

### Agenda

#### Day 1

- 8.00 am Welcome and Introductions  
Review of Evening Work
- Module 1: ISO 19011:2018 Overview**  
Activity 1 – Auditing Terms and Definitions
- Break
- Module 2: Managing an Audit Program**  
Activity 2 – Audit Program Priorities
- 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
- End of Day 1 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
	End of Day 2 Knowledge Check Course review
5.30 pm	Course Close