



Gap Analysis

Identifying non-conformities and risks at an early stage

Prior to an audit, conformity assessment, certification or authorisation of medical devices or in vitro diagnostic medical devices, it is crucial that the product, processes and documentation are thoroughly prepared. Incomplete evidence, missing processes, outdated standards or unresolved requirements often only come to light during the conformity assessment procedure. This can lead to queries, rework, non-conformities, delays and additional costs.

What is a gap analysis?

VDE Health's gap analysis systematically compares your project against the relevant legislation, standards and guidelines. It shows which requirements are already met, where discrepancies exist and what significance these have for the formal procedure. The result is an overview of the discrepancies and risks, ranked by relevance. It serves as a working basis for preparing for audits, conformity assessment, certification or authorisation.

Your outcome

By systematically comparing your current status with regulatory requirements, you gain a robust foundation for further preparation. You can identify which issues need to be addressed before the formal procedure begins and which can be taken into account later on. The following aspects are considered in particular:

- Intended purpose, qualification and classification as a frame of reference
- Relevant regulatory frameworks from the MDR and IVDR
- Relevant standards and their current status
- Completeness and auditability of the technical documentation
- Maturity and verifiability of the processes and the quality management system
- Clinical evaluation, performance evaluation and post-market obligations
- Requirements from related regulatory frameworks
- Relevance, effort involved and regulatory risk of the identified non-conformities

The gap analysis process

1. Defining the audit framework

Aligning the product, target market, procedures, level of scrutiny and scope of documentation, as well as identifying the relevant legislation, standards and guidelines.

2. Reviewing documents and processes

Comparing the available documentation, evidence and process descriptions with the defined requirements, including consistency and traceability.

3. Assessing non-conformities

Classifying the identified non-conformities according to regulatory risk, urgency and effort involved, as well as their impact on the remaining schedule.

4. Derive recommendations for action

Summarising the results in an overview ranked by relevance, with specific recommendations for further action.

Depending on requirements, the process may include discussions, consultations or workshops, for example to prepare for the process, to clarify any questions that arise and to jointly classify the results.

Your benefits

- A clear overview of the actual state of preparation
- Early identification of issues that may become critical during the process
- Assessment based on regulatory risk rather than gut feeling
- Potential for fewer queries, rework, non-conformities and complaints
- More realistic planning of time, effort and resources
- An independent external perspective on existing documentation and processes
- A transparent basis for decision-making to support internal and external coordination

Would you like to know whether your docs and processes are audit-ready?

VDE Health assesses your project against the relevant standards and specifications. You will receive an overview of the identified deviations and risks, organised according to our expert assessment, along with recommendations for possible next steps.

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

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