PI & PILs for ZA eCTD Submissions

13 & 14 October 2022

Hosted online, by SAAPI

Presented by Henriette Vienings

Overview of Training

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 11:00 – 15:00 with a 30 - minute lunch/comfort break.

The training will take the delegates through the various guidelines related to PIs & PILs.

It will provide a PI & PIL template with links to the references for content that must be addressed.

The topics that will be covered over the 2 days include:

1. Regulatory requirements
2. Writing a PI and PIL for eCTD submission purposes
3. Understanding the differences between writing a PI for an Innovator product or a generic;
4. Amending the PI/PIL
5. Converting the PI to an SmPC

Training Outcomes

Delegates should have an understanding of the following by the end of the training:

- The references to use when writing a PI & PIL.
- Authoring functionalities in MS Word
- How to create a template for PIs & PILs
- How to amend a PI & PIL.
- How to convert a PI to SmPC.

Who should attend?

- ☑ Responsible Pharmacists,
- ☑ Regulatory Information Managers,
- ☑ Regulatory Pharmacists;
- ☑ Regulatory Specialists,
- ☑ Regulatory Assistants,
- ☑ Medical Writers etc.

Any questions/concerns that delegates would like to have specifically addressed during the workshop, can be emailed to: henriette@mra-regulatory.com | Subject: SAAPI PI & PIL workshop