



- Aligned Elements

Overcoming the regulatory challenge of medical device development



Aligned Elements – prove you're right

Aligned Elements is a professional product suite built to easy and effectively keep the project documentation compliant to regulatory demands throughout the product development process.

Doing product development in a regulated environment brings extensive challenges to the product development team. Strict regulations in the medical device industry, such as the FDA CFR 21 Part 820 (QSR) and EU IVD-D norms, do not only require you to build a safe, high-quality product. You must also be prepared to present the documented evidence that you have actually done so.

However, an R&D organization is usually not put in place in order to administer regulatory related tasks, but rather to develop products. The increased workload and the unfamiliarity with the task described will inevitably slow down the project progress and may in the end, have severe effects on the release schedule.

We, at Aligned, have realized that the main obstacle during the product development process is not necessarily capturing and recording requirements, specifications, test cases etc. but the immense number of minor tasks needed in order to keep the project documentation consistent through-out the project-life time. Repetitive, time consuming and badly coordinated administrative tasks effectively eat up valuable development time and critical inconsistencies are often first discovered just before the product release.

Good requirement management and consistent project documentation is important in all industries requiring high quality products. However, what makes these things so important in the regulated environments are the severe punishments imposed on a manufacturer if he cannot prove his work. Failing in being compliant to the regulations in question can have dramatic effects such as:

- delayed releases
- lost revenues due to withdrawal of products from the market
- fines and penalties
- law suites expenses
- sever damages to the company brand
- criminal prosecution of company executives

Unlike conventional requirement management tools, Aligned Elements takes its starting point in these regulatory related challenges. It is focused on effectively reducing over-head and increases consistency by targeting the re-occurring, compulsory tasks taking place in the regulatory project development environment.

By using Aligned Elements, the development team is free to spend more time on building products and less time on worrying about the regulatory state of the project documentation.

Aligned Elements ensures:

- Consistency
- Completeness
- Certainty



Aligned Elements features and benefits

- Encompasses all relevant artefacts in the product development process

Aligned Elements is built for much more than to merely manage requirements. Since specifications, risks, tests, validation plans, reviews etc. are natural components of the project documentation, Aligned Elements makes sure that all these relevant artefacts in the product development process are captured and managed. All artefacts can be freely traced to each other, using drag-and-drop, and therefore enables the project manager to get a complete overview over the entire project topography at any point during the development process.

- Easy data entry and flexible project structure

Capturing requirements, specifications, tests, risks etc. is done via easy natural language entry in rich text format allowing the user to use pictures, bullet points, underscoring etc. to increase readability. To each artefact, file attachments can be made which are, just like all other project artefacts, subject to change control.

The project structure is completely flexible, enabling arbitrary chapter and subchapter depths. Artefacts and chapters can be freely moved and copied throughout the project.

- Round-trip documentation management with MS Word

Being able to work with requirements or specifications in MS Word is often the preferred method in many companies. Aligned Elements supports round-trip document editing which makes it possible to work in MS Word or Aligned Elements as preferred. One or several project items or chapters can be exported in MS Word format, using Aligned Elements enclosed Word templates or, if preferred, customized user templates. Changes in the text document are automatically synchronized back into Aligned Elements.

- Traceability and transparency

Thanks to Aligned Elements trace diagrams, each artefact is graphically represented in its context where its dependencies are clearly marked out. This gives a clear picture of how all artefacts in the project is associated with each other. Tracing through drag-and-drop, colour coding of states and types, zooming etc increases the usability of this feature.

- Complete change history, comparison of artefact revision.

At any given point in time, the history of each individual artefact can be access. The complete history of each revision of each artefact is carefully managed and available at any time. All changes made can be accessed for analysis.

- Change Impact Assessment

Like ripples on a water surface, a change in an artefact might affect the artefacts associated with it. When an item has been changed, the user is immediately notified about which other artefacts may be affected by the change. The user is can easily assess the impact and resolve any types of problems entailed by the change. Hence, change impact is consistently managed through out the entire project structure.



- Project linking

Since most products consist of modular components being used in multiple end-products, it makes sense to create consistent documentation for each sub-module and link them together. Interlinking of projects in Aligned Elements allows efficient reuse of existing product documentation as well as increased transparency of the impacts entailed by modification of a sub-module used in several end-products.

