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Medical Device - Engineering Change Control

Instructor: Edwin Waldbusser

Date: Wednesday, 21 June 2017 | Time: 10:00 AM PDT, 1:00 PM EDT | Duration: 60 Minutes

This webinar can help you control your engineering change process, reduce your change order cycle times and eliminate ambiguity when communicating product changes to your extended supply chain.

Companies need to be able to adapt quickly in today's constantly changing environment, and often that means making changes to their products. Engineers make modifications during development and production with the intent of adding functionality, improving manufacturing performance or addressing the availability of a particular part. To make sure proposed changes are appropriately reviewed, a solid process is critical especially if members of your product team are scattered across multiple locations (for instance, design engineers in Boston, the manufacturing team in St. Louis and component manufacturers all over the world). At the heart of a solid change process is the engineering change order.

Objectives of the Presentation

- The stages of the engineering change process
    - Issue identification & scoping
    - Engineering change request creation
    - Engineering change request review
    - Engineering change order Creation
    - Engineering change order review
    - Engineering change notification/notice (ECN)
- Change implementation
- Engineering change order benefits
- Pre release and post release change control
- Change transfer between company and suppliers

Why Should you Attend

FDA and ISO call for change control but do not provide any further guidance as to how to create a compliant system. The situation gets complicated when a company has suppliers or contract manufacturers and changes and approvals must pass from one to the other. This webinar will describe a system, based on the regulations and years of practical experience that will allow for efficient control of the change process. It will be compliant but not cumbersome or overly time consuming.

The difference between pre release and post release change control will be explained. Methods to control the transfer and approval of changes between the company and its suppliers or contract manufacturers will be explained. Change control forms will be provided and described in detail.

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Areas Covered

- What is an engineering change order?
- Where does an ECO fit in the engineering change management process?
- Change control procedure
- Pre release and post release change control
- Change transfer between company and suppliers
- Forms and SOP's

Who will Benefit

- Development Engineers
- Production Management
- Engineering management
- Regulatory personnel
- Quality Control personnel
- Quality assurance personnel
- Research and Development
- Software
- Maintenance
- Process Design and Development

Topic Background

An engineering change order (ECO) is a documentation packet that outlines the proposed change, lists the product or part(s) that would be affected and requests review and approval from the individuals who would be impacted or charged with implementing the change. ECOs are used to make modifications to components, assemblies, associated documentation and other types of product information. The change process starts when someone identifies an issue that may need to be addressed with a change to the product. It ends when the agreed-upon change is implemented. ECOs are used in between to summarize the modifications, finalize the details and obtain all necessary approvals.

Webinar Cost :-

$250.00 Live Session | **$375.00 Recorded Session** | **$500.00 Training CD** | **$1250.00 Corporate Live Session**

$500.00 Live Session + Recorded Session | **$625.00 Live Session + Training CD**

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Instructor Profile:

Ed retired from industry after 30 years in management of development of medical device products and development of company Quality Systems. He was involved in the development of products such as IVD devices, kidney dialysis

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systems and inhalation devices. His QS experience includes, design control, risk analysis, CAPA, software validation, supplier qualification/ control and manufacturing/non-conforming product programs. He now consults in the area of quality systems for medical devices with emphasis on design control, software validation, risk analysis and human factors analysis.

Ed has a B.S. Mechanical Engineering from NYU and a M.B.A from Drexel University. He is certified by Lloyds of London as an ISO 9000 Lead Auditor and is a member of the Thomson Reuters Expert Witness network. He has 5 issued patents. He is also owner of www.meddeviceadvisors. com which offers over 80 easy to customize medical device Quality System SOP's.

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