



Test Method Validation for Medical Devices (Paperback)

By Emmet Tobin

Createspace Independent Publishing Platform, 2017. Paperback. Condition: New. Language: English . Brand New Book ***** Print on Demand *****.This concise book fits right in the Engineers pocket. It provides a brief introduction to Test method validation and is a useful resource that defines key terms and concepts. The following points are addressed: Examples of Test Method Validations What is test method validation? Why should TMV be performed? When should methods be validated? Regulatory Overview US Food and Drug Administration W.H.O ISO 13485 Definitions and Key Concepts New Test Methods Changes to Existing Methods Accuracy Precision Ruggedness Representative/Continuous Sampling Range Resolution Probability Of False Alarms P (Fa) Probability Of Misses P (M) Validation Protocols What Can Impact the Accuracy of a Test Method? General MSA requirements Variable MSA Studies Attribute MSA Studies Measurement Capability Index.

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