EMWA Professional Development Programme

Safety Reporting for Medical Devices Part I (MDF6)

Beatrix Doerr

Pre-workshop assignment

Please complete the following before the workshop.

Pre-workshop reading

Read Article 2 Definitions of MDR 2017/745 (available from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745) and MDCG 2020-10/1 and -2 (Guidance - MDCG endorsed documents and other guidance | Public Health (europa.eu)).

About you

Participants should answer the following questions:

1. What previous medical writing experience (any/for medical devices) do you have?
2. What previous safety experience (any/for medical devices) do you have?
3. What do you expect from the workshop, and what are your particular areas of interest?

Please email your answers to the workshop leader: beatrix.doerr@googlemail.com

Time required
2 hours