Minerva Medical Device PLM white paper

Minerva White Paper

Design Control in the Medical Device Industry

Minerva
Optimizing business

Introduction

Medical Device makers have to comply with many FDA and ISO regulations.

These regulations include CFR Part 820, Part 11 as well as ISO 13485 and ISO 14971 for risk management. PLM can enable compliance to these regulations in the areas of Record Control, Corrective and preventative actions (CAPA), Design Control with Design History Files (DHF) and Material Control.

This whitepaper focuses on the challenges regarding Design Control

Goal of Design Control

The goal of design control regulations is to prove that you have designed a safe product and that it meets user needs and fulfils all the requirements.

The specific FDA regulation that talks about design control is 21 CFR 820.30 and ISO 13485 section 7.3 Design and Development. Both expect documentation and records of design though-out the product development process

Typical Industry Practice

As it is a regulation to have a DHF and DMR the typical industry practice is to design and print, meaning do the design and then print to paper and store in a binder.

Some “design and file”, meaning that they store the electronic file onto a file system that is structured to look like a DHF binder.

A common industry practice is to make extensive use of spreadsheets to keep track and traceability of the user needs, design inputs and outputs along with their verification and validation plans along with the results.

Very often the documents are printed, signed and scanned, and stored both electronically in file folder structures, as well as physically in binders.

In all cases this is a manual process that is very labor intensive and error prone. Even if the product is correct, having data that is incomplete or the wrong version can trigger problems with audits.

DESIGN CONTROL RISK

Unfortunately, this is the landscape seen in many companies, with file systems, spreadsheets and silo systems.

Anyone can very easily see the inefficiencies, data duplication, lack of traceability and opportunities for error. This provides for a situation where design control is full of risk.

DESIGN CONTROL – DHF/DMR

Minerva's Medical Device PLM running on Innovator can be used to reduce risk and improve design control.

The structures of the DHF and DMR are created as a template. For a device all the deliverables are defined.

The deliverables include things like documents, requirements, test specification, parts, BOM's, etc. Each deliverable is then mapped to a location in the DHF and/or DMR along with a rule that states when that deliverable is complete.
This can be based on a workflow completion such as a release, user action or phase/gate completion.

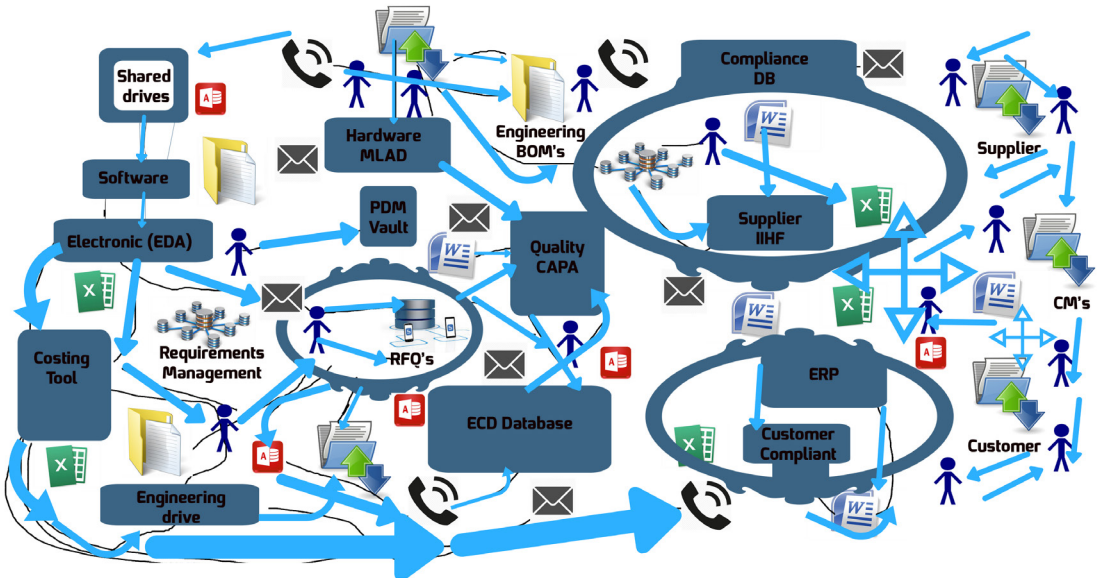
The combination of these two items allows the DHF and DMR to be created automatically as a result of users work.

Baselines, complete DHF and DMR structures are created automatically as a result of any change to a project or deliverable as well as a completion of a phase/gate.

TRACEABILITY MATRIX

The traceability matrix from Minerva is a unified view of the design control. It utilizes Aras' content modeling framework (CMF) in an excel like format to map the user needs, design inputs and outputs to their validation, verification results.

