

ISO 13485:2016 Gap Analysis Checklist

4 QUALITY MANAGEMENT SYSTEM

| ISO 13485:2016 Gap Analysis Checklist New 2016 Requirements are Shaded in Yellow | | |
|---|--|--------------|
| REQUIREMENTS | | OBSERVATIONS |
| 4.1 | General Requirements | |
| 4.1.1 | Is there a Quality Management System in place that has been established and documented to meet the requirements of the ISO 13485:2016 Standard and the applicable regulatory requirements? | |
| | When the standard specifies that a requirement, a procedure, an activity or arrangement be "documented", is it implemented and maintained? | |
| | Are the role(s) undertaken by your company under the regulatory requirements (as a manufacturer, a distributor, an authorized representative, or an importer) documented? | |
| 4.1.2 | Determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization | |
| | Is a risk-based approach to the control of processes applied? | |
| | Are the sequence and interaction of the processes determined? | |
| 4.1.3 | Determine criteria and methods needed to ensure that both the operation and control of these processes are effective | |
| | ensure the availability of resources and information necessary to support the operation and monitoring of these processes | |

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