- Custom artefacts and properties

For full flexibility, Aligned Elements supports addition of customized artefacts and customized properties to all preconfigured artefacts. Company specific attributes such as technical cost, risk level, due dates etc. can be added on demand. A large range of data types are available for additional properties. The user can also set up completely new artefacts and populate them with properties of his or her own liking.

- Multiple simultaneous clients

Multiple users on the same network can work on a project simultaneously at any time and automatic synchronization between multiple users' changes is ensured. Aligned Elements also supports off-line mode where changes are synchronized back to the database when the user connects back to the network. At each new session, the user can easily monitor the summary of changes that has been made to the project since last log in.

- Labelling

A powerful labelling/base-lining mechanism enables the user to store a snap-shot of the current state of any part of the project. This feature enables the user to consistently mark the state of a project before reviews, milestones etc. A previous label of the project can be brought from the database and compared with the current state.

- Review coordination

Speed up your review process with the integrated Review Coordinator that automatically helps you create well-traced and complete review documentation. By automating several of the review tasks reviewing will finally be a constructive and naturally integrated part your project instead of being an time-consuming source of red-tape.

- Issue tracking

Issues that evolve during a project, is the first and most immediate part of any change management. Issue tracking is an integrated part of Aligned Elements which allows users to record and trace Issues to existing artefacts.

- Document management

Aligned Elements further also supports version management of documents in order to adequately trace changes that are not found in artefacts. All your top level documents such as plans and reports can be stored and managed from Aligned Elements making them an natural, integrated part of the project documentation.



The Aligned Elements components

Aligned Elements is an extensive product suite containing a growing number of product components. The basic version of the product comprises the following modules.

Requirement management

Capture and manage structured requirements with the Requirement Management module. Attach files to the items, prioritize your requirement, keep complete track of all changes made and even add your customized properties. With a flexible labelling mechanism you can create and restore a requirement baseline at any time.

Risk management

Risk handling is an essential task for almost all types of regulatory related product development. However, capturing and managing risks and the corresponding mitigations can be tedious, hard and right out exhaustive. The Risk management component helps you, by using an FMEA approach, to record, analyze and track your product risks. Reuse of potential failures across your project is easily done as well as the management and tracing of the mitigations. The sources of risks and the mitigations created to deal with the risks are managed through the transparent tracing mechanism integrated into the risk management.

Specification handling

Aligned Elements provides a collaborative environment to compile your specifications, using natural language or using use cases. Use attached files to further provide supportive documentations or rationales to your specifications. Publish the specifications to your project development team and let them take part in the refinement process.

Setting up and performing tests

Keep complete track of your test progression and make sure that your entire specification set is tested as planned. Integrated test execution recording, change tracking and reviewing are integrated parts of the regulated product development and therefore also in Aligned Elements. Tracing your test cases back to its origin, namely specifications, requirements and hazard mitigations gives a crystal clear transparency where inconsistencies, weak points and dead ends are immediately revealed. This prevents you as well as the audit board to be subjects to unpleasant surprises.

Review coordination

Reviewing is a corner stone of all quality procedures. However, few things can be as painstaking and time consuming as review meetings. Bad preparations and low commitment from the participants often end up in poor reviews, usually requiring a second or even a third round of meetings just to get the complete signoffs. In Aligned Elements, a large part of tasks needed to make a review complete and consistent is generated by automatically extracting information from other parts of the system.

By using these benefits you can cut your time spent in review meetings significantly and still end up with better and more consistent reviews.



Conclusion

Aligned Elements uses a practical and automated approach to manage the efforts regulatory challenges bring to product development. The Aligned Elements product suite is built to enable the product development team to focus on building products instead of spending time on administrative project documentation tasks.

Ultimately, Aligned Elements will help you build better products, hold your time lines and provide you with the proof that you have done your work as specified.

Aligned AG has set out to become the leading player for ensuring and documenting the compliance of products in highly regulated markets. We are here to help our clients to develop and manage products in regulated markets with higher confidence and within shorter timeframes. Our clients are manufacturers, end customers and sub-suppliers in the medical device industry, companies who develop and market products which are subjects to regulations such as the FDA Quality Systems Regulations or the EU In Vitro Diagnostic Directives. Aligned AG was founded in 2006 with headquarters in Zurich, Switzerland. You can find continuously updated information about our product and services on our web-site www.aligned.ch.