

Internal Quality Management System Audit Checklist (ISO 13485:2003/ISO 9001:2000)

| Q# | ISO 9001:2000 and/or ISO 13485:2003 Clause Text | Sample Audit Question | Evidence |
|---|--|---|----------|
| 4 Quality management system | | | |
| 4.1 General requirements | | | |
| 4.1a | The organization shall establish, document, implement and maintain a quality management system and maintain (continually improve) its effectiveness in accordance with the requirements of this International Standard. | Has Organization established, documented, implemented and maintained a QMS and maintained (continually improved) its effectiveness in accordance with ISO 9001/13485? (Questions in section 4.1 are verified throughout the audit) | |
| 4.1a1 | The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2). | Where has Organization identified the processes needed for the QMS and their application throughout the organization? (See 4.2.2) | |
| 4.1a2 | The organization shall b) determine the sequence and interaction of these processes. | Where has Organization determined the sequence and interaction of QMS processes? (See 4.2.2) | |
| 4.1a3 | The organization shall c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective. | What are the criteria and methods Organization uses to ensure that the operation and control of QMS processes are effective? | |
| 4.1a4 | The organization shall d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes. | Has Organization provided resources and information needed to support the operation and monitoring of QMS processes? (See section 6) | |
| 4.1a5 | The organization shall e) monitor, measure and analyze these processes, and | How does Organization monitor, measure and analyze QMS processes? (See section 8) | |
| 4.1a6 | The organization shall f) implement actions necessary to achieve planned results and maintain the effectiveness (continual improvement) of these processes. | How has Organization implemented actions necessary to achieve planned results and maintain the effectiveness (continual improvement) of processes needed for the QMS? | |
| 4.1a7 | These processes shall be managed by the organization in accordance with the requirements of this International Standard. | Are processes needed for the QMS managed by the organization in accordance with the requirements of ISO 9001:2000? | |
| 4.1a8 | Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. | When Organization outsources any process that affects product conformity with requirements, how is control ensured over such processes? (See 7.4) | |
| 4.1a9 | Control of such outsourced processes shall be identified within the quality management system (see 8.5.1). | Where is the control of outsourced processes that affect product conformity with requirements identified within the QMS? (See 7.4) | |
| NOTE: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement. | | | |

Internal Quality Management System Audit Checklist

JG Myers



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