



Audit Management Highlights

- Define audits by assigning the lead auditor, and by describing the audit type, scope and timeframe
- Define and manage the requirements for each audit.
- Leverage pre-defined requirement checklists for ISO 13485-2003 and the Medical Device Directive
- Manage internal, external and supplier audits
- Record audit results marking each requirement as conforming, non conforming, or not applicable
- Record observations, major non conformances, and minor non conformances
- Document findings with appropriate completed actions and/or Corrective And Preventive Actions (CAPAs)
- View the audit summary report including all findings, actions, and CAPAs

5.1 - Management Commitment

ID	Description	Requirements Addressed	Result	Items / Resources Reviewed	Audit Findings		
					Type	Description	CAPA Request / Audit Actions
Edit 13485-15	Is the top management - communicating to the organization the importance of meeting customer and other applicable requirements, - establishing the quality policy, - establishing quality objectives,... (see Info)	5.1	Nonconforming	Company schedule for quality activities.	Major Nonconformance	No management reviews have been held in the last 12 months.	CAPA Request <ul style="list-style-type: none">• New Request Audit Actions <ul style="list-style-type: none">• Have scheduled a management review meeting.

5.2 - Customer Focus

ID	Description	Requirements Addressed	Result	Items / Resources Reviewed	Audit Findings		
					Type	Description	CAPA Request / Audit Actions
Edit 13485-16	Is the top management ensuring that customer requirements are determined and are met?	5.2	Nonconforming	Customer requirements tracking.	Minor Nonconformance	No evidence that they link their customer requirements to the product they design and build.	CAPA Request <ul style="list-style-type: none">• CAPA-00083