



Aligned Elements - Prove you're right

What is Aligned Elements?

Aligned Elements is a Design History File Management Software System dedicated to the needs of the Medical Device Industry.

Aligned Elements is built to efficiently manage a large number of individual but related Design Control items such as Requirements, Specifications, Tests, Risks, Reviews etc. as well as the project and product documents that constitute your Design History File.

Aligned Elements keeps your Design History File complete and consistent during the entire project development process with minimal effort.

How does Aligned Elements work?

Aligned Elements incorporate the management of all important parts the Design History File:

- Requirement, Specification, Use-case and Test-case management. These Items are individually kept under strict Version & Design Control in Aligned Elements.
- Integrated Reviews. The Design Reviews of the Items under Design Control are performed within Aligned Elements and the reviewed Items are consequently marked as reviewed.
- Traceability management. Multiple views and diagrams visualize traces between the items under Design Control. Potential damage to the DHF consistency is clearly highlighted to signalize impact of changes made to Items.
- Risk management. Using an FMEA approach to analyze and manage failure modes, hazards and create mitigations which are traced back to new requirements, specifications or test cases.
- Consistency control. A large number of configurable validation rules detect inconsistencies within and between the individual items under Design Control. These automatically detect abnormalities like:
 - Are traces missing?
 - Have the latest changes been reviewed?
 - Are Risks left unmitigated?
 - Are there un-assessed Defects?
 - Have all tests been executed for the latest product version?

By bringing all crucial DHF parts into one application, Aligned Elements provides excellent transparency, consistency and control of your product documentation.



Why Aligned Elements?

In many firms, an un-proportional amount of development time and money is spent on collecting and managing the product and project documentation, sometimes as much as 30% of the entire R&D effort.

Design History File Management is not only time-consuming, it is also difficult. Even after completion, a remarkable number of DHFs repeatedly displays inconsistencies and incompleteness. This can have severe consequences at audits and certificate applications.

We think that R&D resources are better used when working with innovation rather than administration. However, the DHF work cannot be neglected. Therefore, we have built Aligned Elements with two goals in mind:

- The state of the Design History File, in terms of consistency and completeness must be transparent at all times.
- The administrative work spent on the Design History Files must be reduced to a minimum.

We achieve this by:

- Using a DHF centred approach to include all relevant Items under in one system.
- Applying a large number of automatic quality checks to the Items under Design Control.
- Automating time-consuming tasks such as creating Trace Tables.
- Allow efficient reuse of already existing DHF documentation.
- Integrate regulatory relevant rules into the system.

Who should use Aligned Elements?

If you are a Medical Device producer, an OEM manufacturer or supplier to the medical device industry, it is very likely that you already are (or soon will be) a maker of products that are subject to strict regulations such as the:

- FDA 21 CFR Part 820 (QSR)
- EU In Vitro Diagnostic Medical Devices Directive (98/79/EC)
- EU Medical Devices Directive (93/42/EEC).

Aligned Elements will help you fulfil the requirements of these regulations in an efficient and structured manner. When you have to prove that you have followed the strict regulations that apply to the Medical Device Industry during your product development, then Aligned Elements should be your product of choice.