Method Validation (for Medical Devices) Regulatory Guidance

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This Handbook chapter addressing medical devices specifically relates to the below FDA definitions: “A medical device is an instrument, apparatus, implement, machine, contrivance, implant or other similar or related article, including a component part, or accessory which is Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, Intended for use in the cure, mitigation, treatment of disease, in man or other animals, or Intended to affect the structure or any function of the body of man or other animals, and which...

Tags:
Method Validation, Regulatory & Industry Guidance

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