



Quality manual, ISO 13485 and MDR, free template

By Guillaume Promé

Sep. 24, 2021 • ISO 13485, Regulation (EU) 2017/745

The European regulation for medical devices requires manufacturers to **write and maintain a quality manual** that documents the quality management system implemented, as specified in Regulation (EU) 2017/745, Chapter L2.2 and Annex XLA.6.2 :

“ All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records.

In this article, you will find a **quality manual template** conforming to the requirements of **Regulation 2017/745** and **EN ISO 13485:2016 + A11:2021**.

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What is quality manual?

The quality manual is a document that presents the measures taken by an organization to meet the requirements applicable to its quality management system.

What is the purpose of quality manual?

The quality manual allows to understand the functioning of a company and its environment and to communicate its objectives. It is often presented to auditors and



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