Managing Risk While Managing Design or Other Changes
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Design Change

• Regulatory Perspective

21 CFR 820.30(i)

• Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation
Design Change

• Regulatory Perspective, continued:

Preamble Comments:

• Documentation of design changes create a history of the evolution of the device’s design
  • Invaluable to failure investigations
  • Invaluable to the design of similar products in the future
  • Prevents repetition of errors during design activities

Preamble Comment #87
Design Change

Preamble Comments:
• Product development is inherently an evolutionary process
  • Change is healthy and necessary
  • Quality is ensured when change is controlled and documented throughout the process
• Ensure change is appropriate for the device’s design
Managing Risk

• There is a need to control changes to a device’s design.
  – Why?
    • Risk:
      – Improper device performance/function
      – Introduction of an unsafe device for use
      – Introduction of an ineffective device for use
Special Challenges

• FDA Perspective:
  – Managing design changes associated with purchased products
  – Managing design changes related to accessories to devices
  – Managing design changes related to how a device is used over time (use evolution)