

EMWA Professional Development Programme

Literature Reviews for Medical Devices (MDA1)

Medical Devices category – Advanced Level – Duration - 3.5 hours

Workshop leader: Gillian Pritchard, Sylexis Limited

Pre-workshop assignment

Objective

The aim of the pre-workshop assignment is to be familiar with the guideline MEDDEV 2.7/1 rev. 4 (June 2016) which explains how to conduct a clinical evaluation of a medical device.

Content

MEDDEV 2.7/1 rev. 4 (June 2016) guideline.

Assessment criteria

The assignment is not assessed. The guideline will be referred to in the workshop so it will be assumed that you have read it.

Instructions

Read the guideline paying particular attention to sections 8-9, A4-A6 and A9 which explain the literature review requirements.

Resources and materials

MEDDEV 2.7/1 rev. 4 (June 2016) guideline.

The guideline is also available via the following link:

https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKewiCw5qH4t7YAhUsBcAKHfnrAVYQFggzMAA&url=https%3A%2F%2Fec.europa.eu%2Fdocsroom%2Fdocuments%2F17522%2Fattachments%2F1%2Ftranslations%2Fen%2Frenditions%2Fnative&usg=AOvVaw1L6oboIQ-Y_oC1BjliwhG

Time required

Up to 2 hours.