AMMI
ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES
PERSATUAN INDUSTRI PERUBATAN MALAYSIA
MEDTECH® MALAYSIA

Medsociate
Authorised Training Provider

Industry Expert Training Series * HRD Corp Claimable Course Scheme

Risk Management for Medical Devices (EN ISO14971:2019)

Training Brochure

HRDCORP CLAIMABLE

Risk Management for Medical Devices (EN ISO 14971:2019)

COURSE OBJECTIVES

This training aims to provide participants with a clear understanding and insight into the EN ISO 14971:2019/ A11:2021 requirements. The training takes a look at the major changes in the 2019 update/revision and also covers some of the commonly used risk management tools such as FMEA, FTA, etc.

COURSE OUTLINE

1. Basic principles of risk management
2. EN ISO 14971:2019/ A11:2021 requirements
3. ISO 14971:2007 vs ISO 14971:2019
4. Changes in ISO/TR 24971:2020
5. Summary of what need to be done to meet EN ISO 14971:2019/ A11:2021 requirements

DURATION

Two (2) full days

MODE OF TRAINING

Remote Online Training or Classroom Training

COURSE AGENDA

Day	Time	Details
1	9.00 am – 12.30 pm	Basic principles of risk management EN ISO 14971:2019/ A11:2021 requirements
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	EN ISO 14971:2019/ A11:2021 requirements (Continue)
2	9.00 am – 12.30 pm	EN ISO 14971:2019/ A11:2021 requirements (Continue)
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	EN ISO 14971:2019/ A11:2021 background EN ISO 14971:2019/ A11:2021 vs ISO 14971:2007 Differences in the structure and content of ISO 14971:2007 vs ISO 14971:2019 Review on EN ISO 14971:2019/ A11:2021 Annex Z Highlighted changes in EN ISO 14971:2019 vs EN ISO 14971:2012

		Changes in ISO/TR 24971:2020 Summary of what need to be done to meet EN ISO 14971:2019/ A11:2021 requirements

CONTACT

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