



Regulatory Support

Putting regulatory requirements into practice

Regulatory requirements must be translated into appropriate processes, robust evidence and verifiable documentation. This applies not only to quality management and technical documentation, but also to conformity assessment, registration, market surveillance, product changes, international market access and related regulatory obligations for medical devices and IVDs. Even after a product has been placed on the market, it must be continuously monitored, findings assessed, and processes and documentation kept up to date. In practice, organisations often lack the capacity, specific expertise or suitable tools to do this.

What is Regulatory Support?

VDE Health's Regulatory Support assists with the practical implementation of regulatory requirements throughout the entire product life cycle. VDE Health provides support in establishing and further developing processes, in the preparation, review and maintenance of the necessary documentation, and in preparing for audits, assessment procedures and contacts with regulatory authorities. Even after a product has been placed on the market, we support you with market surveillance, vigilance, product changes and the ongoing updating of your documentation. The scope is tailored to your needs, ranging from one-off support to ongoing assistance.

Your outcome

VDE Health supports you in the development and refinement of suitable processes, as well as in the preparation and review of regulatory documentation, in particular:

- Establishment and further development of the quality management system according to ISO 13485
- Structure, content and consistency of the technical documentation
- Evidence relating to risk management, verification, validation and software
- Clinical evaluation, performance evaluation and clinical follow-up
- Procedural documentation for conformity assessment and certification
- Registration requirements, UDI and EUDAMED
- Market surveillance, vigilance and regulatory assessment of product changes
- Preparation for audits, assessment procedures and regulatory enquiries
- Documentation for national and international market access

The Regulatory Support Process

1. Clarifying requirements

Agreeing on the product, life cycle phase, target market, procedures, timeframe and desired scope of support.

2. Assessing the current status

Review of existing processes, documents and supporting evidence, and identification of any necessary adjustments or additions.

3. Defining the scope of work

Defining the necessary tasks and agreeing on the allocation of roles.

4. Implementation and further development

Creating, revising and coordinating processes, supporting evidence and documents, whilst continuously checking for completeness, consistency and traceability. Adjustments to new requirements, product changes and findings from market surveillance are continuously taken into account.

Where necessary, coordination meetings or workshops support the implementation process, for example to clarify any questions that arise, to assess interim progress and to agree on the next steps.

Your benefits

- Practical implementation of regulatory requirements
- Support with documentation without the need to build up additional capacity on a permanent basis
- Reduced workload for development, quality and regulatory teams
- Consistency between the product, processes, evidence and documentation
- Fewer queries and less rework during audits and formal procedures
- Ongoing maintenance after the product has been placed on the market
- Adaptation of existing documentation to new requirements, markets and product changes
- Flexible scope, ranging from ad hoc support to ongoing assistance

Do you need support with regulatory implementation?

VDE Health supports you throughout the entire product life cycle in establishing and further developing suitable processes, robust evidence and audit-compliant documentation.

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Please note: This description is intended solely to provide general information about the range of services offered by VDE Health. It does not constitute a binding offer. The nature, scope and specific details of the services will be agreed upon jointly on a case-by-case basis and set out in a separate agreement.