



ISO 13485 Small Business Package

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

Planning

Gap Analysis Checklist

A detailed, 40 page checklist (MS Word) with guidance on what to look for to evaluate your current processes and their compliance to the ISO 13485 Requirements.

Project Manager's Guide

This walks you through the process of planning and executing your project.

Training

Introduction to ISO 13485 PowerPoint Presentation Materials

Use these presentation materials to educate management, employees, customer or other groups on ISO 13485. This package includes 61 PowerPoint slides with speaker notes, quizzes and a Trainer's Guide

Introduction to ISO 13485 Computer-based training

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

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.

ISO 13485 Documentation (Quality Manual, Procedures, Forms)

Quality Manual

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

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

See detailed list of contents on next page

ISO 13485 Documentation Contents

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. Validation of Processes for Product Realization
14. Identification and Traceability
15. Customer Property
16. Preservation of Property
17. Control Of Monitoring and Measuring Devices
18. Post Production Feedback
19. Internal Audits
20. Monitoring and Measuring of Product Realization Processes
21. Control of Non-Conforming Product
22. Statistical Techniques
23. Root Cause Analysis
24. Corrective Action
25. Preventive Action
26. Product Recall and Advisory Notices

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