

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,

Iso 9001 Quality Manual For Manufacturers

Roy M. Chiulli



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International Standards for Design and Manufacturing Nick Rich, F. Tegwen Malik, 2019-11-03 International standards ensure that organisations operate the right processes to support their objectives International Standards for Design and Manufacturing is an accessible guide for manufacturing and production managers and students It guides readers through the standards needed to build operating systems which are robust integrated and used to drive the continuous improvement of business performance International Standards for Design and Manufacturing is based on many years of research collaboration between Swansea University and leading manufacturing and production practitioners from key companies from around the world Each chapter includes an introduction to the standards being discussed definitions examples of using the standards in practice why these standards are important conclusions seminar topics and mock exam questions to allow the reader to test their knowledge and understanding Tool and Manufacturing Engineers Handbook: Continuous

Improvement Charles Wick, Ramon Bakerjian, Society of Manufacturing Engineers, 1983 Part of the renowned TMEH Series the book contains hundreds of practical new ways to make continuous improvement work and keep on working quality management guidelines quality and productivity improvement ideas cost reduction tips continuous process improvement plus how to use world class techniques such as TPM TQM benchmarking JIT activity based costing improving customer supplier relationships and more You ll also learn from best practices examples for quality training teamwork empowerment self assessment using Baldrige Quality Award criteria ISO 9000 audits and certification and more **Business Management**

for Biodiesel Producers Jon Harlan Van Gerpen, 2004 *Parts Selection and Management* Michael G. Pecht, 2005-02-25 Increase profitability and reduce risk through effective parts selection and management Corporations recognize that technology can be the key to fueling product design and development But just as crucial if not more to a company s success are the decisions about when what and how a technology will be used Few companies have failed because the right technology was not available many have failed when a technology was not effectively selected and managed Parts Selection and Management is a guide to increasing company profitability and reducing the time to profit through the efficient management of the process of parts selection and management Taking an eyes on hands off approach to parts selection this guidebook addresses risk assessment decision making steps and subsequent management activities The book covers everything from methodologies for parts selection and management product requirements and specifications and manufacturer assessment procedures to ways to track part changes through the supply chain reliability assessment and environmental legislative and legal issues Written by a seasoned professional teacher and author in the field the book enables companies to Employ effective risk assessment and mitigation techniques Make an informed company wide decision about parts selection and management Choose parts to fit the functionality of the product and other constraints Maximize system supportability by preparing for parts obsolescence Improve supply chain interactions and communications with

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