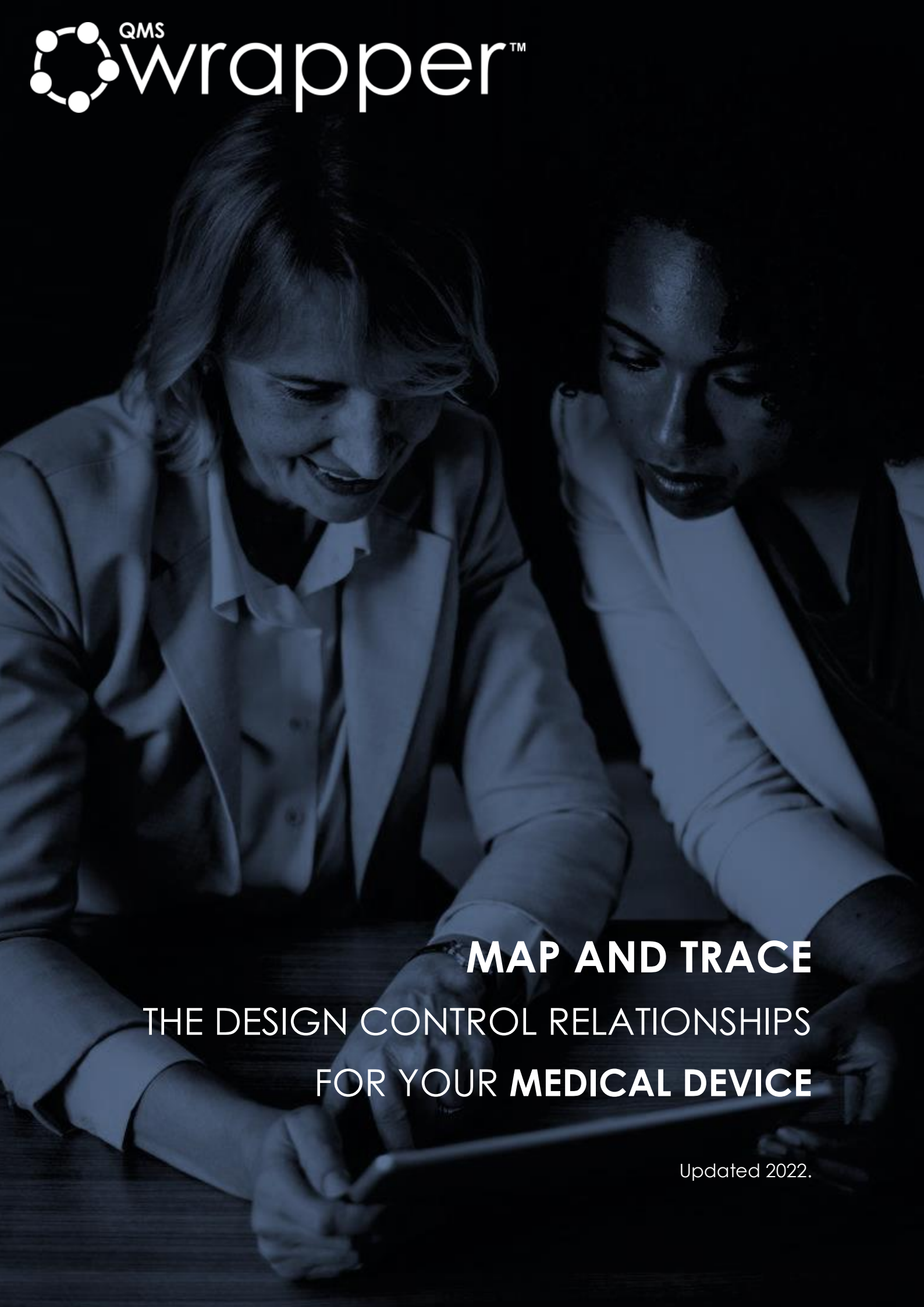
QMS wrapper™



MAP AND TRACE

THE DESIGN CONTROL RELATIONSHIPS FOR YOUR **MEDICAL DEVICE**

Updated 2022.

Traceability

An essential criterion for **FDA** and **CE** Mark success is **Traceability** of medical device requirements. Technically referred to as a Requirements Traceability Matrix (RTM), it's central to the development of safe medical devices as, when it's done right, it's the foundation of your FDA ***Design History File (DHF)*** and your CE Mark ***Technical File (TF)***.

