

ISO 13485:2016

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

5 DAYS CQI & IRCA UNITED KINGDOM CERTIFIED (KELMAC Group® Course ID: 17584)

BEMCON
INSTITUTE OF MEDICAL TECHNOLOGY

**KELMAC
GROUP**
BUILDING SUSTAINABLE COMPETITIVENESS



CQI



IRCA

CERTIFIED COURSE 17584

THIS ISO 13485:2016 LEAD AUDITOR COURSE PROVIDES THE MD QMS LEAD AUDITOR WITH THE CONFIDENCE, AUDIT TOOLS AND TECHNIQUES TO BE ABLE TO EFFECTIVELY AUDIT A MD QMS BASED ON ISO 13485:2016 IN ACCORDANCE WITH THE AUDIT PROTOCOL OF ISO 19011:2018.



رؤية
2030
المملكة العربية السعودية
KINGDOM OF SAUDI ARABIA

SAUDI ARABIAN GOVT. APPROVED TRAINING CENTER

المؤسسة العامة للتدريب التقني والمهني
Technical and Vocational Training Corporation

CREATIVE
CONSULTANTS
TRAINING CENTER



BEMCON
INSTITUTE OF MEDICAL TECHNOLOGY

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GROUP**
BUILDING SUSTAINABLE COMPETITIVENESS

FOR FURTHER DETAIL COURSE FEE & REGISTRATION, PLEASE CONTACT AT CUSTOMER.SERVICES.SAUDIA@BEMCON.CO.UK

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CERTIFIED COURSE 17584

COURSE SESSIONS

- SESSION 0 - COURSE INTRODUCTION
- SESSION 1 - MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM
- SESSION 2 - COMPLIANCE MGT. SYSTEM - HOW TO AUDIT COMPLIANCE REQUIREMENTS?
- SESSION 3 - INTRODUCTION TO AUDITING
- SESSION 4 - INITIATION AND PREPARATION
- SESSION 5 - CONDUCTING THE AUDIT
- SESSION 6 - AUDIT REPORTING
- SESSION 7 - FINAL AUDIT TEAM/CLOSING-EXIT MEETING

HOW WILL I BE ASSESSED?

1. Full or 100% attendance is required during the training course.
2. The Learner is assessed during the virtual class delivery based on participation and performance throughout the duration of the course. This includes all exercises, role plays, case study and all other activities during the virtual course. The Learner is expected to turn their webcam on during all class sessions.
3. The Kelmec Group and CQI-IRCA Assessment auditor examination is phased during this learning event.
4. The Assessment examination is closed book; however, the learner is required to have a hard-copy or digital version of the relevant management system standards (ISO 13485:2016) for class use.
5. The minimum pass rate for each written theory and practical auditor Assessment is 70%.



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FOR FURTHER DETAIL AND REGISTRATION, PLEASE CALL OR SEND PERSONAL DETAIL TO ANY OF THE BELOW MENTIONED STAFF.

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