Turn regulatory challenge into competitive advantage

By adopting a traceability tool, manufacturers can considerably reduce the time spent on compiling regulatory documentation for market submission. **Aligned**'s **Karl Larsson** explains how.

When faced with the challenges of medical device regulations, many manufacturers fear that increased documentation work will have a serious impact on innovation and their ability to bring new competitive products to the market. However, it should not be forgotten that competition is always relative and that there are many ways in which the regulatory challenges can be met. By being the more efficient player, your company can gain a significant advantage along this new dimension of competition.

An obvious example can be found in the management of design history files (DHF). The design history file (FDA) or technical file (IVD-D/MDD), which is essential to the submission of documents to obtain market approval, is a well-known challenge to any development team that has worked with medical devices.

Paper-based approach

Usually, the DHF documents are vertically separated according to the design control categories (see Table 1) and contain the items under design control specific to each category. The manufacturer is required to show adequate evaluation of conformance between these categories. For instance, it must be shown that specifications correctly cover the requirements, that tests verify the content of specifications, that risks and hazards are adequately based on evaluations of specifications and so on. In the case of a paper-based documentation approach, it is common to use textual references as means to illustrate that the conformance is correctly tracked. However, textual references are vulnerable to change.

Introduce: change

While a change alters parts of the documentation, it is essential to verify if referenced parts are also affected by the update. A large manual effort is normally needed to track down the ripples caused along the chains of textual references. Since textual references are typically unidirectional – the referred part does not 'know' or does not show any sign that it has been referred – it becomes virtually impossible to back-track and correct the referring parts. Due to the innate inflexible nature of textual references, a rapid deterioration of the documentation consistency occurs once changes start to affect the items under design control.

The result is a continuous struggle to track down the changes along the reference paths in order to keep the documents consistent and up-to-date. As changes multiply during the project lifetime, this administrative burden increases and finally presents a serious threat to launch time-lines.

Table 1: Selection of design control categories according to ISO 13485 and the associated types of items under design control.

Design control categories	Typical items under design control
7.3.2 Design and development inputs	Requirements, risks
7.3.3 Design and development outputs	Specifications
7.3.5 Design and development verifications	Tests, deviations
7.3.6 Design and development validations	Tests, deviations

Traceability software controls consequences

By introducing the appropriate traceability support software, it is possible to mitigate these types of risks. Traceability tools have the power to highlight the reference chains of updated items and clearly display the parts that potentially need modifications. State-of-the-art traceability software can also perform time-saving operations such as:

- visualising the trace landscape including all item types (risks, requirements, specifications, tests and deviations)
- analysing and presenting the current trace coverage
- highlighting missing traces
- automatically creating, updating and publishing trace tables.

Each of these tasks would require a considerable effort if manual labour was required. The time savings made by automatically creating and updating trace tables alone comprise days of saved work.

There is no question that the process of entering the items under design control into traceability software and setting the traces involves an upfront investment in terms of time and resources. However, in the long run these costs will appear small compared to the savings generated by the benefits of proper traceability support software. ■

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