

# Course Syllabus

## ISO 13485:2016 Medical Device QMS Auditor (24hrs)

*The ISO 9001 and ISO 19011 portions of this course are recognized Exemplar Global Certified courses. Our classes are interchangeable to allow for simple adoption of various international standards and sector-specific requirements. Each course day, as well as individual module, can be offered ala carte or customized for use internally within your organization. Additional charges may apply. Each 8-hour class is worth 0.8 CEUs.*

### Day 1 – Champion & Overview

8:00am - 9:30am	Introduction, gathering of expectations & initial self-assessment
9:45am - 11:00am	The importance of systems
11:15am – noon	Overview of the ISO 13485:2016 standard (part I)
Noon – 1:00pm	Lunch break
1:00pm – 1:45pm	Overview of the ISO 13485:2016 standard (part II)
2:00pm – 3:15pm	FDA requirements & online resources
3:30pm – 5:00pm	ISO 9004 & ISO 19011

### Day 2 – Champion > Process Owner & Auditors

8:00am - 9:30am	ISO 13485:2016 clause 1-4 and 5-6
9:45am - 11:00am	Audit scenarios
11:15am – noon	ISO 13485:2016 clause 7 (part I)
Noon – 1:00pm	Lunch break
1:00pm – 1:45pm	Audit scenarios
2:00pm – 3:15pm	ISO 13485:2016 clause 7 (part II)
3:30pm – 5:00pm	Audit scenarios

### Day 3 – Champion > Process Owner & Auditors > Auditor II

8:00am - 9:30am	ISO 13485:2016 clause 7 (part III)
9:45am - 11:00am	Audit scenarios
11:15am – noon	ISO 13485:2016 clause 8
Noon – 1:00pm	Lunch break
1:00pm – 1:45pm	Audit scenarios
2:00pm – 3:15pm	The Basics of Auditing
3:30pm – 4:00pm	Post-course self-assessment, Q&A and course feedback
4:00pm – 5:00pm	Final exam

### OPTIONAL ADD ON:

#### Day 4 – Champion > Process Owner & Auditor > Auditor II > Lead Auditor

8:00am - 9:30am	Module 1 – Pre-course self-assessment & Overview of ISO 19011:2018
9:45am - 11:00am	Module 2 – ISO 19011:2018 clause 5 Managing an audit program
11:15am – noon	Module 3 – ISO 19011:2018 clause 6 Conducting an audit
Noon – 1:00pm	Lunch break
1:00pm – 1:45pm	Module 4 – ISO 19011:2018 clause 7 Competence & evaluation of auditors
2:00pm – 3:15pm	Module 5 – Annex A Guidance for auditors planning & conducting audits
3:30pm – 5:00pm	Module 6 – Auditing pitfalls & best practices