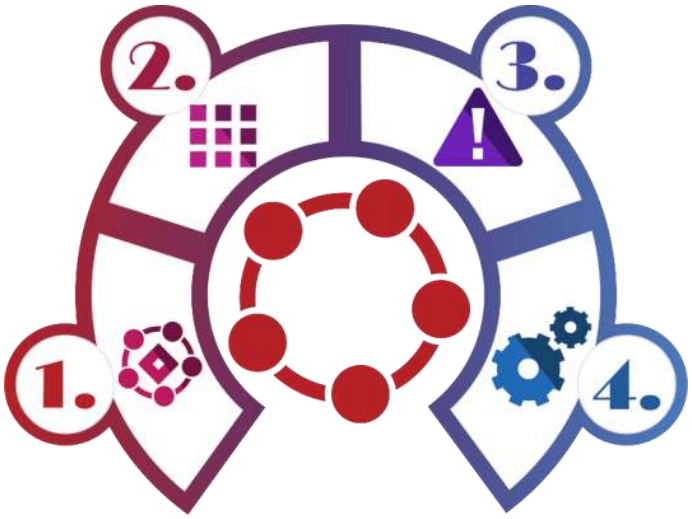

It's new.
v6.0
It's the version you've been waiting for...
QMS
wrapper™

New v6.0 now includes

4 new functional modules:



V6.0 transforms your single focus QMS into your

FDA (510k or De Novo) and CE Mark

Submission Preparation Framework

qmsWrapper is ideal for use by MedDev companies developing Class I and Class II (FDA) or Class I and Class IIa and IIb (CE Mark) medical devices.

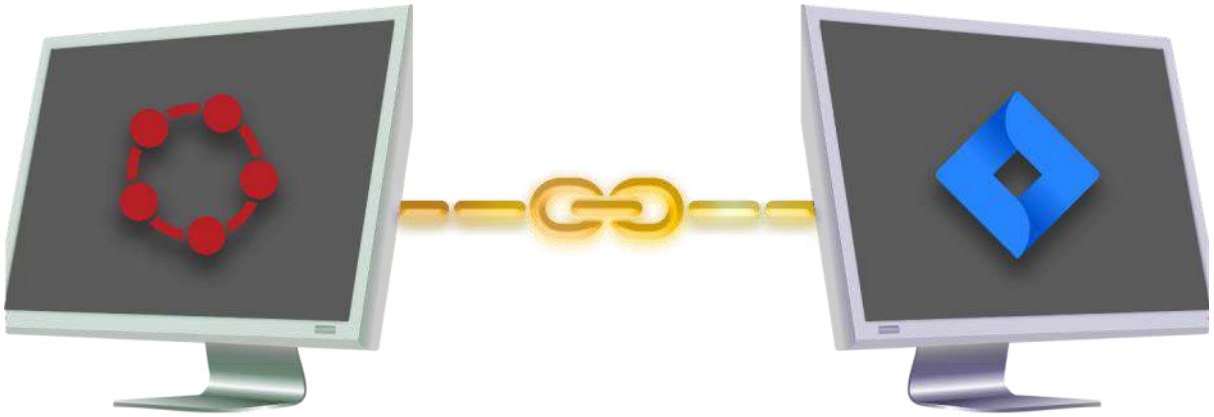
This is more than your ISO 13485:2016 and FDA CFR 820 quality system, it's a medical device project management system that now supports Jira.

This is going to help you:

1. **Save time**
2. **Work smarter**
3. **Work as a team**
4. **Get to market faster**
5. **Stay in compliance**

Jira is now “wrapped” with qmsWrapper

qmsWrapper is designed to be wrapped around Jira. This extends the benefits of Jira in the medical device world. MedDev startups and small businesses that use Jira can be linked to qmsWrapper.



