The Gap Analysis Checklist

This table outlines the changes to align your organization with the 21CFR820 requirements. The applicable parts of the regulation that result in additions for the QSR 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 FDA-and-ISO-13485:
- Buy copies of the ISO13485 standard & the (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

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 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 19011:2002, Guidelines for quality and/or environmental management systems auditing
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.

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.

As you work through the checklist:

- Take notes on what is in place, and what needs to be developed.
- Reference procedures or other documents that you have reviewed and that will provide information for the new QMS.
- Take notes on the status of the documents, will they need to be revised for the new system or can they be used as is.
- Also note where processes are in place, but documentation is needed.

Focus on what is in place, and what needs to be developed. *While you do want to know if procedures and processes are being complied with, compliance is not your main focus for this audit.* Remember that the final outcome of this audit should be a list of things that your organization needs to do to have an ISO 13485:2003 QMS that is FDA compliant.

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!
## 4 QUALITY MANAGEMENT SYSTEM

<table>
<thead>
<tr>
<th>REQUIREMENTS</th>
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<th>COMPLIANT Y/N? Estimated % Complete</th>
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### 4.1 General Requirements

This clause asks you to identify how management applies the process approach to achieve the effective and efficient control of processes, resulting in maintaining the effectiveness of the quality processes. Specifically this section is looking for an overall process evaluation of all quality related processes and their interrelationships. Look to see that your organizational processes are defined and documented, and that consideration is given to those items described in a) through f).

- 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)?
  - Is the system maintained and is there evidence that its effectiveness is maintained?
  - a) Look for documentation of the processes included in the QMS.
  - b) Look for documented procedures on the relationship and sequence of the QMS processes.
  - c) Ask Management if operation and control of processes is effective.
  - How do they know if it is effective?
  - d) Ask how they are able to know if resources and information needed to support processes have been provided.
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<tbody>
<tr>
<td>Does the Quality Manual outline the structure for the documentation used in the QMS?</td>
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**4.2.3 Control of Documents**

A documented procedure is required for the control of documents. Documents such as, work instructions, procedures, specifications, forms and records, must be controlled.

- Do you have a formal procedure regarding the control of documents for your organization?
- a) Are documents reviewed and approved for adequacy prior to issue?
- b) Are documents updated and re-approved?
- c) How are changes identified?

How does the organization ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions?

How does the organization ensure that approved changes to documents are communicated to the affected personnel in a timely manner (820.40)?

Do the records of changes include a description of the change, identification of the affected documents, the signature of the approving person(s), the approval date, and when the changes become effective (820.40).
## 7 PRODUCT REALIZATION

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<td><strong>7.1 Planning of Product Realization</strong></td>
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This section may be addressed in a documented procedure. Does your organization understand the processes needed to meet product requirements? The planning activity for the processes related to product realization must address the requirements in section 4.1.

For the realization of products, has the organization planned and established quality system processes that are appropriate for the specific medical device(s) designed or manufactured (820.5)?

How is planning initiated?

a) Where are quality objectives and requirements of the product documented?

b) How does planning determine documentation needs and resources for the process?

c) Does planning address verification and validation requirements?

Where are the monitoring, inspection and test and criteria for the product documented?

d) Does planning identify what records are required for the process?

What is the output of your planning process?

Does the organization have documented requirements for risk management throughout product realization?