



QualityKick
Whitepaper

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01 Why QualityKick?

01

Foundation Stone

QbD software was founded in 2017. The company is a part of the larger **Quality by Design Group** which is a leading consultancy company with predominant operations in Europe and Latin America. Initially, the Quality by Design Group started its operations in Belgium in 2011 and has now expanded its business operations exponentially in countries like the Netherlands, Spain and France, but also in Latin America, in Colombia and Mexico.

The need for the **QualityKick™** eQMS solution came into existence as an outcome of continuous interaction of **QbD** consultants with their various clients in pharmaceutical, biopharmaceutical and medical device companies. These organizations were seeking expert consultation services from the QbD consultants to set up and maintain state of the art Quality Management Systems.

During these projects the consultants identified the need for a paperless and transparent Quality Management System which would better prepare the clients for frequent regulatory inspections. **The ask was for development of an efficient, easier and cost effective Quality Management System.**

This laid the foundation stone for **QbD software** and the company began its journey towards development of a 'Software as a Solution' (SaaS) to fulfill this frequent requirement.

01

Reasons

Ease of Implementation

QualityKick™ is a cloud based software as a service (SaaS) solution. Therefore it is easy to implement as it does not require any installation within the company's network or infrastructure. This offloads the IT department from the installation, maintenance and provisioning of hardware resources.

User-friendly

Secondly, **QualityKick™** is a web-based solution which makes it **extremely intuitive and user friendly**. Generally, users are already familiar with several web-based platforms such as ticket booking systems, food ordering systems and various social networking websites. Hence, users easily adapt to the web-based environment.

Pre-validated

The third and most important advantage of **QualityKick™** is that it is prevalidated. **We perform 95% of validation activity** at our end so that our customers don't have to needlessly repeat the same work at their end.

Standardized

Our solution is created with an intent to fulfill requirements of a huge client base. Hence we have developed a solution which serves 85% of the market need. Therefore, the users can be doubly assured of possessing a standardized solution which is created by keeping the '**one size fits all**' philosophy in mind.

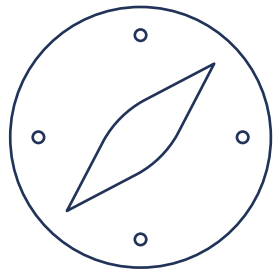
02 Technical Aspects



02

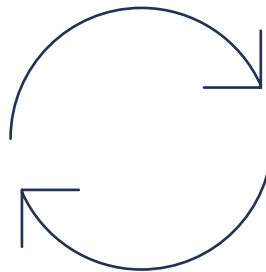
Environment

You will get three different types of **QualityKick™** environments.



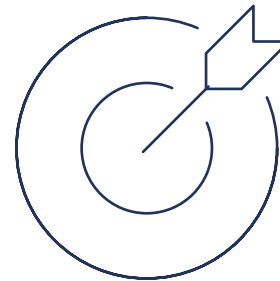
Test

You can use this environment for **testing** the application and trying the newest features before they are live.



Validation

This is an environment which can be used to perform the **last validation steps**.



Production

This is the **live environment** where the actual Production data is stored.

02

Structure

QualityKick™ is a flexible solution in which only the desired QMS **Modules** can be activated depending on your needs.

