



ISO 13485:2016 Medical Device Management System Implementation Handbook

with sample Policies, Procedures, Forms and Examples



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Usage note

The intent of this document is to help you recognize the activities related to establishing a MDMS. This document should not be considered as professional consulting for establishing or implementing a MDMS.

Use of this handbook does not guarantee a successful implementation nor an implementation that is ready for certification. If you want to implement a MDMS, consider hiring a professional consultant who specializes in implementing ISO 13485 compliant MDMS.

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Introductory Note

We suggest that you study this Guide after you have completed Module 2 of your Course; better still, after you have completed the entire Course. This is because...

1. The detailed content of the Course is not needlessly repeated here.
2. The purpose behind many of the recommendation in this Guide will be clearer to you after you have studied the Standard itself in detail.
3. You will be better able to judge what is required of, and to recommend to, your organization in securing Certification to ISO 13485:2016 with a knowledge of both the Standard and the Guide.