

# aligned



## Aligned Elements

The professional Product Suite built to keep the Design History Files complete and consistent at all times, using minimal effort and tying up a minimum of resources

# Aligned Elements will shorten time-lines and free up personnel for innovation, rather than burden them with administration

## Overcoming the regulatory challenge

Medical Device Manufacturers in today's strictly regulated market are faced with an increasing amount of documentation administration in their every day work, where qualified staff are often burdened with menial tasks.

Moreover, keeping the content and the traceability of requirements, specifications, verifications and risks consistent is a crucial pre-requisite for gaining access to the Medical Device Market in the first place.

Failing to stay compliant with industry regulations can have dramatic effects on business including:

- Delayed releases
- Lost revenues due to product withdrawal
- Fines and penalties
- Law suit expenses
- Severe damage to the company brand
- Criminal prosecution of company executives

Aligned Elements provides absolute consistency by strictly controlling the management of all Design Control Items, including requirements, specifications, verifications, validations, risks, design reviews and deviations, keeping them in a single controlled repository throughout the entire project life cycle.



## No surprises, nothing forgotten

Aligned Elements offers unmatched transparency of the Design History File and a complete control of all changes made to the included Items. At any time, an assessment can be made to monitor if all traces have been set, all risks have been mitigated and all documents have been reviewed, well in time before the auditor does.

## Maximal results, minimal effort

Aligned Elements applies automation whenever possible and reuse wherever sensible to minimize the administrative work associated with Design History File management. This will shorten time-lines and free up resources for innovation, rather than burden them with administration.

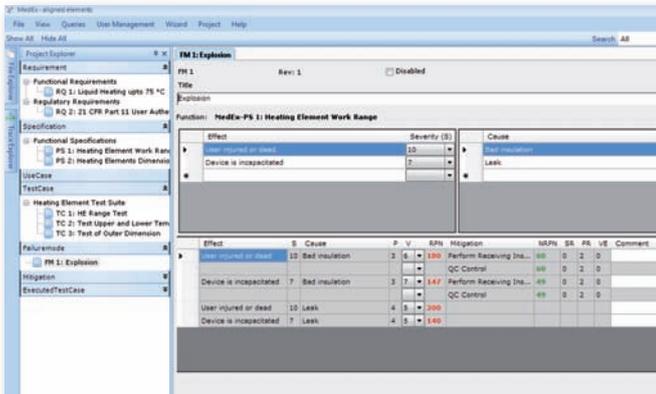
## Specifically made for the Medical Device Industry

Aligned Elements pays equal attention to the quality of the output and the ease-of-use in daily handling. It is based on many years of practical work with Design History Files and has been specifically developed to overcome the challenges posed by regulations such as FDA 21 CFR Part 820, IVDD 98/79/EC, EN ISO 14971 and ISO 13485.

„We can now document our specifications and use cases in a structured manner, perform FMEA analysis on our customers' behalf, carry out design reviews and keep the DHF traceability consistent at all times as our customers' projects grow, a stunt that would have been impossible with other tools available on the market.“

Dieter Speidel, CEO, Xeronics

## Enter the Items under Design Control



Items under Design Control such as requirements, specifications, risks and verifications are entered into Aligned Elements by any of the following methods:

- Enter data using the Document Object Entry Forms
- Import legacy data from existing company databases
- Extract data from current DHF MS Word documents
- Generate content based on applicable regulations using the Aligned Elements Regulatory Wizards
- Reuse existing Design Control Items from other Aligned Elements projects
- Download and import examples and best-practice Design Control Items from the Aligned website

Additionally Aligned Elements provides a broad spectrum of mechanisms for rich-content handling to enhance readability, such as:

- 10 different attribute field types including text, table, file and enumerations
- Chapter capability for arranging Items in structured hierarchies
- Rich Text support for images, bullet points, tables etc.
- “As-you-type”-spellchecking, similar to MS Word
- File attachments to provide additional support data
- OLE objects support, where Microsoft Visio Diagrams, Microsoft Excel Sheets, Microsoft Power Point presentations or any tool which features OLE support can be used to add rich data, such as UML diagrams

## Manage the Design History File activities



Aligned Elements has gone a long way to provide a set of powerful tools to efficiently manage the daily DHF activities:

### ■ Traceability

Straightforward trace-setting between any types of Items, single or multiple, performed via simple drag and drop, between any views in the project. Suspect Traces clearly highlight the impact of changes made to existing Items.

### ■ Risk Management

The integrated Failure Mode and Effect Analysis approach manages failure modes, causes, effects, hazards and mitigations. Hazards are created by automatically combining available causes and effects and the RPNs are calculated and evaluated while providing full traceability of mitigations back to specifications or tests.