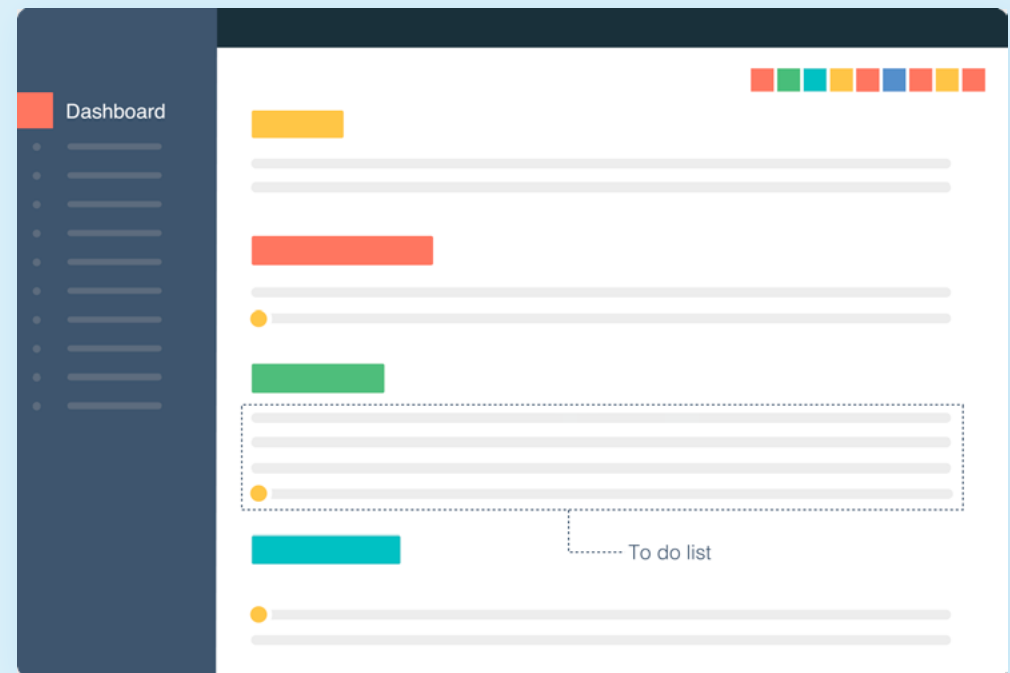
The structure of the modules is really simple to understand as there are only four screens which are used throughout each module to provide you with all the functionality you need. The four screens are described one by one as follows:



02

Structure Dashboard

This is the place where users can see the '**To Do list**' of QMS activities which the user is responsible for within the application. It includes pending sign off activities on CAPAs, Events and Documents. It also includes a list of training activities which the user needs to accomplish.

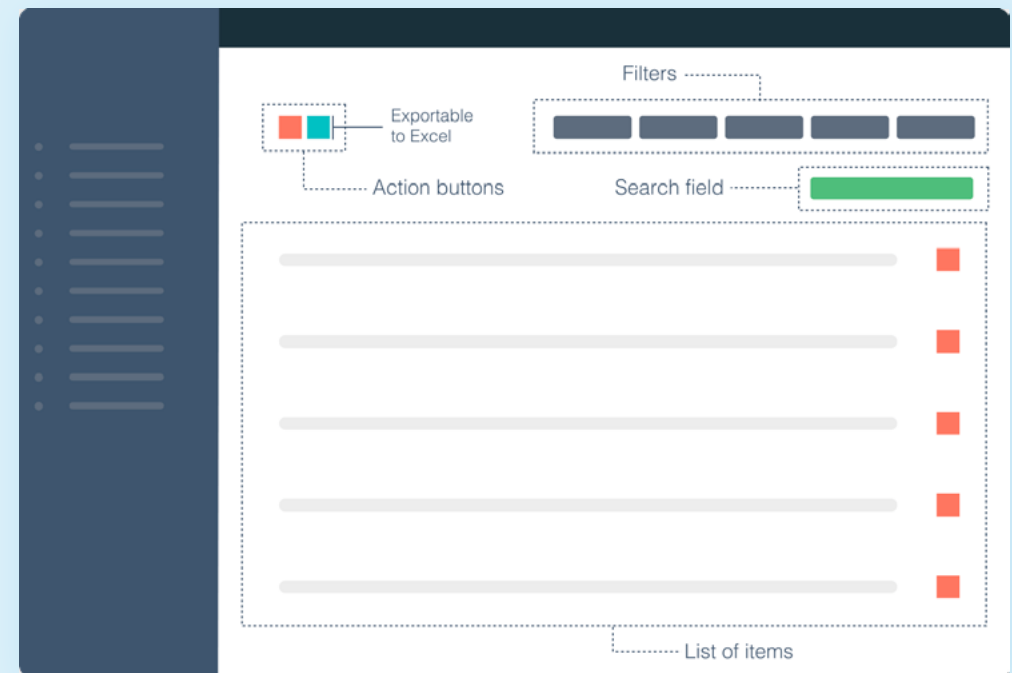


02

Structure

List Pages

The user can see list pages by clicking on items listed under each module. The lists have action buttons in the top left and filters in the top right. The action buttons can be used for creating a new item or exporting the listed items in CSV or Excel format.



02

Structure

Form Pages

The form pages can be seen when a user creates a new item. They are extremely user friendly as they all are alike. The user only needs to enter the information with the help of fields in the form. The fields are self-explanatory and are also provided with help text, to help the user understand which input is expected.

