

ISO 13485:2016 Medical Devices Internal Auditor

Agenda

Day One

Time	Subject
8:00 a.m.	Welcome and Introductions
	Module 1: Quality Management Systems
	Activity 1 – Legal Compliance vs Conformity
	Activity 2 – Quality Terminology
9:45 a.m.	Break
10:00 a.m.	Module 2: Audit Fundamentals
	Activity 3 – Terms and Definitions of ISO 19011:2018
	Module 3: The ISO 13485 Standard
12:00 p.m.	Lunch
12:45 p.m.	Module 3: The ISO 13485 Standard (cont'd)
	Activity 4 – Understanding risk-based approach to controls
	Activity 5 – Auditing a Quality Policy
3:00 p.m.	Break
3:15 p.m.	Module 3: The ISO 13485 Standard (cont'd)
	Activity 6 – Auditing Quality Objectives
	Activity 7 – Competence and Awareness
	Activity 8 – Product Realization
	Risk Management Overview
	Review of Day 1 and complete End of Day 1 Knowledge Check
5:10 p.m.	End of Day 1

Evening Work: Review Case Study Documentation

Agenda

Day Two

Time	Subject
8:00 a.m.	Review of Day One
	Module 3: The ISO 13485 Standard (cont'd)
	Activity 9 – Quality Performance and Evaluation
	Activity 10 – Effectiveness of a QMS
10:00 a.m.	Break
10:15 a.m.	Module 4: Managing an Audit Program
	Activity 11 – Considering Risk
	Activity 12 – Audit Objective and Scope Statement
12:00 p.m.	Lunch
12:45 p.m.	Module 5: Audit Planning and Preparation
	Activity 13 – Prepare Audit Plan
	Activity 14 – Prepare Work Documents
3:00 p.m.	Break
3:15 p.m.	Module 6: Conducting Audit Activities
	Activity 15 – Opening Meeting
	Activity 16 – Interviewing
	Review of Day 2 and complete End of Day 2 Knowledge Check
5:10 p.m.	End of Day 2

Agenda

Day Three

Time	Subject
8:00 a.m.	Review of Day 2 Module 6: Conducting Audit Activities (cont'd) Activity 17 – Undertaking an Audit and Writing NCR's
9:45 a.m.	Break
10:00 a.m.	Module 6: Conducting Audit Activities (cont'd) Activity 18 – Closing Meeting
12:00 p.m.	Lunch
12:45 p.m.	Module 6: Conducting Audit Activities (cont'd) Module 7: Preparing and Distributing the Audit Report Activity 19 – Audit Report
2:45 p.m.	Break
3:00 p.m.	Module 8: Completing the Audit and Conducting Follow Up Activity 20 – Corrective Action End of Day 3 Knowledge Check
4:45 p.m.	Course close