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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.



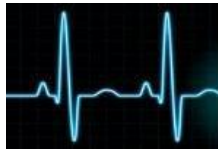
Agenda

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

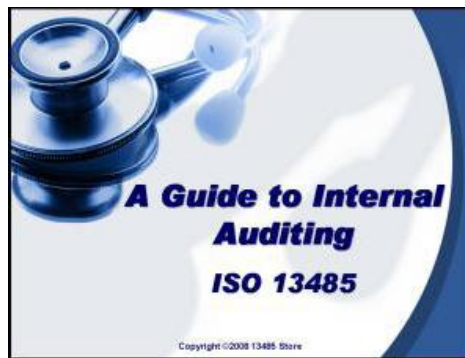


The Standard

Introduction to Auditing

This section will familiarize the students with the requirements ISO 13485:2003 quality management system (QMS).

1. Review the “**Guide to Internal Auditing 13485**” Power Point Presentation with the group.
2. Review and discuss the organization of the ISO 13485:2003 document so the students can familiarize themselves with how the standard is structured.
3. Complete the exercise “Is it a Requirement?” below.



Exercise: Is it a Requirement?

Have the students open to “**Is it a Requirement**” in the student manual. Working in groups of 2 or 3, have them determine whether or not:

- The statement is true or false
- Write down the clause of the standard where they found it.

Notes:

- This is not a test, but an exercise to get them familiar with the standard, so the trainer can go around and help the teams, particularly the slower teams.
- This can be done individually ahead of time to reduce class time

After one or two teams finish, or after a maximum of about 45 minutes, you can go through the statements and discuss the answers.

- An answer key is on the next page.
- Remind the students that there are some things that are mentioned in more than one place in the standard, so there could be more than one correct answer in some cases.

Is it a Requirement? *(answer key)*

The standard requires that: If the requirement is true, circle True and list the clause. If it is false, circle False and list the clause used.	True	False
14. Work instructions may be changed if quality assurance approves the changes.	T <i>Clause:</i>	F <i>Clause:</i> 4.2.3
15. All work instructions must be the current revision.	T <i>Clause:</i> 4.2.3.c	F <i>Clause:</i>
16. Only one copy of each work instruction may exist.	T <i>Clause:</i>	F <i>Clause:</i> 4.2.3.d
17. Purchasing may order from any vendor as long as the President of the company approves the order.	T <i>Clause:</i>	F <i>Clause:</i> 7.4.1
18. For process control and product traceability, it is necessary to maintain records of batches of products	T <i>Clause:</i> 7.5.1.1	
19. Documented procedures are not required for specific requirements relating to cleanliness and contamination control, installation and servicing activities, and sterile process parameters.	T <i>Clause:</i>	F <i>Clause:</i> 7.5.1.2.
20. Documented procedures are required for the validation of computer software	T <i>Clause:</i> 7.5.2.1	F <i>Clause:</i>
21. Documented procedures are required for maintaining the identification and traceability of product.	T <i>Clause:</i> 7.5.3.1& 2	F <i>Clause:</i>
22. Particular traceability requirements apply to implantable medical devices	T <i>Clause:</i> 7.5.3.2.2	F <i>Clause:</i>
23. Release of nonconforming product to customers must only be done when customers provide concessions and regulations are still met.	T <i>Clause:</i> 8.3.b	F <i>Clause:</i>



ISO 13485:2003 Requirements

Now that the students are familiar with the organization of the standard, this section will outline ***the requirements*** of each section – what it is really asking them to do.

Requirements of ISO 13485:2003 Power Point presentation

First, there is a brief 7-page introduction to serve as a review:

- What is ISO 13485?
- Steps to registration
- Benefits of registration
- The Process Model/Process Approach

Second, the rest of this presentation outlines the requirements of ISO 13485.

- If you use the speaker's notes this review could take about 2 hours
- Students can take notes in their manual.
- We've included the presentation in this Trainer's Guide so you can review the notes while presenting.

1. Review **"Requirements of ISO 13485:2003"** Power Point presentation
2. Complete the exercise "Find the Requirement" below.
3. Answer questions about ISO 13485:2003 to ensure they understand the material.



Exercise: Find the Requirement.

1. Introduce the 2nd exercise **"Find the Requirement"** in their student manual.
2. Have them find the clause in the standard that applies.
3. Have them work in groups as in the previous exercise.
4. Discuss the answers together.

To conclude this first section of the course, open it up to questions and answers on the standard.

Benefits of Registration

- Improved operations
- Improved operating margin
- External recognition
- Market expansion

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Improved Operations:

Remember, the requirements of ISO 13485 are good business practice. Experts from around the world got together and identified the basic elements a business should put in place to have a good quality management system. By using the ISO 13485 standard to design your quality management system you are drawing on this expertise. You will be designing an effective quality management system that will lead to improved operations.

Improved Operating Margin:

This improvement in operations also leads to an improvement at the bottom line, an improvement in operating margin. A survey of 700 companies showed an average improvement of 5% that managers attributed to having an ISO 13485 quality system.

External Recognition:

ISO 13485 is recognized worldwide. When you are ISO 13485 registered other companies know that you have a quality management system in place. They know you have a corrective action system, a system to handle client complaints and nonconformances. They know that you are continually addressing problems and improving your operations and performance.

Market Expansion:

Some marketplaces require ISO 13485 registration. You will be able to sell services or products to these markets. Some marketplaces do not openly require registration, but prefer to work with ISO 13485 registered suppliers. An unregistered company faces a definite disadvantage in these markets.

