Corrective Actions - Current expectation of ISO 13485 and FDA auditors

Description: This presentation will provide an understanding of the current expectations of ISO 13485 notified body auditors regarding containment or correction of a nonconformity. There will be a review of the corrective and preventive action requirements. We will cover how corrective actions should be used throughout your Quality Management System. Definitions of Correction and corrective actions, their differences and importance will be covered.

Examples of each will be provided. Information will be provided to make sure your Corrective Action system including your procedures meets current FDA Quality System Regulation and ISO 13485 expectations. This includes how this leads to a robust Corrective Action system for meeting FDA Corrective Actions expectations.

Why should you Attend?: For many year, early in the life of ISO 9001 and ISO 13485, it to a lot of education on the part of ISO auditors to teach companies the difference between Corrections (fixing the problem) and Corrective Actions, fixing the root cause of the problem. And companies learned that well, and generally meeting expectations of their ISO auditors. However, now, although corrections are usually being done, they are usually done under other portions of ISO 13485, such as control of nonconforming product and customer feedback and complaints.

These often have little visibility in the Corrective Action system, and generally do not address at all containing or correcting quality system issues that are often a major part of a Corrective Actions system. So now ISO auditors, or at least ISO 13485 Notified Body auditors, are expecting that companies now document and provide evidence that they are doing containment or correction, and quickly as well.

Areas Covered in the Session:

Overview of CAPA system for Current ISO 13485 compliance
Why Containment and Correction have been overlooked
Why this is a hot item with ISO auditors
What is really the difference between correction and corrective action
What kinds of containment can be done for Quality System nonconformities
Defining and documenting Containment actions - Quickly
Where does Preventive Action fit in
Examples of Containment actions


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