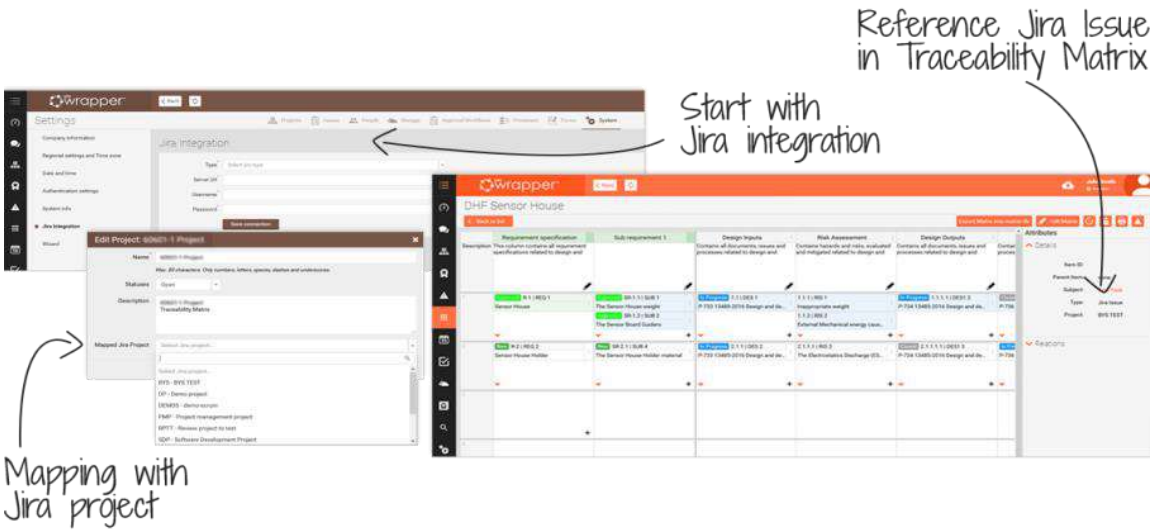
Integration means better control of the development process.

The combination of Jira with qmsWrapper brings a system in which medical device manufacturers are able to track, manage and organize all CE Technical Files and FDA Design History Files, and do it in the most effective manner possible.

This integration will help medical device companies reduce their development risks and increase their **agile effectiveness**, whilst still **keeping an eye on quality.**

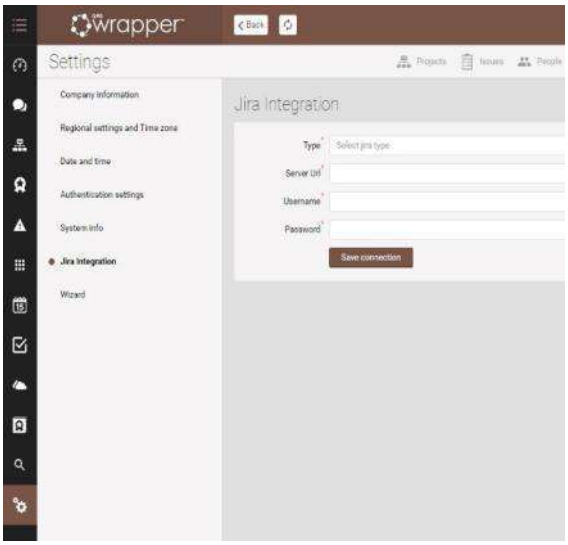
Integration with Jira adds 3 main advantages:

1. Projects created in Jira are visible in qmsWrapper, they are connected.
2. Issues created in Jira can be seen in qmsWrapper and tracked in Traceability Matrix.
3. Connects a risk identified through Jira issues in the Traceability Matrix in a risk-related column.



Start integration with Jira

1. General settings
2. Jira integration
3. Fill up the form
4. Click “save integration”



A new Traceability Matrix so powerful, it becomes the products dashboard

TM is now more effective and useful feature that serves as a dashboard for product development leading to submission.

It's also the cornerstone to Design History File (DHF) and Technical File (TF).

