QMS wrapper™

THE DUAL NATURE
of qmsWrapper

Risk Control shown through Traceability Matrix

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To place your Medical Device to market you need FDA approval/clearance. To get their approval you have to be compliant which means following product safety regulations set by the FDA. But keep in mind; it's not the end of your obligations. You have to make sure that your Medical Device stays in compliance with its lifespan.

Being FDA approved practically involves certain documentation of compliance in your development process. And how will you manage in that pile of documents? Let's say, auditor asks you for certain document that is connection between some other two, how you will find it without struggle, within a minute? Here traceability steps in.

What is Traceability?

Traceability quicken your Time-to-Compliance. Traceability accelerates the processes. It creates links across your projects. Traceability makes it easy to verify and validate your device. All those elements together are being called the Traceability Matrix.

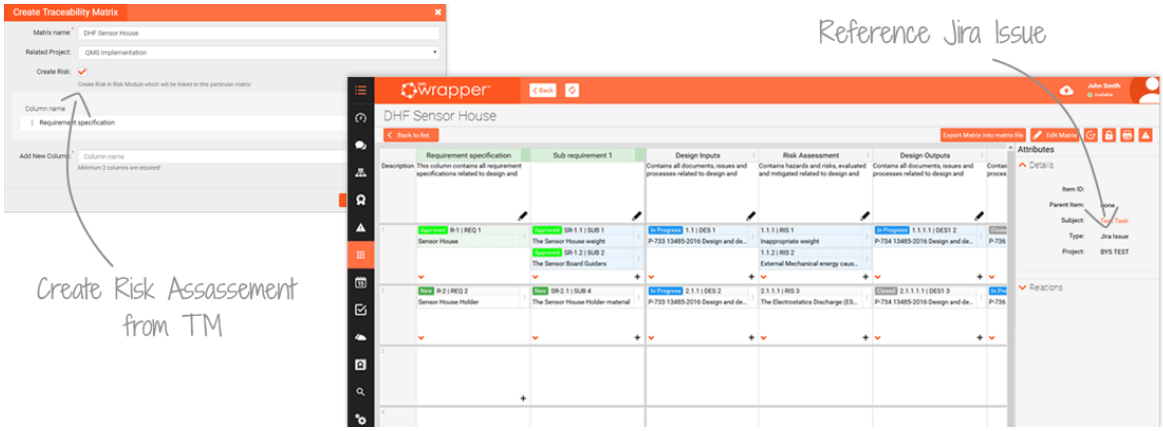
Imagine to manually manage and track all those activities that are taking your time considerably and it's very disposed to possible mistakes.

Through Traceability Matrix (TM) you will be able to verify that your requirements are met.

qmsWrapper's Traceability Matrix

What makes qmsWrapper unique, however, is its Traceability Matrix that is so powerful, it becomes the products dashboard. It is the center of your Medical Device development, starting with the use cases, user requirements, endpoints, and connecting all of the development, design, risk analysis, testing, verification, validation, practically life-cycle of your Medical Device.

Traceability can also be used for decision-making throughout product development. You'll be able to understand how product design will be impacted by requirements. And, if a requirement changes, you'll be able to analyze the impact of that change across development.



From Traceability Matrix, development tasks can be assigned, either through Jira to support Agile development or through qmsWrapper's own Task Manager, internally. The Risk Management Module works in conjunction with the TM requirements. Testing for verification and validation can be tracked and verified through TM that are initiated processes.
That automatically assigns tasks for completion and track results. Documents are connected, to the TM from the Document Management Control module, where they are approved for use.

The testing column could be a web form as well. It's a kind of a new form of feature where you can directly input any data. This possibility is given for any test case you want. As addition to this feature, it can be exported in PDF.

The main purpose of the TM is to ensure that columns capture the details of how the device was developed and tested and provide an overall view of that process. The actual work is done at the process and task level, or data that are directly collected with a web form in the Project Management. The sum of all effort is portrayed in the TM for that particular Medical Device element.

