

ISO 13485 Implementation and Maintenance Time Requirements

3 QRC Visits	Purpose	Who Involved	What done	Time
QRC - Visit 1 3 days Definition: ISO Coordinator – your project manager who works with QRC staff person	Introduction to Top Management	Top Management – top several decision makers in the company	Project overview & responsibilities of Top Mgt.	60 to 90 minutes
	Obtain information for documentation	QRC Staff person and your ISO Coordinator Dept. Managers Interview with people who do each process	Joint planning for interviews 30 minute interview with each Dept./Group Manager Determine department processes and what is missing that is required by ISO standard. Determine how what is missing will be done. Flowchart all department processes/ approximately 20 - 30 minutes for each process/activity	Balance of 3 days
Interim time	QRC writes Quality Manual, Operating Procedures and prepares process Flowcharts. QRC sends documentation for review & correction	ISO Coordinator – routes documents to Dept./ Group Managers Assignments may be given when work is more effectively done by your staff. Ex. Job descriptions	Managers review documentation; make corrections and changes. Return documents to QRC Example: define job descriptions, qualifications and required training (if these do not exist)	Time to read and edit documents. This is a standard HR function and likely exists.
QRC - Visit 2 Total days: 5 Install – to present documents to users Scope Sheets – Identify dept./group processes and who is responsible for ISO requirements Primary Responsibility – Dept Manager, person/ or group responsible for an ISO requirement 2ndary Responsibility – dept or group that must follow ISO requirements	Install new documents by group. Number of groups determined on 1 st visit.	Ranges from 9-13 employee groups depending on company. All Dept. employees involved.	Review new documents with each group so they are aware of changes. Review requirements of the standard that apply to the group.	3 days 45 minutes to 1 hour per group
	Train company Internal Auditors	Suggest 4 auditors be trained for company of 100 people	Review of ISO 13485 standard. Learn steps to conducting an audit and reporting audit results.	2 days classroom time Optional 1 day of supervised audits.
	QRC writes Scope Sheets for Dept./groups. Scope Sheets tell what is included in Install Training for a Group. Scope Sheets also identify the processes and ISO requirements that will be included in a dept./group audit.	QRC	A Scope Sheet identifies the processes performed by a dept. and the ISO requirements that the department is responsible for. ISO Responsibilities Primary Responsibility: 1 person or group is responsible for Control of Documents. 2ndary Responsibility: All departments/groups must follow ISO requirements for documents.	QRC writes Scope Sheets off-site before document Install Training by Dept./group
Interim Time Implement System Implement – to ensure that ISO requirements and new documents are being followed Conduct internal audits Hold Mgt. Review Meeting	Implement System	Top Management, Dept Managers, Personnel	Ensure ISO requirements and new documents are being followed	On-going event
	Internal audit of company	Audit Program Mgr. Internal Auditors	Plans, assigns and manages audits Desk audit/audit & Audit Report; usually are 8 or 9 audit groups	1 hour 4-5 hours per audit group
	Correct nonconformances	Responsible Manager	Plans and carries out Corrective action related to nonconformances	Depends on nonconformance
	Management Review is a review of audits and complete performance review of the organization.	Management Rep. (a member of mgt.) Dept./Group Managers Top Management conducts review	Collects department reporting Prepares Agenda, leads meeting and writes Mgt. Review Report Submit reports to Mgt. Rep / may be asked to deliver report at Mgt. Review meeting. Top Mgt. decides what actions are needed to maintain system effectiveness and objectives for the company.	4 hours or longer Report on status of Department/ Group & objectives set for dept. (if any) 4 hours or longer

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Visit 3 Pre assessment audit 3 days	Complete audit of organization to determine readiness for certification audit. Audit conducted by 2 nd QRC staff person.	ISO Coordinator overseas audit (3 days) Employees Department Managers Mgt. Representative	May observe all audits or selected audits. 5-10 minute interviews with those who do process work QRC auditor reviews audit results With Dept./Group Manager upon completion of audit QRC auditor reviews Audit Report with Mgt. Rep.	1 hour per group or less/ 3 day audit 5 minutes or less 30-45 minutes
Correct audit nonconformances	Correct nonconformances	Manager responsible for process/activity	Plans and carries out corrective action on audit nonconformances	Time depends on what required

Audits by Registrar

Activity	Purpose	Who Involved	What done	Time
Submit documents to registrar that indicate system is fully implemented	Ensures company is ready for the certification Audit.	Management Rep.	Responsible for liaison with registrar auditor and arrangements for audits. You sign a 3 year contract with a Registrar auditing Firm.	4 hours
Certification audit by registrar	Certification of ISO 13485 system	Registrar usually sends 2 people for 3 days for Certification audit.	Conduct audits. Audit results are reviewed with Mgt. Rep. upon completion of audit. Time agreed for completion of corrective actions. Organization awarded certificate when registrar auditor confirms that corrective actions are completed.	Usually 3 days
Surveillance audits by Registrar	Surveillance of system to ensure on-going compliance to ISO 13485 standard	Registrar auditor Employees who responsible for processes Management Rep.	Schedule of what will be audited in years 2 and 3 is defined when the Certification audit takes place	1 or 2 day audits - depends on size of company and number of processes
Renew 3 year contract with Registrar	On-going validation of compliance to Standard			

Fixed Price Quotes

- Quality Resource Center, Inc. (QRC) provides a fixed-price quote for Implementation Assistance.
- Quotes identify the number of hours for an activity. If we exceed the hours quoted, you are billed for the original time quoted.
- If QRC takes fewer hours than quoted to complete an activity, you are billed for the actual time taken to complete the activity.
- QRC invoices after the completion of a visit.

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