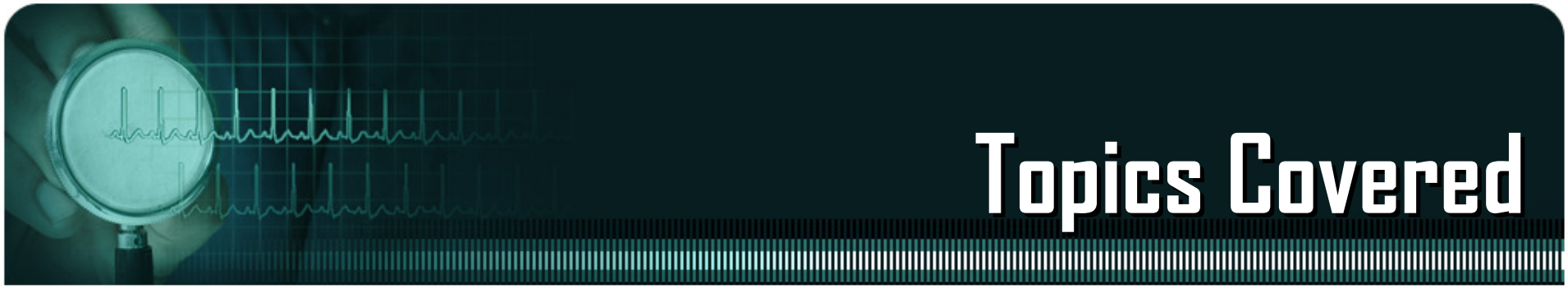
ISO 13485-9001 All In One Documentation and Training Package

Contents

* Sample pages included



Topics Covered

- **Overview**
- **The 13485 Standard**
- **Importance of 13485**
- **Benefits**
- **Requirements**
- **Process Approach**
- **Details of the Standard:** Sections 4 through 8
- **Summary**
- **Tools for Implementation**

The Gap Analysis Checklist

This table outlines the changes to align your organization with the ISO 13485:2003 standard. ISO 13485 items which are in addition to ISO 9001 are highlighted in yellow.

Throughout this document, you will find the following assistance:

- Links to supporting information are underlined blue text
- Links to buy Standards directly from the source (TechStreet) are **Underlined Bold Red text**

Here are some resources you will want to complete your Gap Analysis:

- Comparison between ISO 9001-and-ISO-13485:
- **Buy copies** of the ISO13485 standard to pinpoint the areas that need attention.
- Risk Management is a requirement product realization clause 7.1
    - See guidance standards.
        - **ISO 14971:2007** Medical devices Application of risk management to medical devices
        - **ISO Guide 73 - 2009** - Risk management - Vocabulary.

Here is a list of the standards referenced in ISO 13485 bibliography

- **ISO 9001:2000**, *Quality management systems — Requirements*
- **ISO 10012**, *Measurement management systems — Requirements for measurement processes and measuring equipment*
- **ISO 11134:1994**, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*
- **ISO 11135:1994**, *Medical devices — Validation and routine control of ethylene oxide sterilization* (Corrigendum 1 published 1994)
- **ISO 11137:1995**, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization* (Corrigendum 1 published 1995; Amendment 1 published 2001)
- **ISO 13641:2002 Part 1** – General test & **ISO 13641:2002 Part 2** – Test for low biomass concentrations, *Elimination or reduction of risk of infection related to* in vitro *diagnostic medical devices*
- **ISO 13683:1997**, *Sterilization of health care products — Requirement for validation and routine control of moist heat sterilization in health care facilities*
- **ISO 14155-1:2003**, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*
- **ISO 14155-2:2003**, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*
- **ISO 14160:1998**, *Sterilization of medical devices — Validation and routine control of sterilization of single-use medical devices incorporating materials of animal origin by liquid chemical sterilants*
- **ISO 14937:2000**, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilizing agent*
- **ISO/TR 14969**:—1), *Medical devices — Quality management systems — Guidance on the application of ISO 13485:2003*
- **ISO 19011:2002**, *Guidelines for quality and/or environmental management systems auditing*

	REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	COMPLIANT Y/N? Estimated % Complete	ITEMS NEEDED
Identification is critical to knowing the status of a product, including raw materials, in-process goods, or finished devices. Traceability is important in knowing which lots of material went into the production of a device. Also, it requires a unique label for a device or lot of devices.				
7.5.3.1	**Identification**			
	What suitable means is used .to identify the product throughout product realization? Is there a documented procedure for such product identification?			
	Is there a documented procedure to ensure that medical devices returned to the organization are identified and distinguished from conforming product?			
7.5.3.2	**Traceability**			
7.5.3.2.1	**General**			
	Has the organization established documented procedures for traceability? Do the procedures define the extent of product traceability and the records required? When traceability is a requirement, is the unique identification of the product			

Documents are in Microsoft Word for ease of editing

4.1 General requirements

Your company has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 13485:2003 and ISO 9001:2000. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

You can search and replace "your company" with your own

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

Blue text throughout the manual highlight areas for customization

- 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, and
- 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

Requirements of the standard are all addressed

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes, and
- 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.
- For each type or model of medical device, a file is maintained containing or identifying documents defining product specifications and quality management system requirements.
- These documents define the complete manufacturing process and, if applicable, installation and servicing.

Documents are all numbered to comply with document control requirements

1.0 Purpose

1.1 This procedure describes Management Responsibilities for the Quality Management System (QMS) at *Your Company*.

2.0 Responsibilities

2.1 Top Management is responsible for Establishing the Quality Policy, and reviewing it for continuing suitability.

2.2 Top Management is responsible for Communicating the Quality Policy, the importance of meeting regulatory and statutory and customer requirements.

2.3 Top Management is responsible for identifying the Key Processes to be included in the QMS.

2.4 Top Management is responsible for identifying the data required for effective review of the QMS.

2.5 Top Management is responsible for identifying the management review team.

2.6 It is the responsibility of the management review team to schedule and conduct management review meetings in compliance with this procedure.

2.7 The Management Representative is responsible for collecting summary reports and data from the responsible functions and for ensuring adequate employee awareness of the company's QMS.

2.8 The management review team members are responsible for bringing information and progress reports on action items assigned to them at previous management review meetings, information on planned changes that could affect the QMS, quality planning needs and activities and recommendations for improvements to the QMS.

3.0 Definitions

3.1 Top Management: *put your definition of top management here*

3.2 Management Review Team: *identify who will be on the management review team. By title of function, not individual names.*

3.3 Product realization processes: the processes that contribute or result in the product being produced or the product being provided.

3.4 Key Processes: product realization processes, customer related processes and quality management system processes that are included in the QMS.

4.0 Equipment/Software

4.1 Not Applicable

5.0 Instructions

5.6.1 Management identifies customer feedback projects during management review. Management assigns responsibility for the projects. Projects may include:

a) Focus group meetings
b) Direct client communication
c) Customer satisfaction studies
d) Return customer studies
e) Other methods identified by management.

Requirements of the standard are all addressed

5.7 Management Review

5.7.1 The management review team performs quarterly reviews to evaluate the continuing suitability and effectiveness of the QMS in satisfying the requirements of ISO 13485, the Quality Policy and Quality Objectives.

5.7.2 The Management Representative schedules the meeting and notifies team members.

5.7.3 The Management Representative collects data and summary reports and provides copies to the members of the management review team one week before the scheduled meeting.

5.7.4 The Management Representative prepares an agenda for each meeting that includes:

a) Data from the QMS
    - § Review of QMS Monitoring, Measuring and Analysis Table and related data and summaries
b) Follow-up actions from previous management reviews,
c) Planned changes that could affect the quality management system,
d) An evaluation of the continuing suitability of the Quality Policy and Objectives.

5.7.5 Management analyzes the data, identifies improvement opportunities and assigns action items, preventive actions and corrective actions as appropriate.

5.7.6 Management updates the table with new quality objectives and improvement goals as appropriate to achieve continual improvement.

5.7.7 Minutes are taken at each meeting, recording discussions, decisions and actions and due dates assigned. Data and reports that are reviewed are attached to the minutes of the management review meeting.