The image shows a wireframe of a web form. On the left is a dark blue sidebar with a vertical list of ten items, each consisting of a small circle followed by a horizontal line. The main content area is white and contains two identical form sections. Each section starts with a teal rectangular button. Below the button are three horizontal input fields: the first is solid light gray, the second is dashed light gray, and the third is solid light gray. A dashed line connects the second field to a rounded rectangular box containing the text 'Help text' and two more horizontal input fields. Below this box is another solid light gray input field. The second form section follows the same pattern with a teal button, three input fields, a help box, and a final input field.

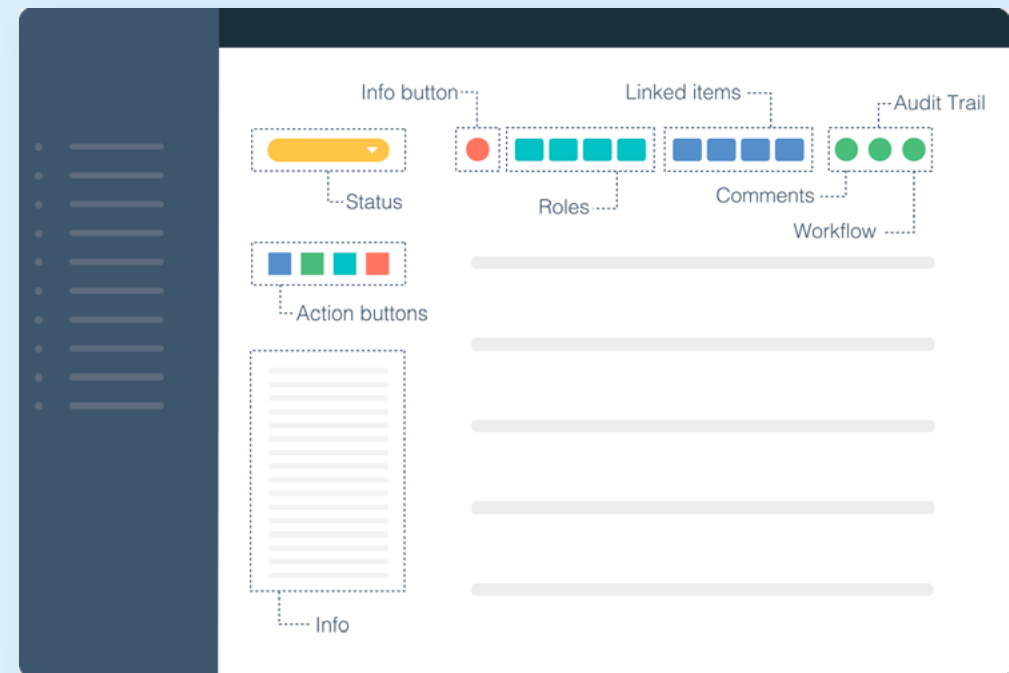
02

Structure

Detail Pages

The detail page of a document looks the same as for a deviation, a CAPA or a change request. In a secondary column you see the status and action buttons. Or the rest of the information and functionality has been organized in tabs on the right in the same way throughout all the modules.

Linked items allow you to easily navigate from one detail page to the other detail page of a related item.





03 Important Features

03

Configuration of QMS Workflows

It is very easy to configure the QMS workflows in **QualityKick™** by selecting options for keeping or not keeping certain roles like author, reviewer, approver and QA in the workflow process.

It is also possible to configure more than one author and more than one reviewer and so on. The workflow for each QMS item can be seen under the workflow tab which also shows the approval status.

03

Electronic Signatures

All the electronic signatures are recorded according to **21CFR Part 11** compliance. The audit trail tab can be used to view actions history such as when the item was created, signed, modified etc.

For documents, every modification results in a new version of the document. The versioning process is automated.

03

Communication

The users can centralize communications within the application by adding a comment to any item. **QualityKick™** also takes care of emailing the relevant individuals about document creation, signing, modification and receipt of a comment.

03

Cross-linking

Items in one module can mostly be linked to relevant items in other modules. This provides traceability making it really easy to know which items are related. Simply clicking on an ID or a title of a linked item will provide you with its full details, having all the desired information just one click away.

03

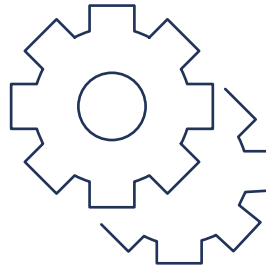
User Roles

It is possible to create four user types depending on the organizational roles and responsibilities of the **QualityKick™** user.



