"This manual is used as a template in developing your Quality Management System covering both the ISO 9001:2015 and ISO 13485:2016 international standards."

ISO 9001:2015

and

ISO 13485:2016

Quality Management Systems Documentation

Quality Manual / Documented Information

Document No. QMD-003

Street Address

City, State, Zip

Tel,

Cell Phone:

Email:

Web Site:

Instructions:

This manual is used as a template in developing your Quality Management System covering both the ISO 9001:2015 and ISO 13485:2016 international standards.

The specific additions for ISO 13485:2016, Medical Devices – QMS for regulatory purposes are highlighted in yellow.
To provide the correlation between the requirements of ISO 13485:2016 and those of ISO 9001:2015, each procedure and instruction contains the paragraph 3.1.2 (also highlighted in yellow) that reflects the corresponding clause numbers.

- Methods and systems used in the development and operation of the QMS vary widely from company to company.
- The blue text and suggestions displayed in the manual are intended to offer some options and to highlight the areas that need attention / update / replacement.
- Review the text and suggestions and at a minimum replace or update them to reflect the unique / customized information of your quality system requirements.
- Delete the blue text after each task is completed.
- Use replace function – enter “Your Company” in find space, enter your company name in replace space – system should make changes throughout the entire document.
- Additional details and instructions in the use of the QM-001 manual template are included in a separate file “QMS-Template-Instructions”.

Additional documentation review.

- Similarly, the blue text and suggestions displayed in the QMS documentation (that will follow) for the procedures, instructions, attachments, forms, and flow diagrams are intended to offer some options and to highlight the areas that require update or replacement.

Blue text offers suggestions and highlight areas that require update or replacement.

1.0 Purpose/Scope

1.1 This procedure describes the process used at Your Company for the handling, packaging, storage, and protection of process outputs in order to preserve the conformity of product through delivery to its intended destination.

1.2 The procedure applies to process outputs where preservation can include identification, handling, packaging, storage, protection, transmission or transportation, and protection.

2.0 Responsibilities and Authorities

2.1 The Operations manager has the prime responsibility and approval authority for this procedure.

2.2 In support of the Operations manager, the Quality team / ISO steering committee is responsible to determine the preservation requirements that apply to the product outputs.

2.3 Additional responsibilities for the Operations manager / Production supervisors / technicians are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 References

3.1.1 This document relates to clause 8.5.4 of the ISO 9001:2015 standard, Preservation.

3.1.2 This document relates to the preservation of product clause 7.5.11 of the ISO 13485:2016 standard.

3.2 No definition

4.0 Resources

4.1 None

5.0 Instructions

5.1 In support of the procedure P-851 for Control of production and service provision, this procedure addresses the preservation of process outputs.

5.1.1 Preservation include protection through the handling, packaging, storage, and delivery of materials, parts, and products where good commercial practices and controls preserve the conformity of product through delivery to its intended destination.

5.1.2 When special or other than commercial handling, storage, preservation, packaging, and delivery practices are required, they are detailed with the procedure P-851 for Control of production and service provision.

5.1.3 Specific to ISO 13485, Preservation:

- Preservation also applies to constituent parts of a product.
- Product is protected from alteration, contamination or damage during processing, storage, and distribution by designing and constructing adequate packaging and shipping containers and documenting requirements for special conditions, such as product with a limited shelf-life or requiring special storage conditions.
- Any special storage conditions are controlled and recorded.

5.2 Handling.

5.2.1 Describe your various methods of handling product, materials, or parts. This may include: Fork lifts, operated by trained employees, ESD protection, Clean rooms or other environments that protect the product from contamination. Handling at each stage of production may be included in work instructions; you can state that in your procedure.

5.2.2 Example:

- Plant equipment used for handling purposes is maintained with the procedure P-710 for Resource management. Equipment such as lift trucks and overhead cranes used to move and lift material in the plant has ratings or lifting capacity clearly shown.

5.3 Packaging.

5.3.1 Describe where you document packaging requirements. This may include product specifications, work instructions, a table of specifications for packaging requirements.

5.3.2 Example:

- Revision date controls packaging. The packaging supervisor maintains a master book of current labels and packaging materials. An example of the current package and the label, such as the traceability label F-852-003 are dated and placed in the master book. As new labels or packaging are put into use, the old are archived and replaced by the new in the master book.
- Before a job order is ready to be delivered or picked up, the inspect / pack / shipper operator prepares and counts the number of shipping packages, ensures that the products are adequately protected to prevent in-transit damage and releases them for delivery.
- All items for a shipment are itemized on the packing slip / invoice form F-851-004.
- When required by customers, additional information such as certificate of compliance or product care instructions is included with the delivery of product.

5.4 Storage.

5.4.1 Describe where storage conditions are identified. Are certain environments required, and if so where are they documented? What kind of tolerance or variance of the conditions is acceptable? This may be

INSERT YOUR COMPANY LOGO/NAME HERE

F-830-002
Design Review Record

Project name:	**Project #:**

Attendees: _____

Meeting Date: _____

Recorded By: _____ **Next meeting:** _____

Agenda items	**Comments** (Record discussion points, decisions and assignments, approvals)
1. Review purpose	
2. Status of Project	
3. Progress since last time	
4. Action items	
5. Current status	
6. Other data	
7. New action items	
Additional remarks:	

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13485:2016 QMS is highlighted in Yellow

INSERT COMPANY NAME/LOGO HERE

ORGANIZATION CHART