

## Agenda

### Day 1

8.00 a.m. Welcome and Introductions

#### **Module 1: Quality Management Fundamentals**

Activity 1 – Quality Terminology

10.00 am Break

10.15 am **Module 1** *continued*

Activity 2 – Legal Compliance vs. Conformity

#### **Module 2: Quality Management Concepts**

Activity 3 – Quality Management Principles

#### **Module 3: Auditing Quality Management Systems**

12.00 noon Lunch

12.45 p.m. **Module 3** *continued*

Activity 4 – Ensuring an Effective Audit Outcome

2.45 pm Break

3.00 pm **Module 4: The ISO 13485:2016 Standard – Clause 4**

Activity 5 – Understanding Risk-based Approach to Controls

4.30 pm Time com work on End of Course Knowledge Check

5.00 p.m Review and End of Day 1

Evening Work – Review Case Study – Medexcel Quality Manual – approximately one hour

**Day 2**

- 8.00 am      Review Day 1
- Module 4 *continued* – Clause 5**
- Activity 6 – Auditing Quality Policy
- 10.00 am      Break
- 10.15 am      Activity 7 – Auditing Quality Objectives
- Module 4 *continued* - Clause 6**
- Activity 8 – Competence and Awareness
- Module 4 *continued* – Clause 7**
- 12.00 noon    Lunch
- 12.45 pm      **Module 4 Clause 7 *continued***
- Activity 9 – Product Realization
- Risk Management Overview**
- 2.30 pm      Break
- 2.45 pm      **Module 4 *continued* Clause 8**
- Activity 10 – Quality Performance and Evaluation
- Activity 11 – Effectiveness of the QMS
- 4.15 pm      Time to complete End of Course Knowledge Check
- Wrap-Up
- 5.00 p.m.     End of Day 2

**Day 3**

8.00 am	Welcome and Introductions Review of Evening Work
	<b>Module 1: ISO 19011:2018 Overview</b> Activity 1 – ISO 19011 Terms and Definitions
	Break
	<b>Module 2: Managing an Audit Program</b> Activity 2 – Scheduling Considerations
12 noon	Lunch
12.45 pm	<b>Module 2 continued</b> Activity 3 – Audit Objective, Scope, Criteria and Method Activity 4 – Auditor Competencies Activity 5 – Selecting the Audit Team
	<b>Module 3: Audit Planning and Preparation</b> Activity 6 – Managing Audit Risks
	Break
	<b>Module 3 continued</b> Activity 7 – Determining Sources for Obtaining Objective Evidence Activity 8 – The Audit Plan Activity 9 – Audit Work Documents
	Work on Course Knowledge Check
5.30 pm	End of Day 3

**Day 4**

8.00 am	Day 3 Review
	<b>Module 4: Performing the Audit</b> Activity 10 – Develop 5 Strategies to Build Relationships Activity 11 – Personality Types
	Break
	<b>Module 4 continued</b> Activity 12 – Opening Meeting Activity 13 – Case Study
12 noon	Lunch
12.45 pm	<b>Module 4 continued</b> Activity 13 <i>continued</i> Activity 14 – Nonconformity Statement Activity 15 – Closing Meeting
	Break
	<b>Module 4 continued</b> Activity 15 – Closing Meeting <i>continued</i>
	<b>Module 5: Reporting Audit Outcomes</b> Activity 16 – Draft Audit Report Activity 17 – Corrective Action
	Complete Course Knowledge Check Course review
5.30 pm	End of Course