

### 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 close

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

## Auditing a Medical Devices Quality Management System

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### Day 2

8.00 am	Review Day 1
	<b>Module 4 <i>continued</i> – Clause 5</b>
	Activity 6 – Auditing Quality Policy
10.00 am	Break
10.15 am	Activity 7 – Auditing Quality Objectives
	<b>Module 4 <i>continued</i> - Clause 6</b>
	Activity 8 – Competence and Awareness
	<b>Module 4 <i>continued</i> – Clause 7</b>
12.00 noon	Lunch
12.45 pm	<b>Module 4 Clause 7 <i>continued</i></b>
	Activity 9 – Product Realization
	<b>Risk Management Overview</b>
2.30 pm	Break
2.45 pm	<b>Module 4 <i>continued</i> Clause 8</b>
	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.	Course Close