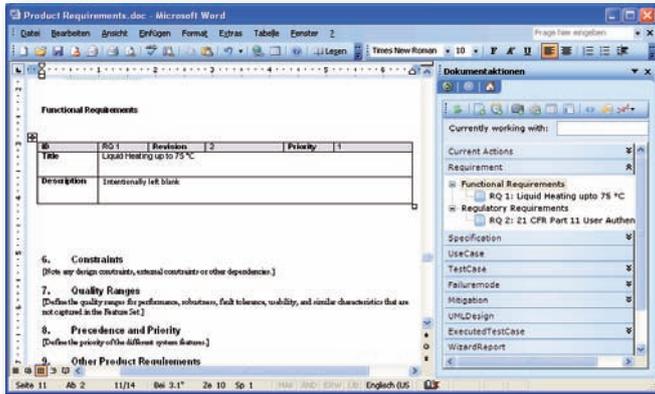
### ■ Design Reviews

Reviewing is the corner stone of every quality process. The built-in Design Reviews functionality permits reviews to be performed and recorded directly in Aligned Elements. Precise and complete records of each review are generated and the application automatically keeps track of the current review status of all Design Control Items.

### ■ Deviation Tracking

Aligned Elements includes its own Deviation Tracking System but can also use deviations from Trac and Jira. Deviations are attached to any type and number of Items and elaborate sorting and filtering allows the user to access the deviations important to him/her.

## Exporting Design Control Items to MS Word documents



All Items created and managed by Aligned Elements can be inserted into MS Word documents, using drag and drop. The MS Word integration supports a two-way synchronization of modifications made in both documents and database. The documents themselves are kept under strict 21 CFR Part 11 compliant Change Control.

- Open for customer specific design

By strictly keeping design and content apart, Aligned Elements allows each customer to decide how the items under Design Control shall be depicted in MS Word, by coupling each Item type to a Word Template.

- Automatic Revision History

Since Aligned Elements is aware of all operations made to a document, an automatic revision history can be applied. Operations such as insertion, deletion, synchronization and modification of Items in the document automatically causes the revision history to be filled with change comments.

- Automatic generation of Trace Tables

Trace Tables, based on the existing trace structure, can be generated and inserted in MS Word by a single click of a button. The established Trace Tables can later be synchronized to match on-going modifications.

- Integrated E-Signatures

Aligned Elements supports Digital Signatures by applying the FDA recommended x.509 V3 Class I certificate standard as flattened signatures in PDF copies of the DHF MS Word documents. This enables users to sign DHF documents electronically and record DHF related project decisions directly in Aligned Elements.

# Aligned Elements applies automation whenever possible and reuse wherever sensible to maximize the utilization of your efforts

The completeness and consistency of the DHF is of utmost importance for all Medical Device Producers. Aligned Elements provides a rigid Change Control and the industry's most extensive range of mechanisms to scrutinize and prevent inconsistencies and gaps in the Design History File content.

- FDA 21 CFR Part 11 compliant Change Control
- Full chronological Audit Trail of all changes
- Integrated DHF Index verifying the current DHF state against company specific processes and SOPs
- A highly configurable data query engine with 9 different filter types to allow an even more precise data analysis
- Customizable company or regulatory specific checklists with automatically generated protocols
- 10 customizable Validation Rules that automatically monitors the DHF content for any irregularities including:
  - Missing traces
  - Suspect traces
  - Unmitigated risks
  - Open deviations
  - Unreviewed items
  - Items updated after review
  - Items not present in a MS Word document
  - Outdated items in MS Word documents
  - Inconsistent item values
  - Overdue dates

„Considering that we installed Aligned Elements in October and got our CE mark in May, we are very pleased to have achieved so much in so little time.“

Giovanni Leo, CTO, Endosense

### Process independence

Aligned Elements is a highly process independent system. Implementing Aligned Elements in the organization requires no changes into the existing processes. As a consequence, each company can adopt Aligned Elements independently of their current processes, workflows and SOPs, minimizing the implementation impact.

### Flexible naming conventions

Requirements, business requirements, market requirements, user needs, stakeholder considerations; each customer usually has good reasons for his specific choice of naming conventions. Aligned Elements allows the customer to adopt his existing naming conventions for all DHF Item types, including associated field names, field types and field layouts.

### Modularized products – modularized documentation

For companies with modularized products, where single components are part of several products, Aligned Elements offers a powerful modularization approach. The DHF of a product can be broken down into modules and thereafter be re-assembled as new products are developed. This efficient reuse of DHF documentation significantly reduces the administration effort and hence the time-to-market for new products.

### Integration with existing systems

Aligned Elements provides integration with external bug tracking systems such as Jira and Trac to leverage the DHF data already residing in the organization. The Aligned Elements client facilitates access and usage of this data to make the DHF product traceability complete. The Aligned Elements team is continuously working on providing integration with further systems on the market.