Why it's so important?

The importance of the Traceability Matrix stems from the fact that it connects requirements and use cases to design inputs, outputs, testing, Risk Controls and Risk Management.

It can also help you to document the life of the product development process, including IEC62304. Everything you do, change, edit, every input and output can be easily linked and traced.

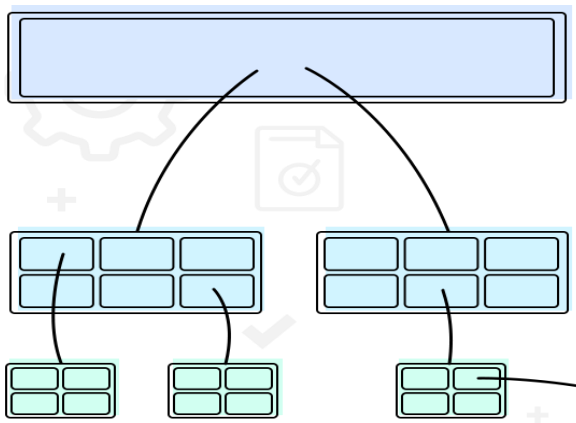
Traceability should be synchronized with your QMS system and needs to be flexible to respond to changes. Development of a product by the requirements of 21CFR 820 and an approved design file needs to be proven by Traceability.

Risk controls and Risk assessment should be integrated with Traceability.

If you are using a manual system, implementation of a Traceability Matrix can be complex and time-consuming. Maintaining it, a nightmare.

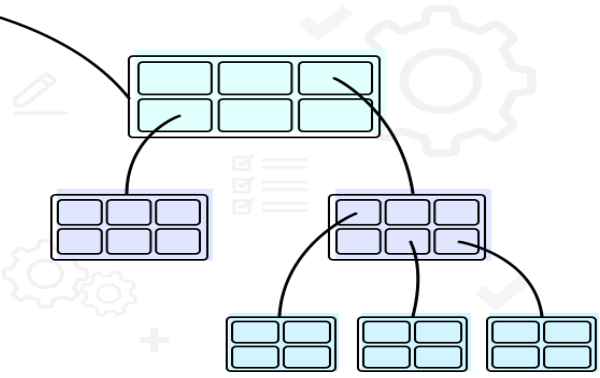
Traceability Matrix by qmsWrapper™, integrates your QMS, Project Management, Document Management, requirements, specifications, design inputs and outputs, testing, life-cycle, making it the core of your DHF and TM, the backbone of your 510k or CE Mark submission.

Traceability Matrix by qmsWrapper



Capture requirements and their traceability in a dynamic multi-level cross-referencing tool.

- Forward & Backward traceability completeness
- Map requirements to test cases.
- Map test cases to requirements.
- Verify each test case is completed.



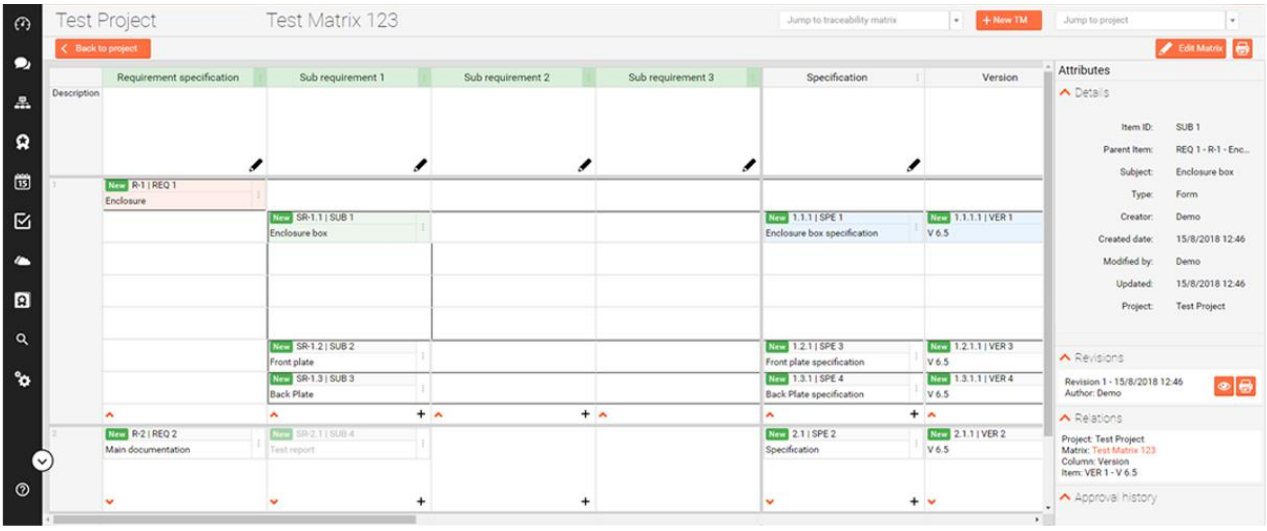
Organize, connect, trace and manage your design controls throughout the life-cycle.

