ISO 13485:2003/FDA QSR - INTERNAL AUDIT CHECKLIST

The checklist provides questions that refer to the ISO 13485: 2003 standard.

- ISO 13485 = ISO 9001 + Additional Requirements (and missing a few ISO 9001 requirements.)
- This checklist adds US FDA QSR (21CFR 820) requirements (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 FDA QSR -and-ISO-13485:
- **Buy copies** of the ISO13485 standard & the **FDA QSR (21 CFR 820) regulation** 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*

GUIDELINES FOR USE OF THE CHECKLIST

The checklist provides questions that refer to the ISO 13485: 2003 standard & US FDA requirements.

- ISO 13485 = ISO 9001 + Additional Requirements (and missing a few ISO 9001 requirements.)
- This checklist adds US FDA QSR (21CFR 820) requirements (highlighted in Yellow)

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.

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 of each requirement, auditors record the status in 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.

Auditor attention is drawn to the requirements in clause 1.2 of the standard for "permissible exclusions" Auditors need to ensure that exclusions and appropriate requirements justified.

Highlighted in yellow are the ones that are additions required for FDA compliance of your Quality Management System. Included in the question is the applicable part of the regulation.

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 that 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**

4 QUALITY MANAGEMENT SYSTEM

	REQUIREMENTS	Observations/Comments/Documents Reviewed	Result
4.1	**General Requirements**		
	Is there a Quality Management System in place that has been established and documented to meet the requirements of the ISO 13485:2003 Standard and the US QSR (21 CFR 820) FDA Regulation (per 820.5)?		
	Has your organization established the management system (QMS) giving consideration to: a) Identifying the processes needed and the application of the processes throughout the organization: b) Determining the sequence and interaction of the processes? c) Determining the criteria and methods for operation and control of the processes? d) Ensuring the availability of resources and information to support the processes and readily available? e) Monitoring, measuring and analyzing these processes? f) Implementing actions to achieve planned results and maintain the effectiveness of these processes. If your organization out sources any processes that affects product conformity, are the outsourced process controlled and identified?		
	Additional questions		

	REQUIREMENTS	Observations/Comments/Documents Reviewed	Result
4.2	**Documentation Requirements**		
4.2.1	**General**		
	Does your quality system documentation include the documentation required by ISO 13485? Does it include: a) Documented statements of the Quality Policy and Quality Objectives? b) A Quality Manual? c) Documented procedures required by the standard? d) Documents required to ensure the effective planning, operation and control of your processes? e) Records required by the standard? f) Other documentation required by national or regional regulations? Note that (for 820.5) some documentation may not be needed due to the expertise (either through training, education, or experience) of personnel.		
	When the ISO 13485 standard specifies that a requirement, a procedure, an activity or a special arrangement be “documented”, is it implemented and maintained?		
	When the regulation (per 820.1.3) qualifies a requirement as “where appropriate”, is such a requirement considered to be appropriate unless it can be justified as not appropriate? Is the justification documented? Is the “appropriate requirement” documented, implemented and maintained?		

	REQUIREMENTS	Observations/Comments/Documents Reviewed	Result
7.5	**Production and Service Provision**		
	Production and Process Controls – (for US QSR (21 CFR 820) Regulation.		
	820.70 (a) General		
	Do process controls describe the controls necessary to ensure conformance to specifications? Where process controls are needed, do they include: (1) Documented instructions, standard operating procedures, and methods that define and control the manner of production? (2) Monitoring and control of process parameters and component and device characteristics during production? (3) Compliance with specified reference standards or codes? (4) The approval of processes and process equipment? (5) Criteria for workmanship expressed in documented standards or by means of identified and approved representative samples?		
	Additional questions		
	820.70 (b) Production and process changes		
	Are changes to a specification, method, process, or procedure verified or validated before implementation? Are changes approved? Are these activities documented?		