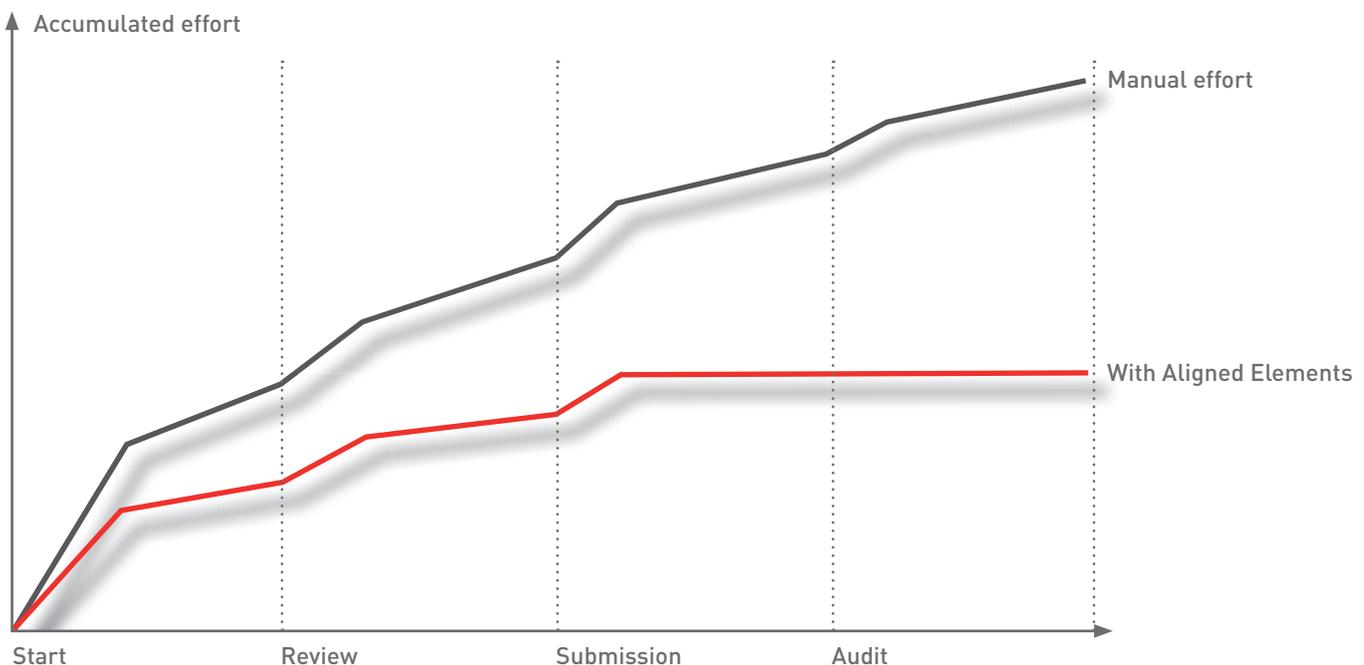
### Reuse data in other systems

For a highly flexible output, Aligned Elements offers an XSLT driven export option, which allows new export formats to be dynamically added on demand. This permits the DHF data to be exported in XML, CSV, HTML, Excel, Text or any other data format where an XSLT transformation can be applied.

### Working offline

Aligned Elements is a client-server application with a single repository for all DHF data. However, it is also possible to take a project offline and continue to work independently of access to the server. When finished, the offline changes can be merged back online again, with automatic synchronization of all modifications.

### Reduced effort by use of Aligned Elements





Aligned Elements is the most powerful tool you can own to ensure regulatory DHF compliance

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#### Client system requirements

Operating system: Windows XP SP 2 or Windows Vista  
 RAM: 1 GB (Recommended: 2 GB)  
 Hard disk space: 10 GB  
 Microsoft Word: MS Word 2003 Professional SP1 or MS Word 2007 Professional

#### Server system requirements

Software: MS SQL Server 2005 or MS SQL Server 2005 Express  
 Operating system: See [www.microsoft.com](http://www.microsoft.com)  
 RAM: 1 GB  
 Hard disk space: 10 GB

#### Deployment options

Client deployment options:

- Standard offline installer
- Web deployment including automatic updates

Additional server multi-site deployment options:

- Deployment on citrix
- Prepared for database replication

#### Included services

- Server setup and configuration
- Any number of client installation
- 12 month support contract
- 2 days of template set up and configuration
- 1 day user training incl. training material and certificate of completion
- Access to free downloadable regulatory content
- Prepared validation templates for tool validation of Aligned Elements
- Prefilled Aligned Elements FDA 21 CFR Part 11 assessment
- Access to the entire Aligned Elements development documentation

#### About Aligned

Aligned has set out to become the leading player for ensuring and documenting the compliance of products in highly regulated markets. We assist our clients in developing, manufacturing and marketing regulatory compliant products with higher confidence, to lower costs and within shorter time-frames.