REGULATORY WRITING WORKSHOP

12 August 2019 @ Glenhove

Introduction

This 1-day workshop aims to provide those in Regulatory Affairs and other Compliance Departments an overview of the expectations related to regulatory documentation and the means to produce and manage the documentation related to their submissions.

Who should attend?

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

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.

Presenter

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