



ISO 13485 All in One Certification Package

Included Contents ([Link to website for more details](#))

Planning

[Gap Analysis Checklist](#)

A detailed, 60 page checklist (MS Word) with guidance on what to look for to evaluate your current processes and their compliance to the ISO 13485 Requirements.

[Risk Management Exercise](#)

Risk Management and risk analysis are required in ISO 13485. Our exercise will take you through the analysis of risks for the product realization steps required for your products.

Training

[Requirements of ISO 13485 PowerPoint Presentation Materials](#)

Use these presentation materials to educate management, employees, customer or other groups on ISO 13485. This package includes 96 PowerPoint slides with speaker notes, quizzes and a Trainer's Guide

[Computer Based Employee Training](#)

Use this training to educate employees on ISO 13485. This online computer training runs approximately 1/2 hour. The training includes slides, audio, quizzes, and a certificate.

[Set of 12 Employee Newsletters](#)

Employee awareness is a critical aspect of a successful project. Keep your employees informed and involved in the ISO 13485 project. These Flyers improve awareness and knowledge of ISO 13485 in your organization. Send them out on a regular basis during the implementation.

Internal Audit Program

[Internal Audit Checklist, Procedure, Audit Plan and Forms](#)

This complete Internal Audit Checklist & Tools Package provides everything you need to establish your Internal Audit Process. Includes Checklist, planning & reporting forms, and a PowerPoint on the basics of Auditing.

[Internal Auditor Training Materials](#)

Conduct thorough training for your internal auditors. This package includes PowerPoint presentations, Student Manual, Trainers Guide, Exercises and a set of documentation for trainees to audit.

ISO 13485 Documentation (Quality Manual, Procedures, Forms)

[Required Documentation Templates](#)

A full documented ISO 13485 Manual for organizations to use as an example and template for their own Quality Manual. Written in MS Word for easy customization.

[Procedures, Forms & Flowcharts](#)

Ready to customize, fully written procedures to be used as a foundation and a template for your quality system.

Procedures

1. Document Control
2. Control of Quality Records
3. Management Responsibility
4. Competence, Awareness and Training
5. Infrastructure
6. Work Environment
7. Planning of Product Realization Processes
8. Customer Related Processes
9. Risk Management
10. Design and Development
11. Purchasing
12. Control of Production and service Provision
13. Customer Property
14. Preservation of Property
15. Validation of Processes for Product Realization
16. Identification and Traceability
17. Control Of Monitoring and Measuring Equipment
18. Post Production Feedback
19. Internal Audits
20. Monitoring, Measuring, and Analysis of Products and Processes
21. Control of Non-Conforming Product
22. Advisory Notices and Product Recall
23. Statistical Techniques
24. Root Cause Analysis
25. Corrective Action
26. Preventive Action

Forms & Attachments

1. Master Document List
2. Software Inventory Spreadsheet
3. Document Change Request Form
4. Document Revision Checklist
5. Quality Records Table
6. QMS Measuring, Monitoring and Analysis Table
7. Key Process Master List
8. QMS Planning Worksheet
9. Management Review Agenda
10. Management Review Checklist
11. Action Plan For Training Form
12. Group Training Sign In
13. Job Description Form
14. Equipment Problem Report
15. Equipment Maintenance Record
16. Clause Inclusion, Exclusion Worksheet
17. Quality Planning Table Form
18. Client Assessment Memo
19. Risk Management Plan
20. Risk List
21. Design Plan
22. Design Review
23. Design Change Form
24. Supplier Quality Report
25. Supplier Corrective Action Request
26. Approved Subcontractor List
27. Process routing summary sheet
28. Process routing detail sheet
29. Process Validation Worksheet
30. Traceability Serial Number Log
31. Equipment List
32. Customer Satisfaction Survey and Analysis
33. Internal Audit Plan
34. Internal Audit Report
35. Procedures by Work Area
36. Audit Checklist
37. Product Realization Monitor, Measure, and Analysis Table
38. Rejected Material / Disposition Report - NCR
39. Root Cause Analysis Action Plan
40. Corrective/Preventive Action Request
41. Customer Property Control Log
42. Storage Inspection Report
43. Quality Policy Attachment
44. Organization Chart Attachment
45. Flow Chart for ISO QMS Attachment

Flowcharts

1. Clause 4 QMS
2. Documentation Requirements
3. Clause 5 Management Responsibility
4. Business Process Map
5. Management Customer Focus
6. Operating Principles
7. PDCA Objectives Planning
8. Organization Chart
9. Clause 6 Resource Management
10. Contributors 5Ms
11. Clause 7 Product Realization
12. Process Flow Chart
13. Product Realization Quality Plan
14. Customer Processes
15. Design Development
16. Stage Gate Idea to Launch
17. Purchasing
18. Process Control
19. Process Steps - Control Points
20. Identification Traceability
21. Clause 8 Measure Improve
22. Continual Improvement
23. Corrective Action