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1 Setting up a Quality Management System

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Introduction

Building a quality management system (QMS) from scratch can be challenging, especially when the appropriate regulatory standards or compliance guidelines are not followed. Management system standards make best practices available to organizations of all sizes, in all sectors. Any organization can implement a system to improve efficiency and effectiveness and manage its way of doing things by:

- ensuring nothing important is omitted
- clearly defining who is responsible
- describing what to do, why, when, how and where
- ensuring people are not just "doing their own thing"
- ensuring the organization goes about its business in an orderly way[1]

Quality management is the set of coordinated activities to direct and control an organization with regard to quality.[2] Quality management systems are central to the medical device regulatory process in many countries to ensure safe products entering the market perform as intended. Streamlining and automating design documentation and quality processes to align with major industry regulations and standards are key criteria for setting up a quality management system. In this chapter, the focus is on ISO 9001 and ISO 13485,[3,4] and subsequently, US FDA's *Quality System Regulation (QSR)*[5] contained in 21 CFR 820. ISO 13485:2016 *Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes* is a QMS standard based on ISO 9001 *Quality Management Systems Requirements*. The ISO 9000 series, originally published in 1987, was based on the British Standards Institution's (BSI) BS 5750 series of standards.[6] ISO 9001 covers both product quality assurance (providing confidence that quality requirements will be fulfilled) and enhanced customer satisfaction. Key differences between ISO 9001 and ISO 13485 are shown in **Table 1-1**.[7] Similarities between ISO 9001 and ISO 13485 are shown in **Table 1-2.** The standard can be applied to all products and services. ISO 9001 is based on the eight quality management principles:

1. process approach
2. system approach to management
3. continual improvement
4. factual approach to decision making
5. mutually beneficial supplier relationship
6. customer focus
7. leadership
8. involvement of people[8]

Table 1-1. Key Differences Between ISO 9001 and ISO 13485

ISO 9001	ISO 13485
6 documents	27 documents
Aims for customer satisfaction through continuous improvement	Does not include customer satisfaction and continuous improvement as objectives
Covers all products	Different requirements for different types of products
Basis for voluntary certification	Basis for regulatory certification