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Webinar on

Medical Device - Engineering change control

Learning Objectives

- *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:*
- *Manufacturing change order (MCO)*
- *Document change order (DCO)*
- *Engineering change order benefits*
- *Pre-release and post-release change control*
- *Change transfer between company and suppliers*

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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*

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.

PRESENTED BY:

Edwin Waldbusser is a consultant retired from the industry after 20 years in management of the development of medical devices (5 patents). He has been consulting in the US and internationally in the areas of design control, risk analysis and software validation for the past 8 years. Mr. Waldbusser has a BS in Mechanical Engineering and an MBA. He is a Lloyds of London certified ISO 9000 Lead Auditor and a member of the Thomson Reuters Expert Witness network.

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On-Demand Webinar

Duration : 60 Minutes

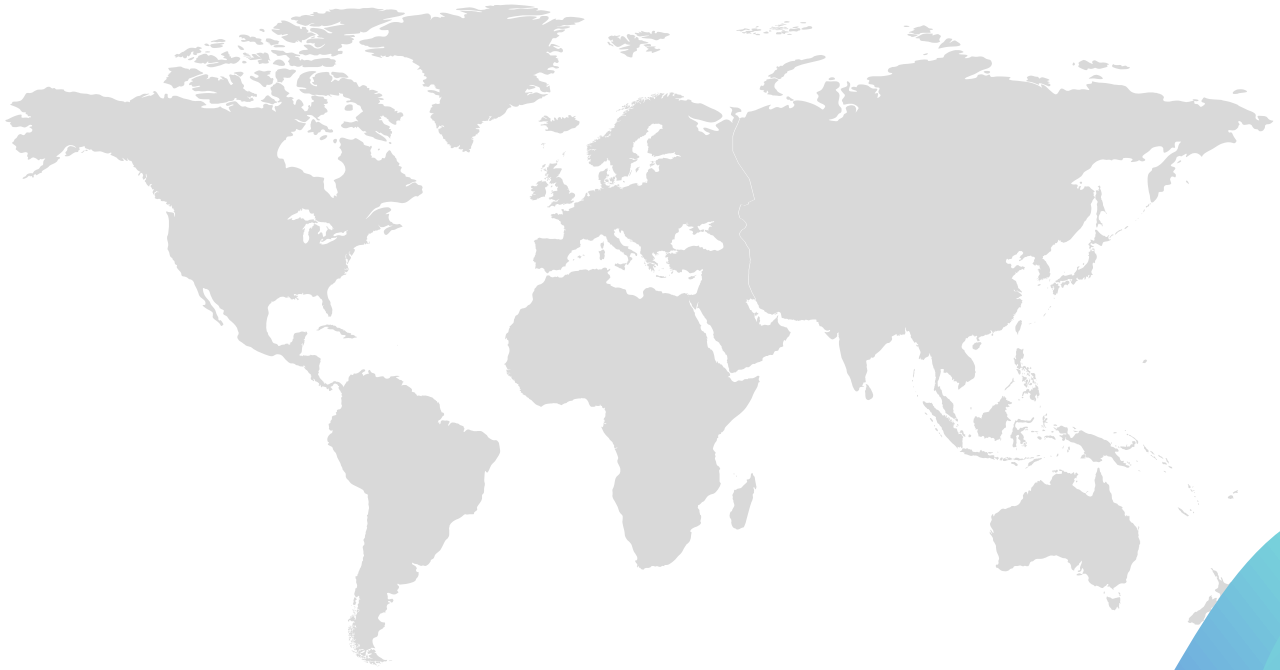
Price: $200

Webinar Description

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, the process is the engineering change order. 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.

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.

Who Should Attend ?



Development Engineers

Production Management

Engineering management

Regulatory personnel

Quality Control personnel

Quality assurance personnel

Research and Development

Software

Maintenance

Process Design and Development

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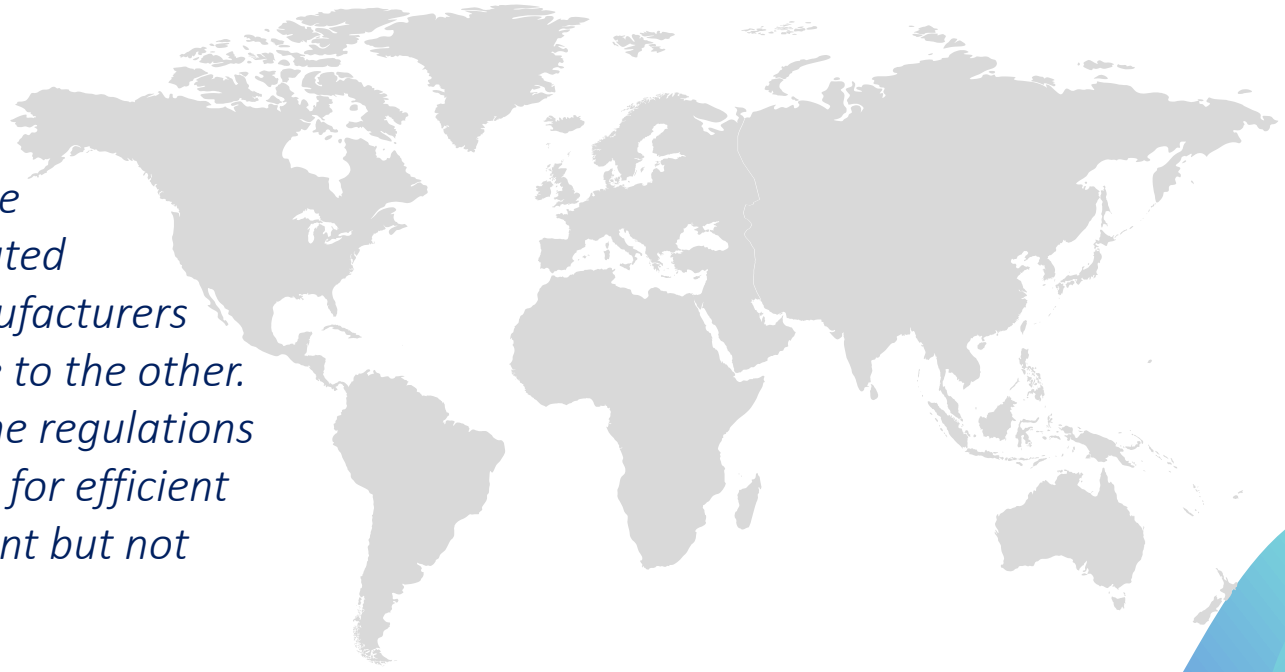
Why Should Attend ?



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 details, and what hospital administration, nurse executives, and nurses themselves should do to prevent the abuse.

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