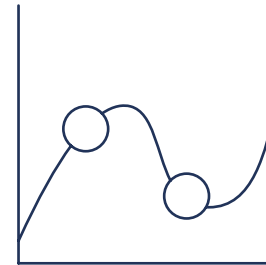
Read-only

This type of user can **only read and view** items. It cannot participate in approval workflows, however, these users can sign off on assigned trainings.



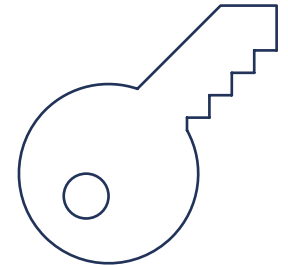
Regular user

A regular user **can create items and participate** in workflows, in addition to what Read-only users can do.



Managers

Managers can do the same as Regular users but can additionally **manage module specific configurations** like document types and event types.



Administrator

This type of user has **full access** to all the features and functionalities in **QualityKick™**.

04 Cost Structure



04

Cost structure

The cost structure of **QualityKick™** uses a pay-per-use model which can be divided into three different parts.

User License cost

You pay a **specific price for each user** which is active in the system according to the User Role and the Modules the user gets access to.

User license cost includes:

- Upgrades
- Support cost
- Infrastructure cost

Storage Cost

The user license cost does not include storage cost as different organizations have different storage needs. Therefore to ensure fair charges storage cost is separately calculated using **GigaBytes of storage required per month**.

Implementation Cost

There is a **one time implementation cost** which is calculated according to:

- Data import requirements
- Integration requirements
- Number of Modules on which Training is needed

The cost structure is fully transparent as we send a price calculator for self-calculation.

Volume discounts are automatically applied by the calculator as well.



05 Onboarding

05

Onboarding process

We have an extremely systematic approach of Onboarding new customers in to **QualityKick™**.

The goal is to get trained, validated and have your data live in production in the least amount of time.

The process is very clear and easy to understand as follows:

Always necessary,
for all customers.

1

Initial Onboarding meeting

The goal of this meeting is to explain the onboarding process. The relevant activities are discussed, and action items are agreed upon.

Always necessary,
for all customers.

2

Training

One-hour of User Training is provided for each module. These training sessions are done remotely and are recorded. After each session, the link to the recorded video is shared with the customer so they can use it to train other/future employees in the usage of **QualityKick™**.

Training can be done in English, Spanish or Dutch.

05

Onboarding process

You can leverage our validation package to do the last validation steps on your end.

This effectively takes away 90%-95% of the validation effort on your end.

*Only relevant if the customer has applied for a validated **QualityKick™** production environment.*

3

Validation

We provide a validation documentation package for each module (each module is validated separately and has its own version). It contains a full validation according to **GAMP5**, drafted and executed on our end.

The package contains the following documents:

- Validation Plan
- User Requirements
- Risk Assessment
- Functional Specifications
- Design Specifications
- Configuration Specifications
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Traceability Matrix
- Validation Matrix
- Validation Report
- Change List

05

Onboarding process

*Microsoft Active Directory
Azure AD
or other integrations*

4

Integrations

Besides out-of-the-box integrations, **QualityKick™** is “API driven” (RESTful API) and can therefore be easily integrated with other systems and applications. In our experience, integration is always possible as long as other systems allow integration with them.

5

Data import

*Most customers already have a quality system running, paper-based or with some other digital solution. Therefore, these customers will need to import their current quality system data into **QualityKick™**.*

The project manager and the technical support team will guide you in analysing your quality system and will help you to take the right decisions. Once everything is clear, you will provide us with the data accordingly and we will take care of the import for you. After the data import has finished, you perform a verification that the data is imported correctly and you are ready for Go Live.

05

Onboarding process

Training, Data import, Validation, Integrations and Weekly meetings are done in parallel.

6

Weekly follow up meetings

In order to ensure the success of **QualityKick™** with the customer and to make sure the different teams are constantly aligned and tasks are assigned and delivered accordingly, a weekly follow-up meeting of 30-minutes will be scheduled.

05

Upgrades

We constantly upgrade our Modules to meet the needs of our customers.

Upgrades occur 1 to 3 times a year per Module.

We provide an updated validation package to our customers which includes a change list containing information on the changes in the current and the new version of the Module. The update validation package is provided 60 days before the new version release, hence the customers have 60 days time to review, perform selected tests and sign off on the validation documents.

Depending on the nature of change, Medium or Major version increase is assigned to the upgraded Module.