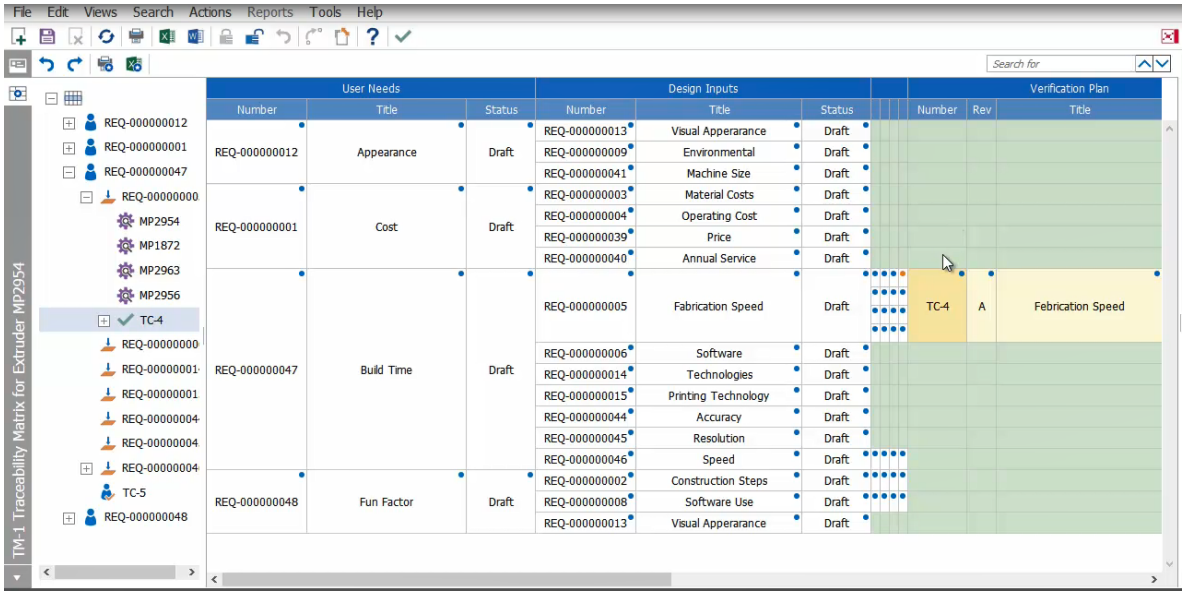
The key differentiator to an Excel spreadsheet is that the traceability matrix is a structured document with relationships to the Innovator business objects. As these business objects change the traceability matrix can receive alerts and updates. For example, when a requirement that is a design input changes the change will be highlight in the traceability matrix notifying the users to review the verification plans and design output.



Typical system scenario in a company. Several islands of information make it difficult to get traceability in data, and add to the risk of having errors in the Design Control data due to manual processes between the system and duplication of data.

Instead of managing requirements as one big Word document Innovator can manage each detailed requirement separately. This is important because requirements can come from many different sources. Requirements can also be classified by type and can be used for user needs and design inputs.

This is a depiction of how the traceability matrix is modeled, in as a structured document in the content modeling framework of Innovator. A user need can have many design inputs all of which are represented as the requirement business object of Innovator. A design input can have one or more design outputs where the output is represented as many different types of business objects. A typical design output will be a part or document but can also be FMEA or Risk Analysis. A user need and design input can have one or more validation and verification plans respectively. The verification plans are represented by test specifications business objects. A verification or validation plan can produce one or more results.