- Connect documentation to processes
- Documentation is connected to approvals and version control
- All requirement documentation in one place

I'll never start another device project without it again!

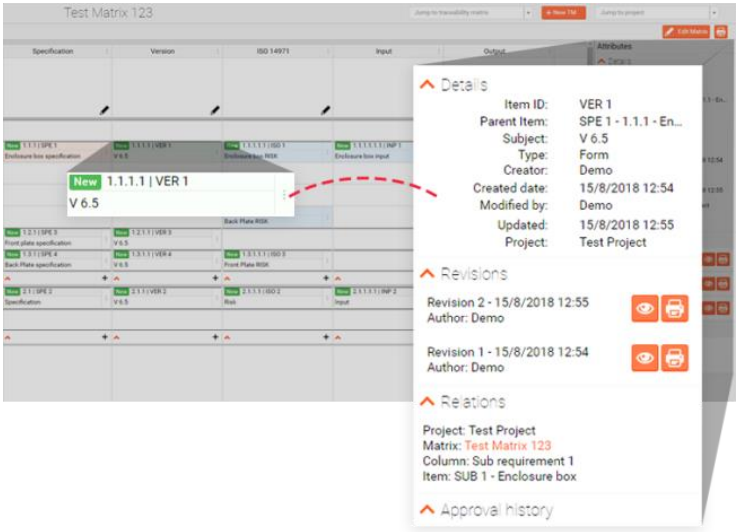
Ivana K., Manager, Cardio-Phoenix Inc.

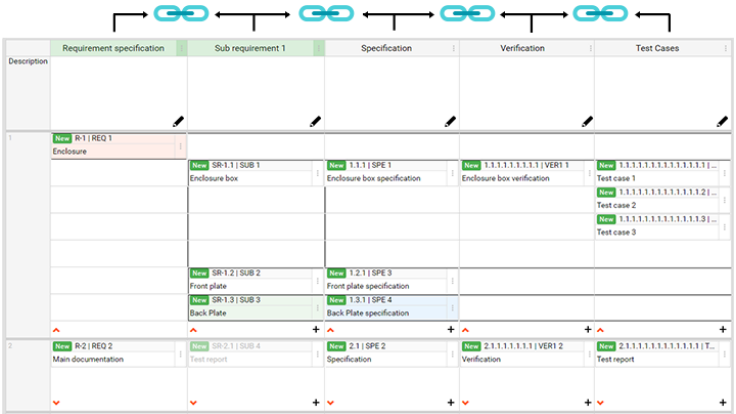
Manage & Track your project's Design controls



Organize

Organize every input into the Traceability Matrix and show the details, revisions, history, for every requirement, ready for your submission, and subsequent regulatory audits.