05

Issue Management

Issues within the application are solved immediately and according to regulation with the help of the **'Low Impact Change Control' (LICC)** process in which we describe the problem along with its solution, describe and perform the necessary tests and send out a signed LICC document to the customers. LICC only causes minor version increases of the Module.

06 Support

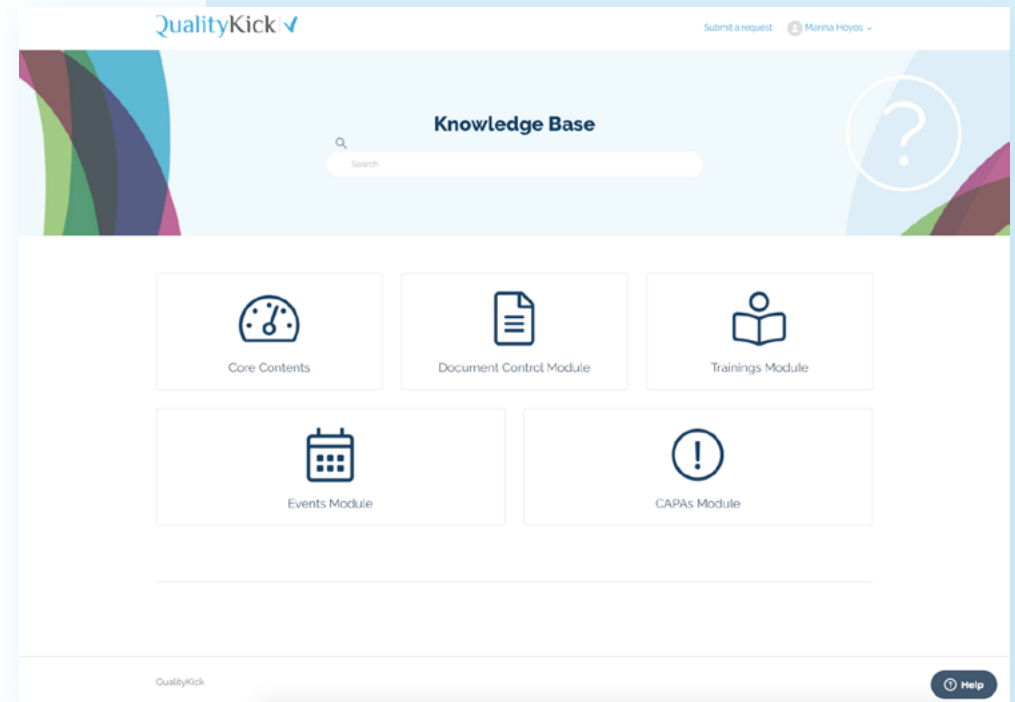


06

Service Desk & Knowledge Base

It is very easy to create a support ticket in **QualityKick™**. A ticket can be raised by clicking on the help button in the bottom right of the QualityKick™ application. The support ticket can be used to communicate issues/problems or feature requests. Our support team reacts to tickets according to priority assessment. The users can keep track of ticket status using email or through the online service desk platform.

Apart from the online service desk, there is a **Knowledge Base** available to you from within QualityKick which consists of a collection of searchable articles that describe how specific things are done within QualityKick™. New articles are constantly added based on feedback from our customers.



07 Cloud



06

Cloud Infrastructure & Security

QualityKick™ utilizes the cloud technology of **Amazon Web Services (AWS)**. There are several reasons for choosing AWS as the cloud service provider. Some of them are:

- **AWS** is still the best-in-class cloud provider as per **Gartner**. It has been ranked on the top of the list for the 10th consecutive year.
- **AWS data centers are secret** which makes them more secure.
- **AWS complies with several renowned compliance standards** as listed on their website.
- **Our QualityKick™ platform is scalable.** The elasticity feature of the cloud allows the application to scale out and scale back in automatically depending on demand. Save costs on infrastructure and we can translate these into savings for our customers. This gives us the ability to provide a highly cost effective solution to our customers as we do not pay for servers when they are not in use.
- **Backup and disaster recovery mechanisms inherently present in the cloud.** Backups are performed automatically every 5 minutes and kept for 30 days. New servers are spun up automatically in minutes when hardware fails are detected.
- **We use the Amazon S3 service for storing documents.** This service replicates files in 3 other geographically separated locations as soon as it is uploaded. This ensures a strong data backup strategy.

If you are interested in more information on the topic of Cloud Security, feel free to [request us](#) for more details.

Doubts?

Let us know if
we can help you

Let's chat