5.7.8 The minutes, with attached data and reports, are maintained as a record of management review.

6.0 Forms and Records

6.1 Minutes of management review meetings

6.2 F-500-001 QMS Monitoring, Measuring and Analysis Table

6.3 F-500-002 Key Process Master List

6.4 F-824-001 Product Realization Monitoring, Measuring and Analysis Table

7.0 Attachments

7.1 None

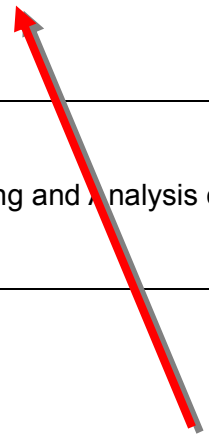
8.0 Related Documents

8.1 Quality Manual

8.2 P-821 Measuring, Monitoring and Analysis of Customer Satisfaction

9.0 References

9.1 None



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

Program Manager:

Program Team:

Roles and responsibilities

Risk management approach:

Include:

- Methods to organize the risks
- Risk and numbering methodology
- Risk identification techniques
- Assessment scales, criteria, equations, prioritization techniques, thresholds for risk levels
- Risk analysis to be performed, cost impact analysis and schedule risk analysis
- Criteria for determining which risks require mitigation plans
- Frequency for updating the date
- Risk data change approval process and the use of a risk review board
- Required vs. optional data to be collected for program use
- Methods for team members to provide data inputs
- Minimum reporting requirements

APPROVALS:

Plan approved by:

Appropriate function: _____ Date:_____

Appropriate function: _____ Date:_____

Auditors must be **careful** and **thoughtful** prior to establishing a **deficiency** against a requirement.

Evidence for visible top management commitment and quality management action must be looked for.

The bold numerical typescripts used in the first two columns of the checklist with titles indicate the **"Requirements"**. The numbers and titles may be referred to on nonconformity reports prepared by the auditor.

During assessment, auditors record the status of the evaluation by marking the right hand column:

Yes - for Acceptable condition or **No - for Deficient condition**

As required during the audit, the assessments do not need to follow the order or sequence shown in the checklist.

Here is a basic summary of the steps:

- Prepare your audit schedule
- Assigned responsibility to your auditors for different areas or processes to audit
- Copy each section of the checklist (and the standard & regulation) for the auditors working with that section.

We offer several other tools to help your organization transition to ISO 13485:2003.

- ISO 13485 Gap-Analysis – Checks that you have all areas of your company ready for 13485.
- Employee-Training – PC based training which can be taken via the web.
  - It can be customized to give you better record keeping and automated deployment.
- PowerPoints - reviewing clause by clause review of ISO 13485
- Step-by-Step-Workbook – to help you complete 28 tasks and steps to a successful ISO 13485 registration.
- Internal-Audit-Checklist - to help you audit to the ISO 13485:2003 Standard
- Internal-Auditor-Training – which includes the materials to train your auditors in the 13485 standard.
- Problem Solving Training – taken online with quizzes, a certificate, and IACET Credits
  - Root Cause Analysis with Corrective Action
  - Etc.

Integrated-standards.com helps you integrate other management system standards:

- ISO 14001 Environmental Management System
- OHSAS 18001 Health & Safety Management System

And **more**!

5 MANAGEMENT RESPONSIBILITY

	REQUIREMENTS	Observations/Comments/Documents Reviewed	Result
5.1	**Management Commitment**		
	Has top management demonstrated commitment to both the development and implementation of the QMS and maintaining its effectiveness by: a) Communicating the importance of meeting customer requirements and statutory/regulatory requirements? Are statutory requirements limited to the safety and performance of the medical device only? b) Establishing a written quality policy? c) Identifying quality objectives d) Conducting management reviews? e) Ensuring resources are available?		
	Additional questions		
5.2	**Customer Focus**		
	Does your organization have a process in place to identify your customer requirements? Are your customer needs and requirements determined and met on a continual basis?		

