

Requirement Engineering in the Medical Device Industry

(Published on www.anforderungen.ch in Dec 2010)

Towards the end of our last encounter, Samuel asked me if I would mind compiling a short entry on Aligned Elements, our medical device requirement management tool. In the end, this article turned out far from short. Nevertheless, I have tried to highlight some of the particular challenges of working with requirement management in a regulated industry and some potential approaches on how to deal with them

Aligned Elements - An RM tool among others

From a requirement management point-of-view, Aligned Elements functions very much like any other requirement management tool. It can capture data entities (such as Requirements), fill them with attributed information (such as descriptions, priorities, release dates etc.) and then create references between the entities (such as traces) to describe relations.

Aside from these basic functions, Aligned Elements is also equipped with all the rest you need to fulfill the primary objective of any RM tool: to achieve a high quality product within given time/resource constraints.

The particularities of the Medical Device Industry

What makes Aligned Elements different is its ability to cope with the particularities of the medical device industry. The heart of the matter lies in the fact that a medical device inherently exposes the patient to elevated risks.

This might sound somewhat counter-intuitive. Isn't a medical device used to diagnose and treat an already sick patient i.e. to reduce the risk that the patient health deteriorates further? Rightly so, as long as the device works as intended.

However, a malfunctioning device, such as an incorrectly sterilized scalpel or an over-dosing infusion pump can cause much more severe damage than the original illness. The risk lies in the fact that a device might not work as originally intended.

How to reduce risks – and its consequences

To reduce the risk of harming patients by malfunctioning medical devices, regulations stipulate criteria on how they must be developed. Furthermore, the manufacturer is not only mandated to develop the device according to the



regulations but also to provide written proof that the regulatory demands have correctly been met during the development.

The written proof, sometimes called the Design History File (in the US) or Technical File (in the EU), is absolutely crucial since a missing or erroneous file prevents you from entering the market. No written proof, no sales. The requirement documents, requirement reviews and requirement traceability are part of this file.

As a consequence, an additional objective of Aligned Elements is to provide means to create and manage the development documentation according to the regulations in question.

Since the administration of the development documentation often constitutes a considerable portion of the total development effort, Aligned Elements also attempts to do complete this process demanding as little effort as possible.

Finding the synergies

Luckily, many appealing synergies emerge when trying to fulfill both these objectives. As an example, let's see what the regulation ISO 13485 has to say about requirements. ISO 13485 is an ISO standard, representing the requirements for a comprehensive management system for the design and manufacture of medical devices. In section 7.3.2, we are told to:

- Make sure the requirements are complete, unambiguous and not in conflict with each other.
- Review the requirements for adequacy and approve them in a review process.
- Keep the requirement documents under document control.
- Place the requirements to rigorous change management.
- Include the requirements in the system traceability.

These are all well-known techniques used in many industries to improve the product quality and are good examples of how medical device regulations mandate the use of established best-practices in order to reduce risk.

As expected, Aligned Elements provides functionality to satisfy these criteria by including integrated consistency checks, change control, traceability, document management etc.

Special cases

However, in order to create a consistent and compliant Design History File or Technical File, a number of additional methods are required, which are generally not provided by regular RM tools.



Complete traceability – from start to finish

The regulations require the manufacturer to establish a complete traceability from requirements, specifications, risks, down to verifications, validation, deviations etc.

Aligned Elements keeps an arbitrary number of customizable “data entity types” in a single repository. This eliminates the problem of tracing across system boundaries and allows analysis for missing and suspect traces do be performed in real time.

Risk Management as a way of reducing risk

Managing risk through a formal risk management process is a core aspect of medical device development and also strictly required by the regulations. There is a close relationship between the risk analysis and requirements since requirements often serve as input for the risk analysis but also serve outputs results in the shape of risk control measures.

Formal risk management is conducted in Aligned Elements using an FMEA (Failuremode and Effect analysis) approach which allows the risks not only to be captured and managed but also to be incorporated in the trace topology.

Keeping track of Design Reviews

In order to enforce legal responsibility and to improve product quality, the performance of Design Reviews is another core aspect of the medical device development. The ubiquitous way of conducting review usually separates the review findings from the reviewed artifact.

Aligned Elements chooses to integrate the review process directly in the RM tool. With this approach, the review findings and review protocol stays linked with the reviewed artefacts. Furthermore, finding out what has changed since the last review or what has not been reviewed at all is done with the click of a button.

Analyzing the content for inconsistencies

As previously mentioned, an incomplete or inconsistent Design History File can have serious consequences, such as not being able to enter a market or, if the finding is done later, having to remove a product from the market.

To mitigate this risk, Aligned Elements provide a number of validation rules that analyses the content of the Design History File in real-time. This provides the user with information such as:

- Missing traces
- Suspect traces
- Unmitigated risks
- Invalid data combinations



- Open deviations
- Entities updated after review
- Entities not inserted in Word Documents

Conclusion

Requirement management is applied in many industries to minimize the gap between what the market wants and what the developer finally creates. The medical device regulations make use of well-known RM best-practices in its pursuit of increased quality through reduced risk.

However, the regulations stipulate medical device specific demands on the requirement management and further require the manufacturer to prove that the regulations have been met. Aligned Elements has been developed to encompass both general RM technique as well as creating and managing the development documentation serving as proof of a consistent and compliant development effort.