



# Modular Design History Files

## An Aligned Elements Case Study

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# Tecan

## Challenge, Solution, Results



### Challenge

Tecan strives to improve time-to-market for new diagnostic products by optimizing the time and resources spent on documenting Design History Files.

### Solution

By using Aligned Elements for DHF documentation and an information structure that permits high reuse of existing DHF data, Tecan manages to quickly assemble the DHF documentation for new products.

### Results

- **Make sure the requirements are complete, unambiguous and not in conflict with each other. Reuse of existing DHF documentation with up to 80%**
- **Initial effort to set up the DHF backbone for a new product reduced with up to 50%**
- **Impact of changes promptly visible and available for assessment**
- **Menial reoccurring tasks are reduced for qualified staff**
- **Data transfer across system boundaries are eliminated**
- **Early detection of errors and inconsistencies eliminates expensive last-minute changes**
- **Higher confidence in DHF documentation consistency**

The image shows a blue-tinted photograph of a modern building with large windows. Overlaid on the left side of the image is the text 'TECAN.' in white, with a small circular logo to its left. Below this, the title 'The company' is written in a larger white font, followed by a horizontal white line.

## The company

Tecan, based in Switzerland, is a leading global provider of laboratory instruments and solutions in biopharmaceuticals, forensics, and clinical diagnostics. With a long and proven track record in the diagnostic industry, Tecan is well-known for its liquid handling robots, providing some of the most flexible diagnostic pipetting platforms available today.

By exploiting the flexibility of an open platform approach Tecan is able to create applications that matches emerging market needs by assembling existing modules into new powerful solutions.

# Using Aligned Elements

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Tecan uses Aligned Elements to modularize the Design History File documentation of their products in a similar manner. By using this approach, Tecan can efficiently reuse existing DHF documentation and significantly reduce the time spent on managing DHFs for new and existing products.

„With Aligned Elements, we have made it possible to generate the necessary documents for new software versions at the fraction of the time it previously took. We reuse an extensive set of existing DHF data which has already been reviewed, verified and approved, without disrupting the traceability and change control for existing product documentation. We can now generate the documentation for a new version in a single day which previously took a week to set up.”

- Phil Costello, Software Manager, Tecan



**"...In the end, this translates to substantial savings in both time and money...."**

"The modular DHF approach has generated a number of benefits. A significant reduction of dependencies and complexity is achieved by breaking down the documentation in maintainable blocks. The advantage of efficient reuse and having a single location for applying any change to the DHF data, allows us to rapidly set up and maintain the DHF documentation for our products. In the end, this translates to substantial savings in both time and money."

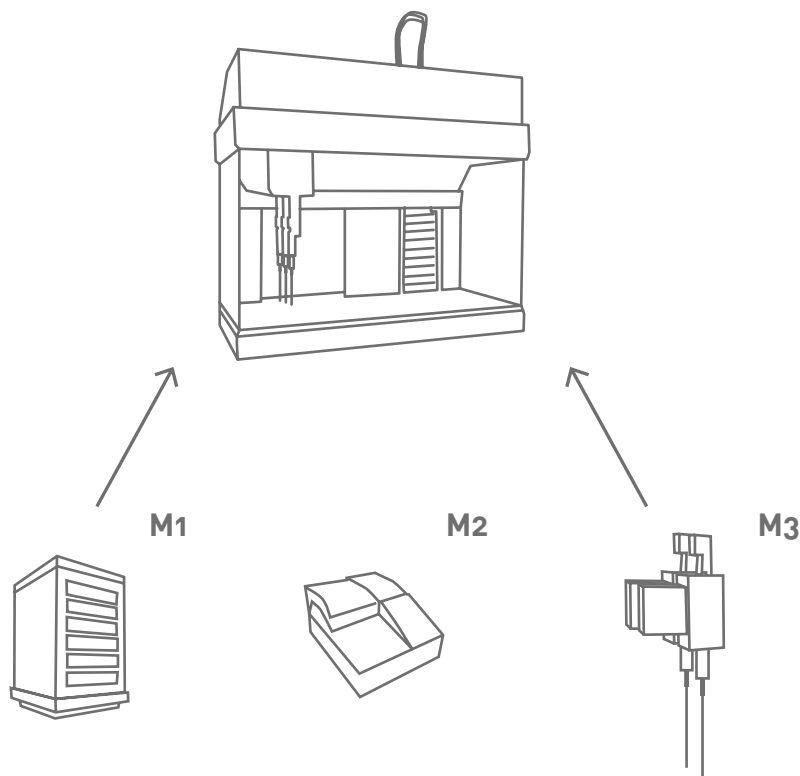
- Juerg Schneider, Project Manager, Tecan