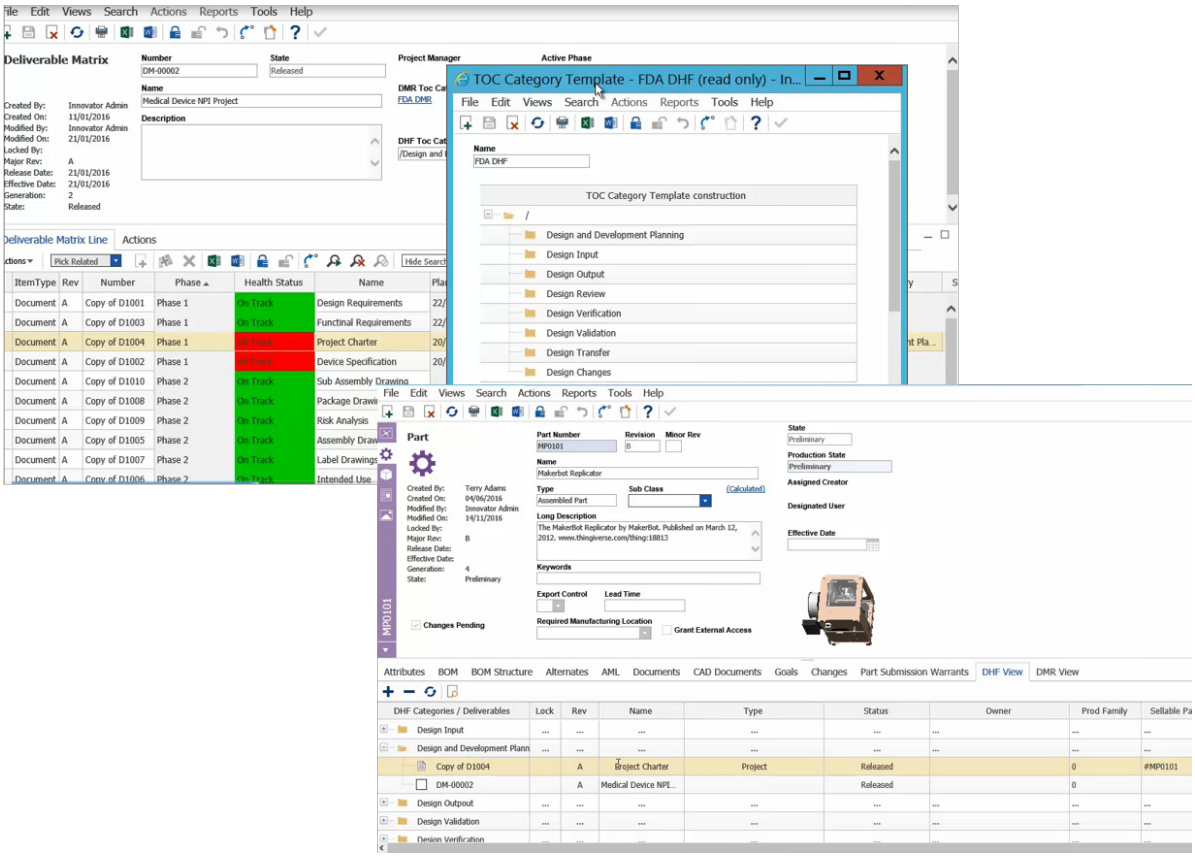
Conclusion

Many companies are still exposed to a high degree of non-compliance when it comes to their Design Controls.

Even if solutions have claimed to help the industry to come to grips with the challenges and provide a complete solution, there have always been gaps that have not been fulfilled and that have led to manual processes, shadow systems and undocumented procedures in order to bridge these gaps.

Minerva, based upon our decades of experience in the industry has created a PLM solution aimed to minimize these gaps and provide a comprehensive PLM solution that is targeted to the Medical Device industry and the challenges we have seen.

Aras Innovator, with its robust platform and unique integration capabilities, provides us with all the tools we need to be able finally to offer a complete solution to our customers.



About Minerva

Innovation, Collaboration, Optimization and Teamwork are reflected in all we do in Minerva Group.

Product Lifecycle Management, Manufacturing Excellence and Supply chain optimization, all leading to innovation, is what we do.

Minerva offers in depth experience in innovating complex manufacturing and supply chain operations. We challenge our customers' ways of operating and assist in developing the organizations execution ability in order to reach the strategic goals.

In Minerva we not only help describing the customers' current state and the ways to reach the ultimate end goal, we also implement the systems to support the change management process.

Measurable results are all that counts! Having agreed on what it takes to reach the defined goals, we implement - by small measurable steps - the way to the optimal way of operating.

Profitability and ROI in all aspects of the business is a cornerstone - internally as well as in the projects we deliver. We want all our customers to experience and to acknowledge the measurable business benefits it gives to partner up with Minerva.

On our web you have access to some of the areas of operation in the Minerva Group, such as ERP, PLM, and Manufacturing Excellence.

How do Minerva & Aras do PLM?

- Provide a full-blown enterprise PLM solution out-of-the-box and make it easy to modify
- Use flexible, modern technology that adapts to the user, not the other way around
- Eliminate all PLM license fees and the hassles that go with them
- Focus on developing mutually beneficial relationships with people we enjoy doing business with
- Foster the Aras community which consists of 1,000s of users- open and paid - worldwide
- Back it all up with world class service and support
- From our technology to our community and the way we do business, we take a very different approach to PLM

Contact information

For more information regarding products and how PLM can help organizations improve check our website **www.minerva-plm.com** or follow us in **LinkedIn** to stay updated with the latest news in the world of PLM.

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For any questions regarding the contents of this document please contact us at **info@minerva-plm.com** and we will assist you as soon as possible.