

aligned



■ Overcoming the regulatory challenge



Aligned provides measures to ensure compliant development documentation for regulated products in the medical device industry.

Developing products for today's regulated markets is a significant challenge as steady growth in both number and complexity makes it increasingly difficult for manufacturers to:

- Ensure compliance
- Avoid delays of product registrations
- Avoid costly recalls
- Maintain a competitive time-to-market.

Our clients develop and manufacture products subjected to strict regulations, such as the FDA 21 CFR Part 820 (QSR), the EU In Vitro Diagnostic Medical Devices Directive (98/79/EC) or the EU Medical Devices Directive (93/42/EEC).

We assist our clients to develop, manufacture and market regulatory compliant products within shorter timeframes, at lower costs and with more confidence.

At Aligned, we believe that management of product and project documentation of regulatory compliant products should be efficient and pragmatic. We advocate an approach that allows your development team to focus on innovation instead of administration.

■ The Design History File – a strategic asset



The regulatory environment does not only require a medical device manufacturer to build safe, high-quality products. The manufacturer must also present the documented evidence that he has actually done so. The "Design History File" makes up a significant part of this evidence.

Successful Design History File (DHF) management requires:

- Consistency and completeness of the entire DHF during the product life time.
- Change control of a large number of items under Design Control.
- Complete traceability across the affected Design Control items.

Creating and managing the Design History File is a complex and cumbersome, but also necessary task since failing can have severe consequences such as:

- Delayed certification approvals and product releases
- Lost revenues due to product recalls
- Fines and penalties
- Criminal prosecution and law suite expenses

Medical device manufacturers have increasingly realized the strategic importance of correct management of the Design History Files. Consequently, these companies decide to give their DHF Management the strategic significance and adequate attention it undoubtedly deserves.

■ Focusing on relevance



Aligned Elements is our DHF Management solution targeted for the need of controlling a large number of individual but related Design Control items with minimal effort.

Aligned Elements includes:

- Requirement, specification, use-case and test-case management. Manage the complete back bone of the project documentation and keep track of all changes over the product life-time using a fine grained revision history and base-line functionality.
- Traceability management. Multiple views and diagrams visualize traces between the items under Design Control. Changes are clearly highlighted to signalize potential damage to the DHF consistency.
- Consistency control. A large number of configurable validation rules detect inconsistencies within and between the items under Design Control.
- Risk management. Using an FMEA approach to analyze and manage failure modes, hazards and create mitigations which are traced back to new requirements and specifications.

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

■ A partner to rely on



Our clients are companies who develop, manufacture and market products which are subject to regulatory guidelines such as the FDA Quality Systems Regulations, the EU Medical Devices Directive and the EU In Vitro Diagnostic Medical Devices Directive.

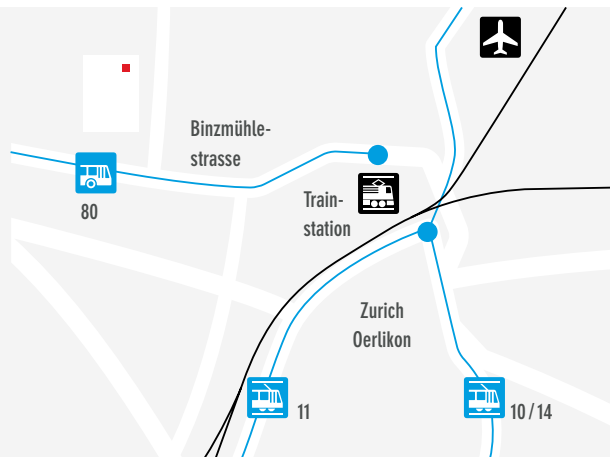
To bring maximal advantage to our clients, we offer our expertise in the following domains:

- Clarifying the regulatory scope applicable to a product and evaluating how these regulations are translated into concrete processes, documents and requirements.
- Assessing the state of compliance of a product, locating the gaps to the applicable norms and regulations, and, if viable, work out the documentation and testing needed to align the product with the applicable regulations.
- Tuning the internal development process for effective handling of regulatory documentation tasks. We advocate a pragmatic approach specifically aimed to eliminate unnecessary administrative work.

At Aligned, we strive to build value that lasts by remaining closely involved with our clients until sustainable result has been achieved.

■ Contact

■ Summary



You can reach us by car or local train approximately 10 minutes from Zurich City Center.

Zurich Airport is located approximately 5 minutes away by car, taxi or local train.

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Aligned provides measures to ensure compliance of regulated products in the medical device industry.

We assist our clients to develop, manufacture and market regulatory compliant products within shorter timeframes, at lower costs and with more confidence.

Our clients operate in the medical device industry and develop, manufacture and use products which are subject to regulatory guidelines such as the FDA Quality Systems Regulations, the EU In Vitro Diagnostic Medical Devices Directive and the EU Medical Devices Directive.

Aligned was founded in 2006 with headquarters in Zurich, Switzerland.

You find continuously updated information on our website: www.aligned.ch.

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