ISO 13485 and FDA Compliant All in One Certification Package

Included Contents (Link to website for more details)

Planning

Gap Analysis Checklist
A detailed, 72 page checklist (MS Word) with guidance on what to look for to evaluate your current processes and their compliance to the ISO 13485 requirements highlighting additional requirements to upgrade an existing QMS to become FDA QSR compliant..

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.

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.

Set of 11 Employee Flyers
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. This checklist contains all the requirements to audit your QMS to both ISO 13485 and to the FDA QSR 21CFR-820.

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)

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-FDA Documentation Contents

Procedure

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 (for ISO 13485)
13. Production and Process Controls (for QSR 21 CFR 820)
14. Validation of Processes for Product Realization
15. Identification and Traceability
16. Customer Property
17. Preservation of Property
18. Control Of Monitoring and Measuring Devices
19. Post Production Feedback
20. Internal Audits
21. Monitoring and Measuring of Product Realization Processes
22. Control of Non-Conforming Product
23. Statistical Techniques
24. Root Cause Analysis
25. Corrective Action
26. Preventive Action
27. Product Recall and Advisory Notices

Form

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