

## Agenda

### Day 1

8.00 am Welcome and Introductions  
Review of Evening Work

**Module 1: ISO 19011:2018 Overview**

Activity 1 – ISO 19011 Terms and Definitions

Break

**Module 2: Managing an Audit Program**

Activity 2 – Scheduling Considerations

12 noon Lunch

12.45 pm **Module 2 *continued***

Activity 3 – Audit Objective, Scope, Criteria and Method

Activity 4 – Auditor Competencies

Activity 5 – Selecting the Audit Team

**Module 3: Audit Planning and Preparation**

Activity 6 – Managing Audit Risks

Break

**Module 3 *continued***

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

## Conducting and Leading Medical Devices Management System Audits

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### Day 2

8.00 am	Day 1 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	Course Close