REGULATORY WRITING & eCTD-READINESS WORKSHOP

1 & 2 December 2022

Hosted online, by SAAPI

Presented by Henriette Vienings

Introduction

The online training will take place over 2 days, using MS Teams ® as the Platform for the training.

The training is structured as 2 half-day sessions from 09:00 – 13:30 with a 30 - minute snack/comfort break.

The training will take the delegates through the various current guidelines, templates and websites. It will address decision-making and process flows.

This workshop aims to provide authors of regulatory information an overview of the expectations related to regulatory documentation and the means to produce and manage the documentation related to their submissions.

Overview of Training

1. Understanding applicable eCTD guidance: ICH & SAHPRA guidelines, with respect to writing, editing and content requirements.
2. Discussion of Data Integrity requirements and Data Governance expectations.
3. Writing Tools – Demonstration of most commonly used functionalities for regulatory writing, using MS Word™& Adobe Acrobat™.
4. Creation of regulatory templates and life-cycle management.

Course Outcomes

At the end of the course, the delegate will have insight and knowledge of the following, as it pertains to regulatory writing:

- The ICH (Q, S, E, M) and the South African Health Products Regulatory Authority (SAHPRA) guidelines – Where to find the information needed for writing and editing.
- Data Integrity, Regulatory and Compliance Information.
- Dossier presentation requirements.
- Preparation of documents to enable reusability and facilitate lifecycle management.
- Using the tools and shortcuts available in Microsoft Word and Adobe Acrobat Professional.
- Digitising legacy documents, OCR, creation of bookmarks & headers and footers, extraction and granulation of documents.
- Using automated ToCs, ToTs and ToFs, line numbering, using Microsoft styles and clearing thereof, editing of tables etc.
- Hyperlinks, fields and the set up and use of quick parts.
- Conversion of authored documents to pdf.
- Creation of templates.

Who should attend?

- ☑ Responsible Pharmacists,
- ☑ Regulatory Information Managers,
- ☑ Regulatory Pharmacists;
- ☑ Regulatory Specialists,
- ☑ Regulatory Assistants,
- ☑ Medical Writers etc.
- ☑ Pharmacovigilance Officers
- ☑ In essence any person involved in the authoring and editing of documents to ensure their readiness for inclusion into regulatory processes and applications.