# Market leadership by engineering ingenuity

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Tecan has managed to become one of the industry's most renowned brands by continuously providing high quality products distinguished by engineering ingenuity.

Similar to the automobile industry's platform concept, Tecan can offer a wide range of products by combining modular hardware components on a single basic platform. This permits a swift and flexible response to new market demands and simultaneously allows effective reuse and capitalization of existing components.



# The regulatory challenge

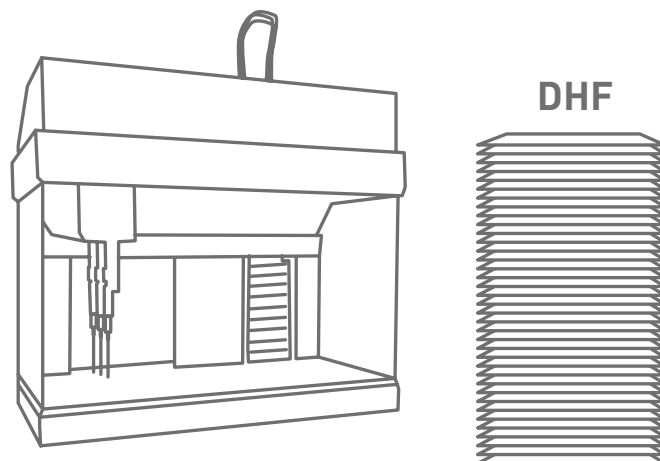
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However, in the highly regulated diagnostic market, engineering alone does not guarantee market success. Like all medical device producers, Tecan is subjected to a growing amount of regulations which demand an ever increasing amount of regulatory documents to be created and maintained.

A large part of the regulatory challenge consists in getting the development documentation (including the Design History File) in place for market submission. As new products and pro-

duct versions are brought to the market, Tecan is facing a growing administrative effort to keep the Design History Files consistent and up-to-date.

Tecan has long adopted a traditional approach to structuring the development documentation where each product had its own Design History File. Each file consists of hundreds of documents, with little potential for reuse and meager possibilities for detecting inconsistencies and assessing the impact of changes in the Design History File data.



# The drawbacks of a paper-based DHF approach

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Medical device regulations prescribe the manufacturer to “...show adequate evaluation of conformance...” between design items. This is usually done by some kind of traceability. By using this paper/file-based system, Tecan was forced to rely on references as means to manifest dependencies between parts of the DHF documentation.

While textual references serve the purpose of pointing out dependencies, they are vulnerable to change. When a change alters parts of the documentation, a large manual effort is normally needed

to track down the ripples caused along the reference chains. Since textual references are typically unidirectional, i.e. the referred part does not „know“ or does not show any sign of being referred; it becomes virtually impossible to back-track and correct the referring parts.

The result is a continuous struggle to track down the changes and keep the documents consistent. As change increases during the project lifetime, this administrative burden finally presents a serious threat to launch time-lines.

# A modularized DHF approach

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With the objective of curbing slipping time-lines, Tecan decided to bring in Aligned Elements to assist the management of their Design History File process in 2007. Aligned Elements is a software specifically developed to facilitate this administration and permits the items under design control to be captured, traced and managed in a single repository, including requirements, specifications, risks and verifications.

