bang', 'Pilot' or 'Phased' roll-out will depend on factors such as the size of your organisation, your target 'go live' and the number of EQMS modules you are deploying. Some organisations find it better to focus on one or two departments / business units before rolling out to the wider operation. Others prefer to configure all elements of EQMS before 'flicking the switch' on the legacy system. In both scenarios Qualsys will advise based on our extensive experience.

Can we pay monthly?

Qualsys work with a software asset finance partner who are able to wrap up training, software and support costs into 36 equal monthly payments. Contact your Account Manager for more details.

Can we evaluate EQMS solution with our own data / workflow included?

Yes. Qualsys provide a Project Scoping Workshop (3 hours) where your team will evaluate an EQMS system which has been configured with customer specific data and workflows. This experience provides the benefit of a 'trained hand' driving the system whilst your Project Team will focus on evaluating and asking critical questions – the best of both worlds.

More Questions?

Ask your Account Manager for the Technical Questionnaire (TQEQ01)



Useful Resources





WEBINAR

EQUIPMENT FOR ASSET CARE AND SAFETY



Download: quality.eqms.co.uk/assetequipment-management



Download: quality.eqms.co.uk/grc-softwaredemonstrations



Download: quality.eqms.co.uk/supplierperformance-management



Download: quality.eqms.co.uk/eqms-buying-toolkit





Download: quality.eqms.co.uk/iso-9001-2015-toolkit





Download: quality.eqms.co.uk/changes-to-iso140012015





Download: quality.eqms.co.uk/iso-15189-toolkit



REQUIREMENTS



Download: quality.eqms.co.uk/iso-27001-toolkit



TOOLKIT ISO 45001 REQUIREMENTS.



Download: quality.eqms.co.uk/iso-45001-toolkit





Download: quality.eqms.co.uk/food-beverage-safety-management-software





Download: quality.eqms.co.uk/iso-ts-16949







Download: www.egms.co.uk/EQMSROI/



Getting Started Checklist

What Next? Checklist to help you make a flying start!

The checklist below provides a few useful suggestions to help you prepare for your EQMS Implementation. Speak to your Account Manager for more resources.

Item	Action	Detail	٧
1	Get Leadership Buy-in	Engaging the Project Sponsor early will give the project visibility and clout to succeed. Qualsys will co-produce a 'CEO Video' as part of the implementation. You may want to ask for a business case statement and/or other internal advocacy to help things run smoothly. See: http://quality.eqms.co.uk/blog/3-leadership-engagement-lessons-for-iso-90012015-cqi-conference-2015-part-2	
2	Establish Project Team	Think about who will be on your EQMS Project Team. This is normally quite small (1-6) to avoid 'too many chefs' and includes key stakeholders from around the organisation. http://quality.eqms.co.uk/stakeholder-engagement-template	
3	Employee Survey – identify pain points and win results	Establish a 'baseline' pre-EQMS by asking your employees for feedback re current processes and challenges. Use this information as part of EQMS implementation and in the annual system health check (see 3.2) Qualsys supply template as part of implementation. Example survey here: www.surveymonkey.co.uk/r/employee-feedback-survey-grc	
4	Define Success Criteria	A common challenge for HSEQ Teams is to clearly communicate success and impact to the wider business. For example, hard data re reduced cost of complaints/returns. EQMS provides the perfect opportunity to define and celebrate success criteria. http://quality.eqms.co.uk/blog/establish-eqms-success-criteria	
5	IT / Technical Survey	Qualsys are very experienced supporting IT departments in organisations around the world. Detailed technical documentation and server requirement specifications are available to help them be prepared for EQMS: http://quality.eqms.co.uk/eqms-buying-toolkit	

Ready to get started?

Talk to us.

E-mail: info@qualsys.co.uk Qualsys

 Tel:
 +44 (0) 114 282 3338
 Aizlewood Mill,

 Fax:
 +44 (0) 114 282 3150
 Nursery Street,

 Web:
 www.eqms.co.uk
 Sheffield S3 8GG, UK





www.twitter.com/qualsysegms



www.youtube.com/QualsysLtd



www.linkedin.com/company/qualsyscompliance.



eqms.co.uk/blog