



In-House Training

Building regulatory expertise within your own team

Regulatory requirements for medical devices and in vitro diagnostic devices do not only concern regulatory Affairs and quality Management. Development, product management, clinical evaluation and senior management also make decisions with regulatory implications. A lack of a shared understanding leads to inefficiencies, incomplete documentation and avoidable rework. External expertise alone is therefore generally not sufficient. Regulatory expertise should also be embedded within the organisation itself.

What is VDE Health's in-house training?

VDE Health's in-house training equips your teams with the necessary regulatory expertise to implement relevant requirements within their respective areas of responsibility confidently and in a practical manner. The content, depth and format are tailored to your product, its stage of development and the specific tasks of the participants. The focus is on your questions and use cases. The training is suitable both for onboarding new staff and teams and for the targeted in-depth exploration of individual topics.

Your outcome

With a training programme tailored to your company, your teams will develop a shared understanding of regulatory matters and learn to apply the relevant requirements confidently in their day-to-day work. The following aspects are covered in particular:

- Fundamentals and structure of the MDR and IVDR
- Intended purpose, qualification and classification
- Conformity assessment, Notified Bodies and CE marking
- Quality management in accordance with ISO 13485 and associated processes
- Technical documentation, risk management and evidence management
- Software, AI, cybersecurity and related legal frameworks
- Clinical evaluation, performance evaluation and post-market obligations
- Roles, responsibilities and interfaces within the organisation

In-depth details of the in-house training

1. Clarifying requirements

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

2. Agreeing on content

Coordinating topics, key areas and practical examples to suit the target group, learning objectives and the desired product relevance.

3. Selecting the format

Determining the format, dates, duration, participant group and organisational framework.

4. Training and practical application

Practical delivery of the content with scope for questions and discussions, as well as the provision of training materials and recommendations for internal application.

The content and key focus areas of the training can be adapted to your specific issues, products and learning objectives to an agreed extent.

Your benefits

- A shared understanding of regulatory requirements across departmental boundaries
- More informed decisions in development and project work
- Potential for fewer queries, rework and coordination loops
- Practical content drawn from your own product and project context
- Documented transfer of relevant regulatory knowledge
- Reduced reliance on external support
- Tailored to the target audience, prior knowledge and available time

Does your team need regulatory expertise?

VDE Health supports your staff and teams in building up regulatory expertise and implementing relevant requirements confidently and in a practical manner.

VDE Health

VDE Association for Electrical
Engineering
Electronics and Information
Technology e.V.
Merianstraße 28
63069 Offenbach am Main
Email: meso@vde.com
Website: www.vde.com/health

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.