

Iso 9001 quality manual example

The ISO 13485 Standard is widely used in the medical device manufacturing industry as a means of establishing compliance with Canadian Medical Device Regulation, European Medical Device Directive and other regulations. Since the majority of medical device manufacturers comply with both 21 CFR 820 QSR and ISO 13485 standards, it is practical to consider establishing an integrated 21 CFR 820 and ISO 13485 Quality Management System (QMS).

Documentation Structure

To establish an integrated QSR and ISO 13485 QMS, an organization may use approaches outlined in the ISO 10013 Standard, Guidelines for Developing Quality Manuals. Among other suggestions, this standard gives an example of a documentation structure that can be used for QSR and ISO 13485 quality management systems. While the standard suggests using a three-level documentation structure, most organizations implement four-level structures to include quality records, as required by both QSR Subpart M - Records and ISO 13485, element 4.2.4. A typical four-level documentation structure includes: Quality Manual, Procedures, Instructions, and Records.

Actually, the documentation structure for an organization should most likely start from the quality policy, as the policy, among other commitments, defines the regulations and standards that a company intends to comply with. If you choose to use this approach, your QMS will have five levels, as shown below:

1. Quality Policy - level 1
2. Quality Manual - level 2
3. Procedures - level 3
4. Instructions - level 4, and
5. Records - level 5

Quality Policy

QSR, section 820.20 (a) and ISO 13485, element 5.3 require the establishment of a quality policy. To satisfy these requirements an organization may develop a quality policy that meets requirements of both QSR and ISO 13485 standards. While QSR requires a quality policy to include a commitment to quality and be "...understood, implemented, and maintained at all levels of the organization", ISO 13485 requirements are somewhat broader. Therefore, an organization can adhere to the requirements of ISO 13485 which requires that a quality policy include:

- A commitment to comply with requirements,

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Tao Wei



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