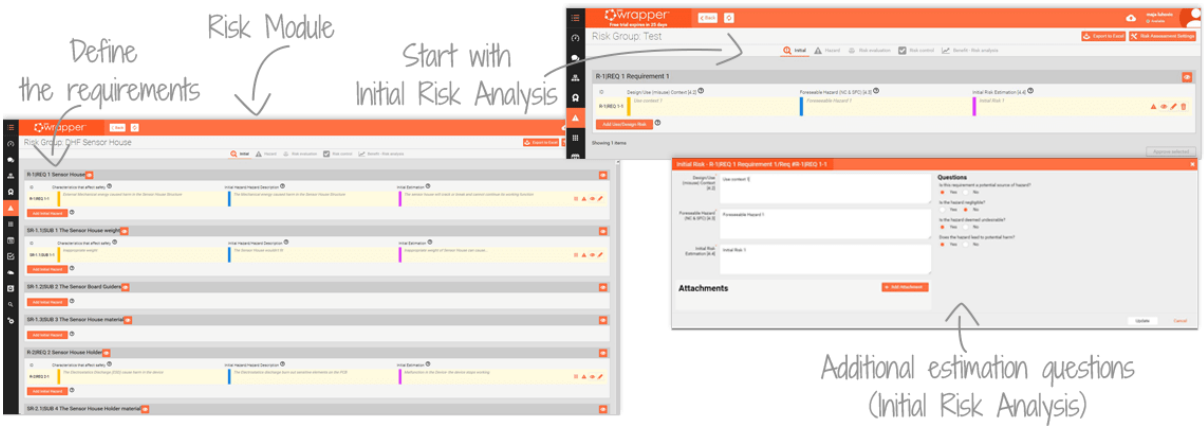
Risk management

A Risk Module is used to assess risk.
It demonstrates severity and probability. And it calculates your risk score — the number that tells you how serious the risk is.

qmsWrapper's Risk Management Module was massively improved to better reflect the need for Risk-Based development. Risk Analysis is encouraged throughout the Medical Device during every stage of the development cycle, as increasingly required for FDA and MDD/MDR.

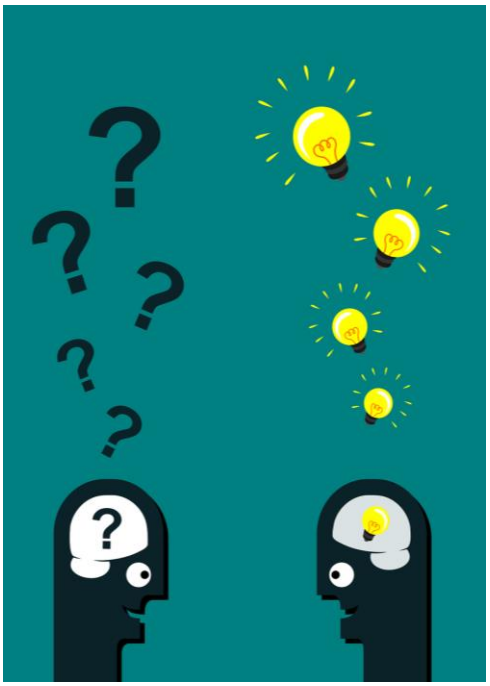
Using a Risk matrix will help you:

- Get visibility into risk;
- Analyze risk — and decide what to do about it;
- Manage risk before it becomes a problem.



The Risk Module can either be independent of any TM or integrated with any TM. A Risk Management Plan can apply to all elements of the project. A Risk Analysis can be tied to a specific TM, better able to relate and analyses the individual requirements of each Medical Device element. When the Risk Analysis Module is tied to a particular TM, it automatically imports all the requirements defined in that TM and its related projects.

Benefits of using qmsWrapper



Medical device developers must have risk assessment and they need traceability, too. It helps them prove compliance and deliver quality products that are safe for patient use.

Using this best QMS software makes easier to maintain compliance and pass audits.

The concept of risk assessment and traceability matrix is more than being able to identify the verification and validation study that was performed in order to verify the effectiveness of risk controls and clear visuals between documents.

By using qmsWrapper you will:

- Get visibility across development of your Medical Device;
- Make better decisions (e.g., on requirements change);
- Accelerate release cycles;
- Rest easy knowing your requirements are fulfilled;
- Prove compliance faster;
- Pass audits without fear.

qmsWrapper is like a level of QMS management, meaning you don't have to add a lot of staff to do your compliance work because it's already integrated into the Project Management.