EVIDENCE PRODUCT CHECKLIST

For Standard ISO 13485:2016

Medical devices - Quality management systems- Requirements for regulatory purposes

A checklist prepared by analyzing each clause of ISO 13485:2016

SEPT Product 89
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Evidence Product Checklist for Standard ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

Overview of the base standard
ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the total product life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product including quality management system-related services to such organizations.

The updates included in the ISO 13485:2016 standard provide for a focus in utilizing risk management processes as not only part of the design and development, but also to be used throughout the quality system implementation as rationale for quality system decisions and in determining level of effort for quality system activities and deliverables.

Introduction to the SEPT checklist for implementing this standard
For 20 years (SEPT) Software Engineering Process Technology has been producing checklists for standards that address software issues. This is another checklist for a software related standard for the Medical devices industry that will aid an organization to comply with regulatory requirements.

The task of getting a new or modified medical device to market in a timely matter is a daunting task. Especially if the organization wants to apply a CE mark to its product. The last thing an organization wants in its product development cycle is to call in a Notified Body for certification and to find out that the organization is lacking the correct records or documents for the auditor to examine. SEPT experts found a 90% increase in artefacts required in the new 2016 standard compared to the previous 2003 version. This SEPT checklist list if used properly will give an organization the confidence that it has all the documentation required by this ISO 13485 standard. The checklist is a tool to ease the pain in becoming certified to ISO 13485 by clearly defining the artefacts required, whether your organization is upgrading to the new version or addressing certification to ISO 13485 for the first time.

The first step that an organization has in meeting the requirements of a quality management process standard such as Standard ISO 13485:2016is to determine what is required. Often these quality systems and technical standards are confusing and laborious because the directions contained in the standards are unclear to a lay person. In order to reduce this fog surrounding these types of standards SEPT has been producing checklists for standards since 1994. The checklists lift this fog around a standard and state what is required and suggested by the standard in a clear and concise manner. To aid in determining what is actually “required” by the document in the way of physical evidence of compliance, the experts at SEPT have produced this checklist. The SEPT checklists are constructed around a classification scheme of physical evidence comprised of policies, procedures, plans, records, documents, audits, and reviews. There must be an accompanying record of some type when an audit or review has been accomplished. This

record would define the findings of the review or audit and any corrective action to be taken. For the sake of brevity this checklist does not call out a separate record for each review or audit. All procedures should be reviewed but the checklist does not call out a review for each procedure, unless the standard calls out the procedure review. In this checklist, “manuals, reports, scripts and specifications” are included in the document category. When the subject standard references another standard for physical evidence, the checklist does not call out the requirements of the referenced standard.

The author has carefully reviewed the Standard “ISO 13485:2016 Medical devices - Quality management systems- Requirements for regulatory purposes" and defined the physical evidence required based upon this classification scheme. SEPT engineering department has conducted a second review of the complete list to ensure that the documents’ producers did not leave out a physical piece of evidence that a “reasonable person” would expect to find. It could certainly be argued that if the document did not call it out then it is not required; however, if the standard was used by an organization to improve its process, then it would make sense to recognize missing documents. Therefore, there are documents specified in this checklist that are implied by the standard, though not specifically called out in the document, and they are designated by an asterisk (*) throughout this checklist. If a document is called out more than one time, only the first reference is stipulated.

There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another document. For example, the "Design and Development Verification Plan" could be a part of the "Design and Development Plan". The Author has called out these individual items separately to ensure that the organization does not overlook any facet of physical evidence. If the organization does not require a separate document, and an item can be a subset of another document or record, then this fact should be denoted in the detail section of the checklist for that item. This should be done in the form of a statement reflecting that the information for this document may be found in section XX of Document XYZ. If the organizational requirements do not call for this physical evidence for a particular project, this should also be denoted with a statement reflecting that this physical evidence is not required and why. The reasons for the evidence not being required should be clearly presented in this statement. Further details on this step are provided in the Detail Steps section of the introduction. The size of these documents could vary from paragraphs to volumes depending upon the size and complexity of the project or business requirements.

General Principles of the Checklist for ISO Standard 13485:2016

This checklist was prepared by analyzing each clause of this document for the key words that signify a:

- Policy
- Procedure
- Plan
- Records
- Document (Including Manuals, Reports, Scripts and Specifications)
- Audit
- Review

This checklist specifies evidence that is unique. After reviewing the completed document, the second review was conducted from a common sense “reasonable man”

approach. If a document or other piece of evidence appeared to be required, but was not called out in the document, then it is added with an asterisk (*) after its notation in the checklist. The information was transferred into checklist tables based on the type of product or evidence.
In total there are 271 required artefacts and 240 suggested artefacts included in the SEPT checklist. SEPT experts found a 92% increase in required artefacts within the new 2016 standard compared to the previous 2003 version.