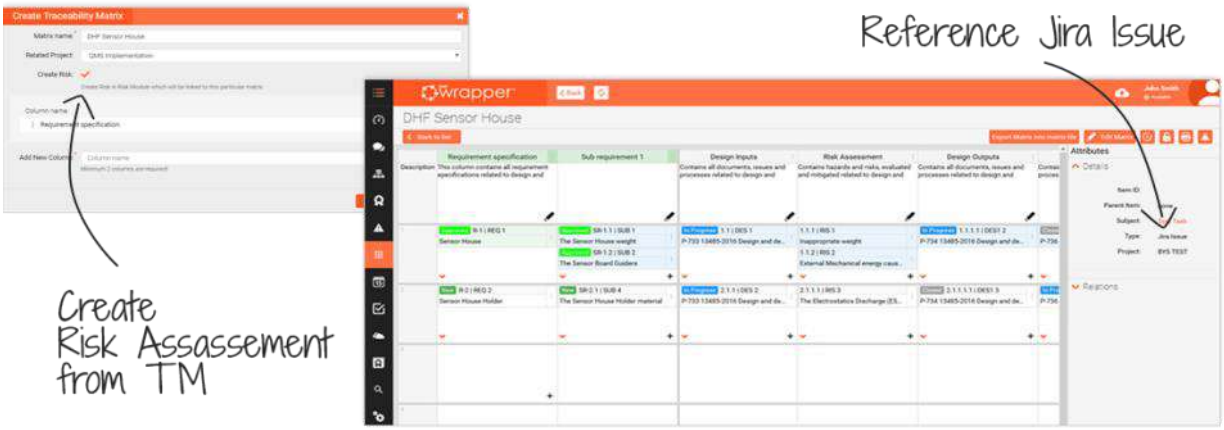
It helps track project requirements through steps that connect the dots. Clearly demonstrates to inspectors/auditors the connection between the requirements, its design inputs, validation and verification, risk analysis, etc.

TRACEABILITY MATRIX IS FOUNDATION FOR YOUR DHF OR TECHNICAL FILE!

Notable features of Traceability Matrix?

- **Multi-User** implementation. All members of team can work at the same time on the same TM
- **Risk Assessment** can be created from within the Traceability Matrix to go feature by feature
- **Jira Integration** - link Jira tasks, to testing, testing to validation

Traceability Matrix by qmsWrapper, integrates with Jira, QMS, Project Management and Document Management. Requirements, specifications, design inputs and outputs, testing, life-cycle makes the core of DHF and TM and the backbone of 510k or CE Mark submission.



New risk module supports Risk - based design

A new Risk Analysis Module (RAM), is introduced to help focus the relationship between requirements, design and benefits, with emphasis on risk-based design. It's updated version of ISO 14971:2019. It's harmonized with new MDR requirements bringing a few changes in procedures that our upgraded software practically predicted.
This new version allows you to choose between the traditional style Risk Analysis and the New Risk Module.

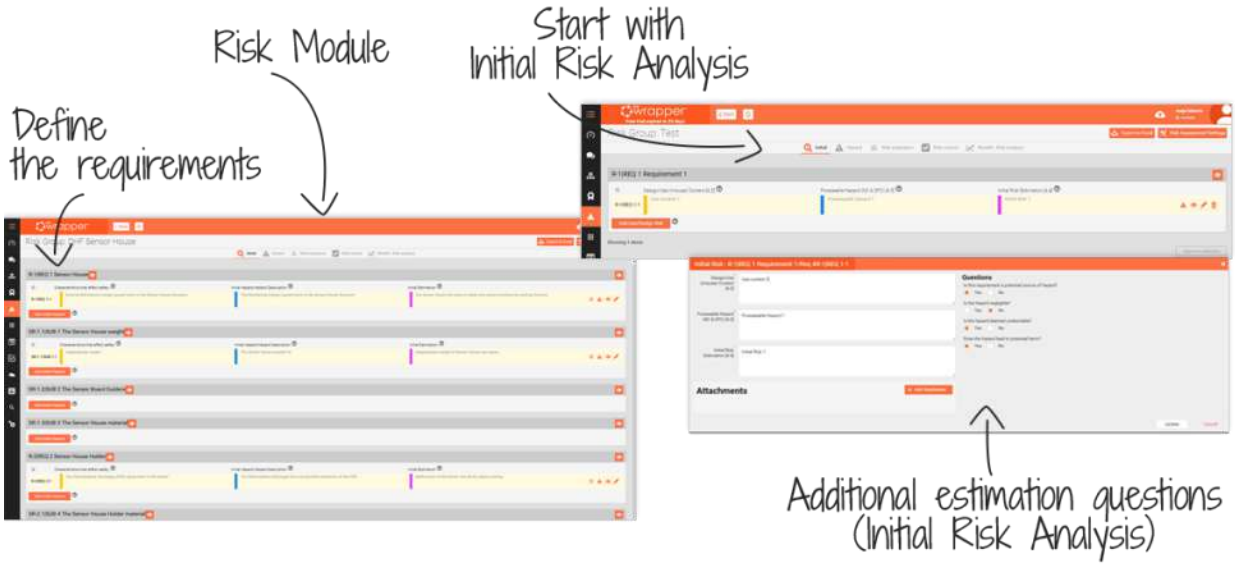
ISO 14971:2007	ISO 14971:2019
In traditional risk management based on 14971:2007 where every requirement needed to go through all 5 steps	**New risk management includes additional specified requirements from MDR 2020.**
It's based on hazard for any part of project and it's not connected to specific requirement	**It's trigers additional questions that gives bigger picture about certain risk**
It's shown as general risk for particular project	**It helps to understand is there a real hazard**
It's driven according to MDD	