As an alternative of having one monolithic, integral Design History File for every product, Tecan used Aligned Elements to document individual modules in separate packages. Aligned Elements permits each

module to consist of a set of specifications, risk assessments and in some cases verifications inferred from a module; all including an over-all traceability and a complete, encapsulated audit trail.

Tecan further separated the product specific DHF data from the module DHF data by defining all product-specific elements in a separate “Product” top-module in Aligned Elements.

By “linking” the product and the module DHF data. Aligned Elements permits the setting of traces between the design items across module boundaries.



# A higher degree of reuse

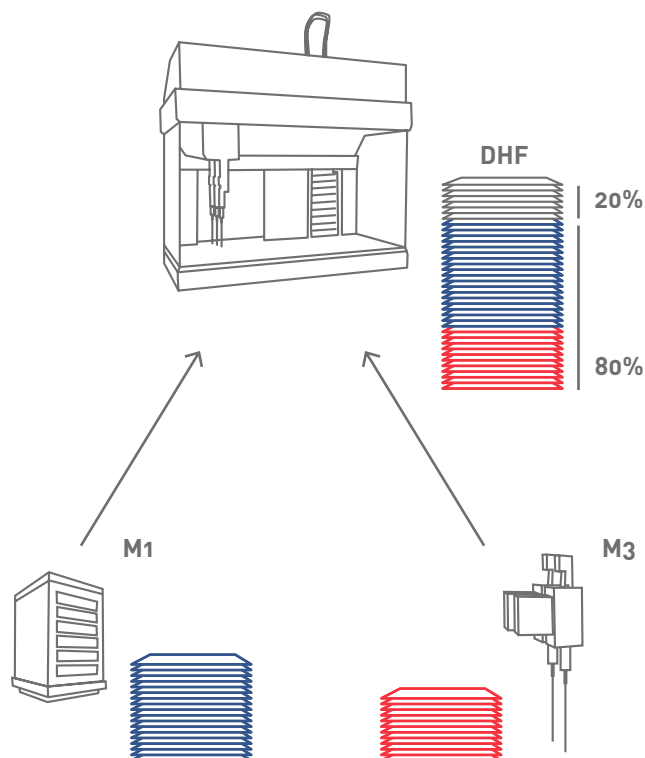
As an example: if the product uses all features that a specific hardware module offers, traces are set from the product requirements in the top-module to all specifications in the hardware module to complete the trace coverage.

However, if the product only makes use of a subset of a module's feature set, only the specifications that denotes that subset is included in the traceability.

Several products can now reuse and share existing module DHF data. When setting up the design his-

tory file of a new product, only the product specific data needs to be created from scratch. The rest of the design data, residing in modules, can be referred to by using traces, which permits a very high degree of reuse.

As the references from product data to module data is comprised by traces which are automatically monitored at runtime, Aligned Elements can provide strict change control and send out alerts that highlights the impact of design item change.



# The results

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Delighted by the potential time savings created by the modular documentation approach, Tecan's diagnostic software department went a step further. It soon became evident that many of the high-level product requirements in the different products were identical. Furthermore, if such a requirement would change in one project, it was very probably that the same change was applicable to any other projects too.

In order to increase reuse even further, the department introduced a "requirement pool" containing all requirements for all products. As an alternative to keep "copies" of identical requirements in several DHFs, the DHF documentation for a product now references the applicable requirements in the pool. Each new product can then pick the appropriate requirements from this item collection which are already traced up with its corresponding specifications.

For new products, Tecan manages to set up a large part of the product documentation within hours by simply referring and tracing to DHF content in existing modules.

With the traceability in place, Aligned Elements can then generate word files such as Product Requirement Documents, Product Specification Documents, Design Reviews, FMEA tables, trace tables by combining existing DHF data with new product specific data.

The high degree of reuse and the increased confidence in the Design History Files permits Tecan to focus on developing world class products instead of continuously treading through regulatory administration work.