Using the Checklist
When a company is planning to use ISO 13485:2016 standard, the company should review the evidence checklist. If the company's present process does not address an ISO 13485:2016 standard product, then this question should be asked: Is the evidence product required for the type of business of the organization? If in the view of the organization the evidence is not required, the rationale should be documented and inserted in the checklist and quality manual. This rationale should pass "*the reasonable person rule*." If the evidence is required, plans should be prepared to address the missing item(s).

Detail Steps
An organization should compare the proposed output of their organization against the checklist. In doing this, they will find one of five conditions that exist for each item listed in the checklist. The following five conditions and the actions required by these conditions are listed in the table below.

Condition	Action Required
1. The title of the documented evidence specified by the checklist (document, plan, etc.) *agrees* with the title of the evidence being planned by the organization.	Record in checklist that the organization is compliant.
2. The title of the documented evidence specified by the checklist (document, etc.) *disagrees* with the title of the evidence planned by the organization but the content is the same.	Record in the checklist the evidence title the organization uses and record that the organization is compliant, and the evidence is the same although the title is different.
3. The title of the documented evidence specified by the checklist (document, etc.) is *combined* with another piece of evidence.	Record in the checklist the title of the evidence (document, etc.) in which this information is contained.
4. The title of the documented evidence specified by the checklist (document, etc.) *is not planned* by the organization because it is not required.	Record in the checklist that the evidence is not required and the rationale for this decision.
5. The title of the documented evidence called out by the checklis*t* (document, etc.*) is not planned* by the organization and *should be* planned by it.	Record in the checklist when this evidence will be planned and reference a plan for accomplishing the task.

Components of the Checklist
This checklist is composed of 9 sections:

- Section 1. Introduction
- Section 2. Composites of all required and suggested "ISO 13485:2016 artifacts.
- Sections 3-8. Individual checklists for each evidence type.
- Section 9. "About the Author"

Product Support
All reasonable questions concerning this checklist or its use will be addressed free of charge for 60 days from time of purchase, up to a maximum of 4 hours' consultation time.

Warranties and Liability
Software Engineering Process Technology (SEPT) makes no warranties implied or stated with respect to this checklist, and it is provided on an "*as is"* basis. SEPT will have no liability for any indirect, incidental, special or consequential damages or any loss of revenue or profits arising under, or with respect to the use of this document.

Section 2
ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	**Audits** and Reviews
4	**Quality management system**					
4.1	**General requirements**					
4.1.1	General requirements (a)	• Organizational Roles Document Procedure* • QMS Document Procedure*			• Organizational Roles Document • QMS Document	• Organizational Roles Document Review* • QMS Document Review*
4.1.2	General requirements (b)	• QMS Processes Used Document Procedure* • QMS Risk Based Approach Procedure*			• QMS Processes Used Document*	• QMS Processes Used Document Review*
4.1.3	General requirements (c)	• QMS Implementation Action Plan Procedure* • QMS Process Monitoring, Measurement and Analysis Plan Procedure*	• QMS Implementation Action Plan* • QMS Process Monitoring, Measurement and Analysis Plan*	• Applicable Regulatory Requirements Records • ISO 13485 Conformance Records		• QMS Effectiveness Review • QMS Implementation Action Plan Review* • QMS Process Monitoring, Measurement and Analysis Plan Review* • QMS Resource and Information Availability Review

* Suggested item QMS = Quality Management System

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	**Audits** and Reviews
4.1.4	General requirements (d)	• QMS Change Procedure*				

* Suggested item QMS = Quality Management System

Section 2
ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	**Audits** and Reviews
4.1.5	General requirements (e)	• Outsourcing of Processes Affecting Product Conformity Control Plan Procedure* • Outsourcing of Processes Affecting Product Conformity Quality Agreement Document Procedure*	• Outsourcing of Processes Affecting Product Conformity Control Plan*		• Outsourcing of Processes Affecting Product Conformity Quality Agreement Document	• Outsourcing of Processes Affecting Product Conformity Control Plan Review* • Outsourcing of Processes Affecting Product Conformity Quality Agreement Document Review*

* Suggested item QMS = Quality Management System

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		**Policies** and Procedures	Plans	Records	Documents	**Audits** and Reviews
4.1.6	General requirements (f)	• QMS Computer Software Validation Procedure		• QMS Computer Software Validation Records		

* Suggested item QMS = Quality Management System