Insert Your Company Name Here

ISO 13485:2003

U.S. QSR (21 CFR 820)

Quality Systems Manual

Street Address
City, State Zip

This manual can be used as a template in developing your ISO 13485 Quality Manual. Review the text; replace text to match your quality system requirements.

At a minimum, the blue text should be replaced with your information.

This Quality Manual is designed for ISO 13485 and can accommodate the U.S. Quality System Regulation (21 CFR 820). The basic additions for the Quality System Regulation are highlighted in yellow and the applicable part of the regulation is indicated.

For example in section 3.0 of the manual, the QSR 820.3 (t) notation refers to part 820.3 Definitions; and in section 4.2 of the manual, the reference to QSR 820.5 indicates a requirement in part 820.5 Quality System.

Introduction

Your Company developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of *Your Company* meets the requirements of the international standard **ISO 13485:2003 and U.S.QSR (21 CFR 820).** This system addresses the design, development, production, installation, and servicing of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of **ISO 13485:2003 and U.S.QSR (21 CFR 820**). Each section begins with a policy statement expressing *Your Company's* obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

Note: At the time that this Manual template was prepared, ISO 13485 had not been updated to ISO 9001:2008. However, the ISO 9001:2008 revisions did not introduce new requirements and are only intended to provide clarifications. For example, in clause 7.6, measuring devices is revised to measuring equipment.

President: _____

4.1 General requirements

Your company has established, documented, implemented and maintained a Quality Management System (QMS) in accordance with the requirements of ISO 13485:2003 and U.S.QSR (21 CFR 820). The effectiveness of the QMS is maintained and the system continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS *Your Company* has:

- Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, *and documented them in quality plans, work instructions and the Measuring, Monitoring and Analysis Table*
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Established systems to monitor, measure and analyze these processes,
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented Quality Policy
- Quality Objectives
- This Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes,
- Quality Records
- Any other documentation specified by national or regional regulations.
- Each procedure, activity or special arrangement that has been documented is also implemented and maintained.

5.1 Management commitment

Top management has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

The procedure P-500 covering Management Responsibility is established and maintained. (*Have minutes of implementation meetings or implementation plans been maintained to be able to show this involvement? As you implement your quality system, prepare to support this statement.)*

Top management provides evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by:

- Communicating the importance of meeting customer, statutory, and regulatory requirements.
- Establishing quality objectives.
- Establishing the quality policy.
- Conducting *quarterly* management reviews.
- Ensuring the availability of resources.

Note: For ISO 13485, statutory requirements are limited to the safety and performance of the medical devices.

For QSR 820.20, *Management* with executive responsibility is focused on meeting those requirements that have as their objective the design, manufacture, distribution, and support of safe and effective medical devices. During the product realization process, requirements that are focused on ensuring safe and effective medical devices are identified.

5.2 Customer focus

Your company's top management ensures that current and future customer requirements and regulatory requirements are determined and are met.

Top management ensures that customer requirements are understood and met, *by requiring compliance with documented customer communication procedures*. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization (P-720).

5.3 Quality policy

Top management (with executive responsibility) ensures that the quality policy includes a commitment to comply with requirements and to maintain the effectiveness of the Quality Management System. The Quality Policy is communicated to all employees. It is included in new employee training and

- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use.
- Records of design and development outputs are maintained.
- Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.

7.3.4 Design and development review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements
- Identify any problems and propose necessary actions
- Include representatives of functions concerned with the design and development stage being reviewed as well as other specialist personnel.

For QSR 820.30.e, the results of a design review, including the identification of the design, the date, and the individual(s) performing the review is documented in the design history file (the DHF).

For QSR 820.30.h, the results of a design review ensure that the medical device design is correctly translated and transferred into production specifications.

7.3.5 Design and development verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and necessary actions are maintained according to the Design and Development procedure (P-730).

For QSR 820.30.f, the results of design verification, including the identification of the design, method(s), the date, and the individual(s) performing the verification is documented in the design history file (the DHF).