Risk module integrates within qmsWrapper's TM

A complete and accurate picture of the risks is represented across products, processes, and teams. It incorporates a complete risk assessment that is effective throughout the product's entire lifecycle.

It's flexible and Intuitive.

Proportionate to the agile system to match the complexity and type of given organization. It's beneficial for an accidental risk manager or a seasoned professional.



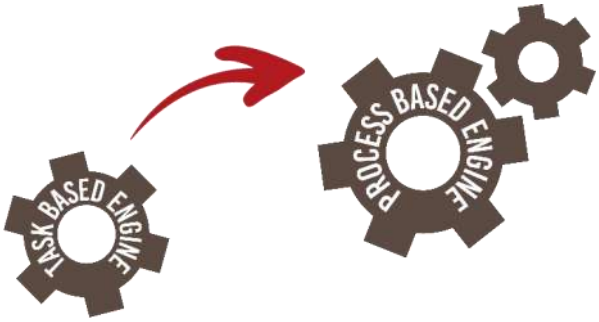
Why is Risk Module now even better?

1. RAM is designed to meet the demands for risk-driven design in medical devices.
2. It helps to document controls that were included in the requirement itself, and by design, controls a hazard.
3. Design decisions can now be explained, linked, to how hazards were mitigated before they became hazards.

qmsWrapper's Risk Management is a powerful, but user-friendly tool that makes risk and compliance management easy and understandable.

Enterprise - grade processing engine

qmsWrapper's new Processing Engine, its new core, transforms qmsWrapper from a task-based engine to Processing Engine – to better support and enable business workflows.



Now, business and QMS workflows, processes and procedures are more effective, flexible and adaptable. They drive the way medical device companies work from the upgraded modules of TM, RA, and Jira. Also, to the existing Document Management and Controls, team messaging, approvals, all driven to support business processes. It brings all the parts together, connecting the "dots".

<u>Added to Process Editors functionality:</u>

1. Form templates made in Form Editor can be attached to any step in the workflow.
2. Processes can be exported from the Traceability Matrix as PDF.
3. Processes can be triggered directly from the TM.
4. Process categories are now available.
5. Changes in processes can be marked by adding notes, as part of revision history process.

V6.0 crosses the line between a **QMS system** focused on quality, to one also focused on creating your **510k** and **CE Mark submissions**.

This is a quality system that supports your regulatory compliance efforts. It will serve as the backbone of **pre-market** regulatory submissions and **post-market** follow up.

It also helps you support your products life cycle, from development to manufacturing.

QMS wrapper™

It's what FDA expects.
It's what MDR 2020 requires.

We offer free live demos,
they really help you to understand,
You just have to **book it!**

https://store.qmswrapper.com