CAB PROFICIENCY TRAININGS

(TRAININGS SANCTIONED BY MEDICAL DEVICE AUTHORITY)

REQUIREMENT?

Section 10 Act 737 4th Schedule MDR 2012

MANDATORY FOR?

Auditors & Technical Personnel (in order to conduct conformity assessment tasks)

SYLLABUS?

Act 737, MDR 2012, MDR 2019, Circular Letters, Guidelines, Guidance Documents

EXAMINATION?

40 Questions (Multiple-Choice) answer in 1-hour

CERTIFICATE TYPE?

Proficiency Certificate (>80%) Attendance Certificate (<79%) Certificate Validity: 3 years

TRAINING FEE?

RM 1,000 per day per participant

TRAINING TYPE?

For NEW PERSONNEL

- > 4-day training
- > Comprehensive training
- > 2 main training courses

Day 1 & 2: Legislation + QMS

Day 3 & 4: MD Conformity Assessments

For EXISTING PERSONNEL

- > 2-day training
- > Refresher training
- >1 training course only

Day 1 & 2: Regulatory Updates



WHY NEED TO ATTEND THESE PROFICIENCY TRAININGS?



To impart information



To impart instructions



To improve competency



To improve performance



To attain knowledge



To attain skills