Introduction to Design Control

This seminar is specially designed to help engineers, scientists, and managers implement Design Control as required by 21 CFR 820.30. FDA expects manufacturers to control each step in any design process that produces regulated medical devices.

This seminar introduces all aspects of design control from Design Inputs through to Design Transfer. Participants will come away with an understanding of the aspects of Design Control that they need in order to perform their job. They may be surprised at the reach of this portion of the CFR. Any change in a production process needs to include a consideration of whether the design of the device has been affected.

Who Should Attend: Engineers, scientists, and managers in product development, production, quality, and support groups; anyone who develops or changes product designs including the design of the manufacturing process

Class Length: Half day

Maximum Class Size: 25

Course Prerequisites: Introduction to QSRs

Course Objectives: At the conclusion of the class, participants will be able to answer these questions:

- Design and development planning. At what point does Design Control start?
- Design input. What are the needs of the user? What are the needs of the patient? How are incomplete, conflicting or ambiguous requirements to be addressed?
- Design output. How are the acceptance criteria that essential for the proper functioning of the device identified? How does one balance the complexity of procedures needed to control large projects with the need to keep the business viable?
- Design review. Who needs to participate in design reviews? When should they be scheduled? What needs to be reviewed?
- Design verification. How does one match up design inputs with design outputs when the design may have changed during the course of the project? What is the Design History File? What training is necessary for Design Verification?
- Design validation. What is the difference between design validation and process validation? What is the difference between design validation and design verification? Where should design validation be documented?
- Design transfer. What procedures are necessary to document proper design transfer to production?
- Design changes. What constitutes a design change? When during a design project must change control be implemented?

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