

# Method Validation (for Medical Devices) Regulatory Guidance



By [Laure Larkin](#) Jan 5, 2013 9:30 pm PST

[Laure Larkin](#)

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...

**This content is only available to IVT members.**

Get help maintaining your knowledge in Method Validation. [Read More!](#)

If you are already a member and you do not have access to this article, [upgrade your membership](#).

Need help? [Read our FAQs](#).

Tags:

[Method Validation](#), [Regulatory & Industry Guidance](#)



[Laure Larkin](#)

Laure Larkin is the Manager of Packaging Qualification Management at DePuy-Synthes USA. Ms. Larkin has acquired over 20 years of experience in FDA regulated industries. She has worked for Fortune 100 Companies...

[View Author Bio](#)

---

**Source URL:** <http://www.ivtnetwork.com/article/method-validation-medical-devices-regulatory-guidance>