7.3.6 Design and development validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the

Procedure Excerpt

Customize with your information

INSERT YOUR COMPANY LOGO/NAME HERE

Documents are all numbered to comply with document control requirements

1.0 Purpose

1.1 This procedure describes the process used to ensure that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

2.0 Responsibilities

2.1 *Any employee identifying nonconforming material is responsible for labeling the material according to this procedure.*

2.2 *Quality Assurance and Management are responsible for documenting the disposition of nonconforming material.*

2.3 *Area Supervisors are responsible for disposition of the material.*

2.4 *Customer Service is responsible for contacting customers for concession if nonconforming product is to be used.*

Recommendations for customization are included in blue type

3.0 Definitions

3.1 None

4.0 Equipment/Software

4.1 No additional equipment or software required.

5.0 Instructions

5.1 *Your Company* makes use of the following ways to deal with nonconforming product:

Requirements of the standard are all addressed

a) Taking action to eliminate the detected nonconformity,

b) Authorizing its use, release or acceptance under concession,

c) Taking action to preclude its original intended use or application.

5.2 For QSR 820.90, a nonconforming product situation considers the control of nonconforming product, and the review and disposition of nonconforming product as outlined below.

Additional requirements for US FDA QSR (21CFR 820) highlighted in yellow

5.2.1 Control of nonconforming product.

- Product that does not conform to requirements is controlled by addressing the identification, documentation, evaluation, segregation, and disposition of nonconforming product.

- The evaluation of a nonconformance includes a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance.

- The evaluation and any investigation are documented.

5.3 When a material, part or product is identified as nonconforming it is immediately identified.

5.3.1 *Put your method of identifying nonconforming product here.*

5.3.2 *Example: Isolate in a controlled quarantined area.*

5.4 If nonconforming product is detected after delivery or use *customer service or the project manager* will contact the customer and take appropriate remedial action, and initiate a corrective action request form (F-852-001).

6.0 Forms and Records

6.1 *Department Scrap Reports*

6.2 *F-740-002 Supplier Corrective Action Request (SCAR)*

6.3 *F-852-001 Corrective and Preventive Action Requests*

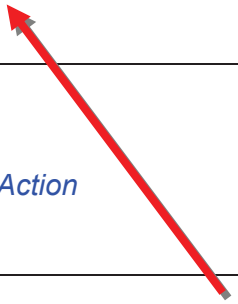
7.0 Related Documents

7.1 *P-740 Purchasing*

7.2 *P-852 Corrective and Preventive Action*

8.0 References

8.1 DHR (device history record)



Related forms, records and documents are referenced to comply with document control requirements.

9.0 Revisions

Revision	Date	Section	Paragraph	Summary of change	Authorized by
A				Initial issue	

INSERT YOUR COMPANY LOGO/NAME HERE

F-752-001-A
Process Validation Worksheet

Supervisor: _____ **Job order #: _____**

Date: _____ **Product / Part #:_____**

The status of inspections and observations are indicated in the sign-off columns by:

[√] - Acceptable / OK conditions
[-] - Not Applicable / Requirements not required
[x] - Not Acceptable / Rejected items

PAINT OPERATION CHARACTERISTICS					INSPECTION		
EMP. #	NAME	*CHARACTERISTIC SAMPLED*	*TIME*	DATE	ACC	REJ	SIGN OFF
		Paint film thick.					
		Color hue					
		Blemishes					
		Orange peel					
		Fish eye					
		Sags					
		--Other--					

ENVIRONMENTAL / HEALTH & SAFETY CONSIDERATIONS					**INSPECTION**		
EMP. #	NAME	*CHARACTERISTIC SAMPLED*	*TIME*	DATE	ACC	REJ	SIGN OFF
		Release to WATER					
		Release to AIR					
		Release to LAND					
		Prevention of injury					
		Prevention of ill health					
		Reduction of hazards					

Comments:

Actions taken for rejects:

Supervisor signature:_____ Date:_____