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Medical device quality audits

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Background: This seminar will help you understand the three types of audits (internal audits, supplier audits, and external audits) and how to prepare for them. You will also learn the purpose and scope of medical device audits, which guidance documents you will need, best audit practices, the similarities and differences between FDA inspections and investigations and Notified Body audits, and what is expected when FDA, a Notified Body, or other external auditing body visits.

Why should you attend - Fear, uncertainty and doubt (FUD) liner for the marketing purpose: Most industry personnel are overwhelmed by national and international quality system laws, directives, regulations, standards, and guidance documents. As such, they believe if they obtain quality system certification from a European Notified Body that they will automatically pass an FDA audit. However, this is not the case. FDA warning letter after Warning Letter prove otherwise…True that Europe's quality management system standard (ISO 13485) and USA's quality system regulation (21 CFR Part 820) are very similar in nature; however, the philosophy, purpose, and scope of the FDA is totally different than of the European Union. Not only is it required under law to perform internal audits, but also to have FDA and the Notified Bodies visit. If top management do not plan for internal, supplier, and external audits, not only may regulatory compliance sanctions against the company occur, but the company may also loose its competitive advantage, have customer lawsuits, perform unnecessary recalls, and be known as a company with non-quality products and services.

Areas covered in the session: This seminar will provide valuable assistance to all medical device companies in preparing for internal audits, supplier audits, and external audits, how to behave during external audits, and what to do after the external audits have concluded. The focus will be a basic understanding of quality system audits without confusing everyone with regulatory compliance jargon. The webinar will include the following:

1. The definition, purpose and scope of audits
2. The three types of audits
3. How audits fit into a quality system
4. FDA and EU medical device history, organization, laws, directives, regulations, standards, and guidance
5. The similarities and differences between the FDA and the EU
6. How to prepare for external audits
7. How to act during external audits
8. What to do after the external audit has been performed
9. The similarities and differences between FDA inspections and investigations and Notified Body audits and
10. FDA's Quality System Inspection Technique

Who will benefit/ Target audience: This topic applies to personnel / companies in the medical device industry. The employees who will benefit most include:

- Senior management,
- Regulatory compliance, and
- Quality Assurance.

However, if you are already familiar with the auditing process you may recommend this webinar to anyone in your company that has questions about internal audits, supplier audits, and external audits.

Biography

George Calafactor is a 28-year food, cosmetic, drug, biologic, clinical, and medical device quality assurance and regulatory compliance veteran with over 21 years of FDA/ governmental experience as an analyst and level II certified international medical device investigator and over 7 years of industrial experience as a biologic, pharmaceutical, and medical device industry quality assurance consultant, regulatory compliance specialist, and ASQ certified quality biomedical auditor.

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