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Regulatory Affairs: Be digital. Be sure.

In medical technology, product safety comes first. To ensure this, companies must comply with a wide range of regulatory requirements – such as laws, standards and guidelines. These requirements apply across every phase of the product life cycle: from design and development through manufacturing to post-market surveillance.

This means: **Medtech manufacturers must**

- maintain and continuously update a library of relevant regulatory documents such as laws, standards and guidelines,
- ensure that the organization fulfills all applicable requirements, and
- evaluate and implement changes in regulatory documents in a timely and efficient manner.

Easier said than done

IEC 60601-1 contains around 1,500 individual requirements![1] Manual tracking is more than challenging.

Teams spend ~30% of their working time searching for regulatory information across different systems[2]

> 60% of all FDA Warning Letters cite deficiencies in the CAPA process or documentation[3]

Meeting legal requirements takes a clear overview, time, and staying power.

Challenges for regulatory affairs specialists

High time investment: The identification of relevant regulatory documents for different application areas costs time when information is spread across multiple systems and people within the organization.

Ongoing changes. Regulatory requirements change or are expanded – keeping up with these adjustments is a complex task that is prone to error.

Manual traceability: Cleanly tracing the applied content of regulatory documents is not only time-consuming but also error-prone without digitally connected information.

Lack of consistency - consistent use of information across all product development areas is difficult to guarantee if it isn't centrally available and up to date.

[1] Electrical Safety Testing for Medical Devices and IVD, TÜV Süd, 2026; last accessed on 10.6.2026

[2] The Crisis Of Fractured Organizations, Forrester, 2022; last accessed on 10.06.2026

[3] Top 10 Form 483 Findings in Medical Devices (2026 Update), Hilling Michelle, last accessed on 10.06.2026

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Get to know avaRegulatory, our specialized software that makes your daily work with regulatory documents easier. It lets you track requirements efficiently and accurately, and manage and apply them cleanly.

Digitalized processes solve or drastically improve the challenges posed by increasing regulatory requirements

How avaRegulatory supports you

Smart, central management of regulatory information (supported by the Nautos interface* from DIN Media)

- Regulatory documents are centrally available with their own metadata.
- Thanks to the Nautos interface, the metadata of standards can be imported from the DIN database as complete data sets.
- The ReqIF data format enables direct import of regulatory requirements in a digital format with audit-proof traceability - manual data entry is a thing of the past.
- Powerful and user-friendly filters (topics, product areas, validity) ensure immediate findability – no more annoying searches in Excel spreadsheets or across different drives.

Effortless document monitoring

- Upcoming reviews are displayed in overview dashboards.
- The List of Applicable Regulatory Documents is updated with confidence and ease: Changes to the source documents are immediately visible – no more error-prone post-maintenance in Word/Excel.
- End-to-end visibility reduces regulatory risks and prevents the use of outdated information.

Automated Gap Analysis & Impact Assessment

- Changes between versions of standards are digitally detected and compared.
- New and changed requirements are clearly presented and provide an ideal basis for a differentiated assessment.
- The product offers optimal support for a portfolio-related impact assessment by highlighting affected products, documents and requirements.
- Required measures can be planned in a targeted manner and necessary changes implemented more quickly.

Efficient integration of regulatory information into development

- Standards and other regulatory documents can be broken down into individual, comprehensible requirements.
- Structured templates enable complete and consistent documentation from requirements to test evidence (e.g. GSPR checklist according to Annex I MDR or IVDR)
- Improved traceability, enabled by traceability reports, and shorter time-to-market through seamless integration into the development process
- Audit readiness without additional effort

*Additional license costs apply for the use of Nautos.

Want to learn more?

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