5.6 Management Review

- Review Outputs
 - Improvement of the effectiveness of the QMS and its processes
 - Improvement of product related to customer requirements
 - Resource needs

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Management review needs to watch for opportunities to improve the QMS and processes.

- Can systems be simplified?
- What processes have room for improvement?
- Data is needed to analyze and review the information the QMS is providing. It will show where to find the opportunities for improvement.

Management must watch for opportunities to improve product.

- Product does not need to be improved past client requirements, but can improvements be made to reduce the amount of nonconforming product?
- Is there new information on customer requirements and expectations? Will this require changes to the QMS or processes?

Find the Requirement *(answer key)*

	Clause:
36. Management review take into consideration a set of inputs with resulting outputs.	5.6.2 5.6.3
37. Resources are needed to implement the QMS, to maintain its effectiveness and meet regulatory and customer requirements.	6.1
38. Validate special processes, computer software and sterilization processes.	7.5.2.1
39. Identify and calibrate the monitoring and measurement devices needed to verify product.	7.6
40. Release of product must be approved by the relevant authority.	8.2.4
41. Ensure that purchased product conforms to specified requirements.	7.4.3
42. Before accepting an order from a customer, review the order to ensure that requirements are defined	7.2.2
43. Conformity of product must be maintained during storage.	7.5.5
44. Document the responsibility for dealing with nonconforming product.	8.3
45. Collect and analyze QMS data to identify opportunities for improvement.	8.4
46. Improvements can result from the internal performance results and external inputs from customer complaints, advisory notices, and notifications to regulators.	8.5.1
47. Schedule audits based on how the quality system is performing.	8.2.2
48. Documented procedures are needed for corrective action and preventive action.	8.5.2 8.5.3



The Audit

The second section is devoted to the auditing process. Normally the class size will vary from 4 to 12, and it is recommended that you divide the class into teams of 2-3. It works best to have an even number of teams for holding opening and closing meetings.

>>>Allow 8 hours for this section.

The students will go through all the steps required for an audit, with hands on involvement in performing each step by conducting an audit of a fictitious company (Sticky Bubble Gum Company or SBG) including:

- Scheduling the Audit
- Planning the Audit
- Opening Meeting
- Audit sections of the Sticky Bubble Gum Company's QMS:
 - 4.2 Documentation
 - 5.0 Management Responsibility
 - 7.2 Customer-Related processes
 - 7.4 Purchasing
 - 8.5 Corrective Action
- Auditors Document Findings
- Final Audit Report
- Closing Meeting
- Creating the Audit File

You will lead this section using the **"Steps of ISO 13485 Internal Audit"** Power Point presentation the entire time, using the materials in this package. The Speaker Notes in the PowerPoint will guide you along as an outline.

Note: The trainer plays the part of "Somersby, the SBG Quality Manager and others SBG personnel as required.

Each team should have:

1. A copy of the ISO 13485:2003 Standard.
2. A copy of the Sticky Bubble Gum (SBG) Documents & Records.
3. The Student Manual which allows them to:
 - Follow the presentation and take notes
 - View sample forms (which are presented in the PowerPoint)
 - Use blank forms (CPAR, etc.) to conduct their audit.



*Steps of an
ISO 13485:2003
Internal Audit*
(Audit of Sticky Bubble Gum Company)

Sticky Bubble Gum

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Internal Auditor Training – ISO 13485

Schedule the Audit



Sticky Bubble Gum

Memo

To: Expert Audit Assistance
From: Somersby
Date: 08/20/08
Re: Request for Internal Audit

As we discussed on the phone, our company will be facing a regulator audit late in October. We have implemented an ISO 9001 System, and performed two internal audits. We would like to have your group of expert auditors perform an audit for us before our registration.

During our last two audits, we have audited by procedure and covered all the applicable clauses of the standard. But what we realize that management is a critical success factor in achieving registration we would like your expert auditors to audit the clauses that management is responsible for in our facility.

I would like to have you come in on September 1st and review our audit files and develop your audit plan. We will schedule the audit for the morning of Sept. 1st.

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Internal Auditor Training – ISO 13485

Review the MEMO from Somersby (Sticky Bubble Gum’s Quality Manager) to “Expert Audit Assistance”.

The class is “Expert Audit Assistance”.

It is now September 12th, and the class is going to perform an internal audit of Sticky Bubble Gum’s management’s area.

Nonconformances: 7.2 Customer-related processes



- There is no way to identify what PO matches a particular quote as required by the procedure.
- Procedure required the president to sign quotes.
 - Form states Sales and Marketing Manager.
 - All are signed by production or customer service.
- Procedure does not identify how differences are resolved.
- There is no “Let’s make a change” form as required.
 - Changes are written on the PO.
- Codes are not documented
- No dates to indicate when quote was initiated or to who.
- No record of quote being sent to customer for PO 1517



Conclusion

After the students have completed their presentations, you can:

1. Show them the final slides in the **“Steps of ISO 13485 Internal Audit”** Power Point presentation outlining the nonconformances for each section.
 - Remember, there is often more than one way to look at a situation, especially in a fictitious setting like SBG. Therefore, encourage open discussion on why they consider items a nonconformance.
 - You may want to add their suggestions to the course material for next time.
2. If you feel that the student has satisfactorily understood the material, you may issue them a certificate (this is a separate MS Word file in your package). Use your judgment to issue this based upon:
 - Participation
 - Ideas
 - Leadership
 - Approach
 - Etc.
3. Schedule an audit of your facility to reinforce the material.

