EMWA Professional Development Programme

DDA28: The Investigational Medicinal Product Dossier: gateway to introducing new medicinal entities in the European Union

Category: Drug Development
Advanced Workshop: 3.5 hours

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Pre-workshop assignment

Objective
The pre-workshop assignment aims to ensure participants have an overview of the EMA guidelines on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products (IMP) in clinical trials.

Content
Participants are required to obtain a copy of the EMA guideline on the requirements for the chemical and pharmaceutical quality documentation concerning IMP in clinical trials available at the link given below as well as complete a questionnaire to assess their background.

Assessment criteria

The pre-workshop assignment is not assessed but you should complete and return the attached questionnaire by **25 April 2021**.

Instructions

Part 1: Prior to the workshop participants should familiarise themselves with the EMA "Guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials". This is available at:

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/11/WC500239381.pdf

Participants should note any sections for discussion and be prepared to raise questions and comments on these sections in the workshop.

Part 2: A questionnaire is provided to assess the background of participants. This also allows you to send in your questions and share your previous experience with IMPDs. Please return this by **25 April 2021** to:

Carola Krause – Carola.Krause@codex-biomed.com AND
Satyen Shenoy – sshenoy@describescientific.de

Name:
Current job:
Years of regulatory writing experience:
Familiarity with the drug development process: ☐ No ☐ Yes
Familiarity with CTD/eCTD modules ☐ No ☐ Yes, but never used a CTD/eCTD for a writing project ☐ Yes, and have used a CTD/eCTD for a writing project ☐ Yes, and have drafted parts of/entire CTD/eCTD
Familiarity with Blockchain technologies ☐ No ☐ Yes
Knowledge of IMPD: ☐ None ☐ Have heard the term ☐ Know a fair amount about it ☐ Have extensive knowledge of it
Experience in drafting an IMPD: ☐ None ☐ Have compiled sections of the IMPD on the odd occasion ☐ Have compiled sections of the IMPD frequently ☐ Have compiled the entire IMPD once/more than once (*cross out the incorrect choice*)
Your question on IMPD: (*Please note that we will discuss your question during the workshop if time allows for it. In certain instances, a question could also be used as a case-study for the workshop. We will address any* ***relevant*** *unanswered questions either after the workshop or later by email*)

Resources and materials
Attendees will need access to the internet to obtain a copy of the relevant guideline.

Time required
1.0-1.5 hours