GOOD PRACTICE

Getting ready for an audit

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Medical devices are products that have a direct impact on the health and safety of patients and users. They must comply with high quality, performance and conformity requirements.

To verify requirements are met, audits are carried out to assess the quality of manufacturers' products, processes and Quality Management Systems (QMS). There are different types of audits, depending on the requirements targeted, the scope covered and the frequency with which they are carried out. They are based on sector-specific regulations and standards, such as the European Medical Device Regulation (MDR), the ISO 13485 standard or the US regulation 21 CFR Part 820.

Audits are independent, systematic assessments to demonstrate quality and reliability. They are also fundamental to continuous improvement and ensuring your company's performance. Indeed, keep in mind that they can be factors of differentiation and competitiveness in the market. But they can also be a source of stress and uncertainty if you are not well prepared. Whatever the type of audit, it is essential to prepare effectively, to avoid non-conformities, deviations or observations, which can lead to delays, additional costs or, in the worst case, sanctions.

So, with that said... How to prepare effectively for an audit? What are the types of audits you may face? What are the best practices to adopt? Here are some elements of answer.

There are different types of audits depending on their origin, scope and frequency. We can distinguish:

- Internal audits: They are carried out by your own qualified staff or by an external service provider, which aim to assess the compliance of your QMS, processes, products and services with internal and external requirements. They are usually performed once a year and allow to detect gaps, non-conformities and potential risks, and to implement corrective and preventive actions. Typically, internal audits are mandatory to maintain the ISO 13485 certification. They are also a means of raising awareness and training your employees on good practices and a way of preparing for external audits (see below) by familiarizing yourself with the auditors' methods, tools and questions, and anticipating potential problems or difficulties

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- External audits: They are carried out by independent organizations, which aim to verify the compliance of your QMS and your products with regulatory and normative requirements. These audits may depend on the target market. For example, regulatory audits or inspections are carried out by Notified Bodies or competent authorities, which issue or maintain the certifications required to market products and/or demonstrate compliance with an applicable standard or regulation. Typically, to market your products in Europe (which implies obtaining CE marking), or to obtain or maintain your ISO certification, audits by a Notified Body is essential. They are generally carried out at defined intervals (e.g., a three-year cycle for ISO 13485 certification, with intermediate surveillance audits). They can cover all or part of the QMS, as well as technical files or batches of products. They can result in the issuance or withdrawal (!) of a certificate, an authorization or a license.

- Customer audits: They are carried out by your current or potential customers, which aim to evaluate the quality and performance of your products and processes. As a partner or supplier, you may indeed be required to be audited. Such audits can be requested as part of a tender, a contract or a follow-up. They can focus on specific aspects, such as design, manufacturing, control, traceability or complaint management. They can have an impact on your customers' satisfaction and loyalty, as well as on your reputation and credibility.

To prepare for an audit, it is essential to know the applicable requirements, to have an up-to-date and complete documentation, to carry out regular self-assessments, to communicate effectively with the auditor and to mobilize your teams. Here are some practical tips:

Before the audit: Identify the type, objective, scope and reference of the audit. Ask the auditor for a detailed audit plan, which specifies the dates, times, locations, people and documents to be audited. Prepare the required documents and check that they are accessible, readable and consistent. Review the results of previous audits and make sure that corrective actions have been implemented and verified. Inform and train your employees on the conduct and expectations of the audit. Appoint an audit responsible, who will be the main contact person for the auditor and who will coordinate the internal activities.

- During the audit: Welcome the auditor with courtesy and professionalism. Introduce him/her to your company, your QMS and your products. Accompany him/her throughout the audit and answer his/her questions with honesty and transparency. Provide him/her with the documents and evidence requested. Do not give unnecessary or unsolicited information. Do not challenge his/her findings on the spot but note them down for later discussion. Participate in the opening and closing meetings of the audit, which are key moments to exchange with the auditor and clarify the points of agreement and disagreement. Ask him/her for an audit report, which summarizes the findings, gaps and recommendations of the audit.

- After the audit: Analyze the audit report and verify its compliance with the audit plan and the facts observed. If you find any errors or inconsistencies, communicate them to the auditor and ask him/her to correct them. If you accept the findings of the audit, develop a corrective action plan, which describes the actions to be taken, the responsible persons, the deadlines and the monitoring indicators. Implement the corrective actions and verify their effectiveness. Provide feedback to the auditor on the results obtained and ask him/her to close the audit. Capitalize on the audit experience and share the best practices and areas for improvement with your teams.

Conclusion

In conclusion, audits can have positive consequences such as compliance recognition, continuous improvement and customer satisfaction, or negative consequences such as non-conformity detection, certification suspension/withdrawal or credibility loss. They are essential tools to ensure the quality and compliance of your medical devices. They are also drivers of performance and competitiveness for your company. To succeed in your audits, it is important to anticipate, prepare and exploit them.

If you are looking for support with developing your medical device then do not hesitate to contact the Debiotech SA team at contact@debiotech.com or visit our website online at www.debiotech.com. This Good Practice document was written by our Quality System Assistant - Sven Boutat. We thank you for reading it.

👉 **Don’t hesitate to stay tuned for more insights!**

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