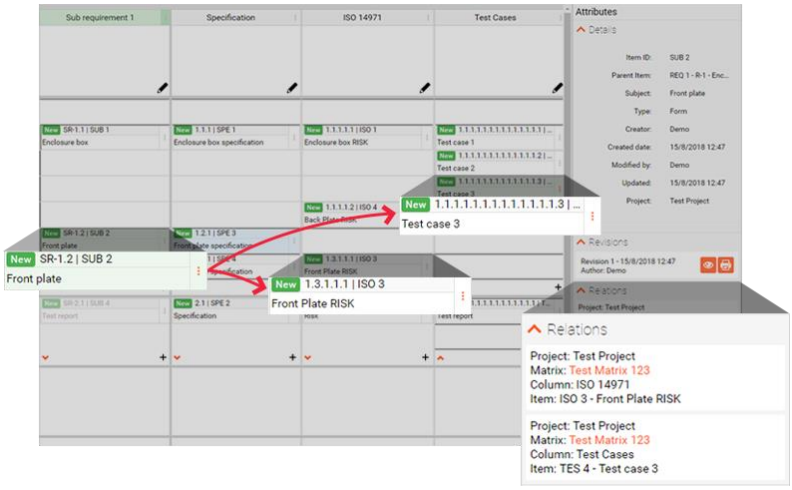
Connect

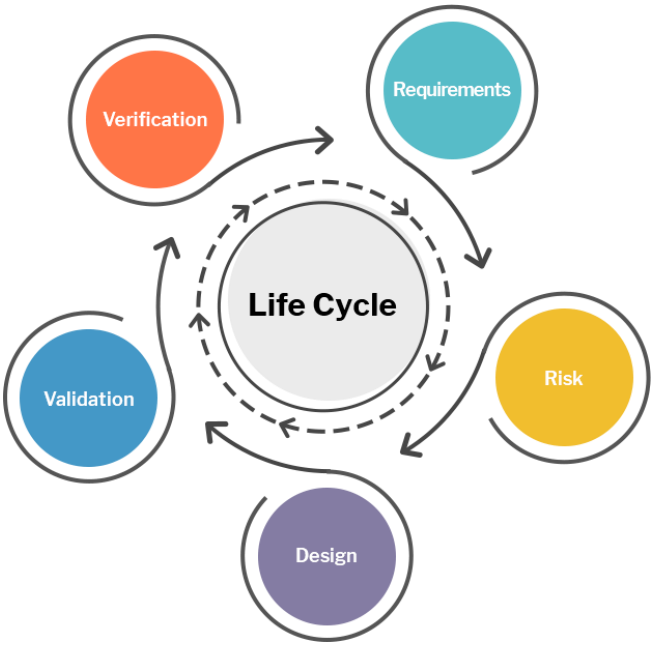
Connect requirements to design specifications, to risk analysis, to SOPs, to test cases, to verification testing, to Validation, to OPS requirements, to whatever custom needs your device development requires, etc…

Trace

Trace the relationships between requirements through the different stages of development and prove they have been successfully addressed.

Trace each requirement back to its original functionality and their testing. Trace each requirement to the device version history.





Manage

Manage the project design control process through the life-cycle. Manage the CE Technical Files inputs and your FDA Design History inputs, managing the relationship between QMS, project management, and your team.

Make your Job Easier

- Integrated and synchronized with the project
- Demonstrate that design was developed in accordance with an approved design plan and the requirements of 21CFR 820
- Create custom verification and validation testing documents
- Export into a print-ready format for your FDA submission
- Flexibility to respond to changes
- Reduce project risk

How it works

A medical device project starts with the Requirements Traceability Matrix.

Then build your Traceability Matrix as you develop and test your product...

Key Functions of qmsWrapper Traceability Matrix:

- Track and show the relationships and connections between requirements
- End to end traceability.
- Design Controls, by column.
- Track numbers automatically assigned and inherited
- Export to a Excel file print-ready format for your FDA submission – it's your DHF.
- Integrate with Document Control
- Integrate with processes
- Integrate Risk controls and Risk assessment
- Integrate approvals and version controls
- Integrate and synchronize with the project(s)
- The cornerstone to your Life-Cycle processes

And most important of all, it's **multi-user**. No longer you need to work alone, when every member of your team can contribute.

Create and link multiple TM, one for each part of your Medical device.

Start with a Master TM, where you keep all the critical Management created Plans, including the Development Plan, the Risk Management Plan, the validation Plan, etc...

Then, for each device element, create a separate TM, one for the device hardware, one for the applied parts, one for the Firmware, one for the UI Software, one for the backend... create as many as you need. Then link them, to each other, either requirement to requirement or TM to TM.

Its a great way to ensure that life-cycle for each element is enabled and tracked.

Do Risk Analysis by requirement, as is now required by FDA and by MDD/MDR.

It's flexible! Dynamic! Expandable!

Reliable!

> *"I was doing the product plans, documentation and testing for the software and firmware of our medical device. It was tedious and time consuming. Half-way through I was given opportunity of using qmsWrapper's TM – wow! In future, I will start with TM, as it's so much easier, faster and clearer."*
>
> – Robi B,
>
> Medical Device Developer.