ISO 13485:2003
Internal Auditor Training

Trainer's Guide

Overview

These course materials are meant to train people to conduct internal quality audits within your organization, which are necessary to meet the internal audit requirements of the ISO 13485:2003 standard.

The course is divided into two sections:

1. The first section will familiarize the students with the requirements ISO 13485 quality management system.
    - Allow 4 hours for this section.
2. The second section is devoted to the auditing process. The students will go through all the steps required for an audit, with hands on involvement in performing each step by conducting a mock audit of a fictitious company.
    - Allow 8 hours for this section.

This guide contains everything the instructor needs to lead the class. **We recommend that you print this guide** as you'll need the PowerPoint speaker notes to lead the class.

Notes:

- It is assumed that the instructor has certified Lead Auditor credentials or equivalent experience. This is not meant as a self study course.
- It is recommended that the first audit the student is involved with be under the leadership of a lead auditor who has audit experience.

Course Materials

The supplies you will need are:

- PowerPoint: **Guide to Internal Audits** (included).
- PowerPoint: **Requirements of ISO 13485** (included).
  - A complete version with Speaker Notes is in this Trainer's Guide
- PowerPoint: **Steps of Internal Audit** (included).
  - A complete version with Speaker Notes is in this Trainer's Guide
- Student Manual (included).
  - Ø Print one copy for **each student**
  - Ø You may wish to have extra copies of the CPAR form
  - Ø It includes reduced versions of all the PowerPoints.
- Sticky Bubble Gum Company Documents and Records (included).
  - Ø Print one copy for **each team** of two or three students.

Qty	Sticky Bubble Gum Documents and Records	# of Pages
1	Quality Manual	10
1	Internal Audit Master Schedule	1
1	P-4.2-009 Control of Documents Procedure	2
1	Master Document List	1
1	P-5.0-002 Management Responsibility Procedure	3
1	SBG Organizational Chart	1
2	Management Review Minutes	2
1	P-7.2-005 Customer Related Processes Procedure	2
4	Quotes with Client PO's	8
1	P-7.4-004 Purchasing Procedure	2
1	F-7.4-005 Approved Vendor List Form	1
7	SBG PO's to SBG Vendors	7
3	F-7.4-003 Subcontractor Problem Log Form	3
1	Product Flow Chart	1
1	750-W-30 Bulk Gum Batching Work Instructions	2
1	750-W-140 Texturizing Work Instructions	2
1	P-8.3-003 Control of Nonconforming Product Procedure	1
1	P-8.5-001 Corrective Action Procedure	2
1	F-8.5-002 Corrective Action Log Form	1
11	F-8.5-001 Corrective Action Request (CAR) Form	11
2	F-852-001-A Corrective/Preventive Action Request (CPAR) Form	4

- The ISO 13485:2003 Standard (**NOT Included***)
  - Ø One copy for every 2-3 students.
  - Ø Standards are available electronically from http://www.13485store.com/BuyStandardsPage.aspx

* The ISO 13485:2003 Standard is a copyrighted document and we are unable to include it.

Agenda

I. The Standard

Introduction to Auditing

0:15 Presentation: Guide to Internal Auditing 13485
0:15 Review Document: ISO 13485:2003
0:30 Exercise: Is it a Requirement?
2:00 Presentation: Requirements of ISO 13485:2003
0:45 Exercise: Find the Requirement
0:15 Questions

II. The Audit

0:30 Scheduling the Audit
0:30 Planning the Audit
0:45 Opening Meeting
0:45 Audit 4.2 Documentation
0:45 Audit 5.0 Management Responsibility
0:45 Audit 7.2 Customer-Related processes
0:45 Audit 7.4 Purchasing
0:45 Audit 8.5 Corrective Action
0:30 Auditors Document Findings
0:30 Final Audit Report
0:30 Closing Meeting
0:30 Creating the Audit File

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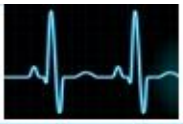
ISO 13485

Employee Training



Questions we will cover today:

- What is ISO 13485?
- Why is it important to our company to get ISO 13485 registration?
- What do we need to do as employees to support this project?
- When will this happen?
- What happens after registration?