



## **VECTOR LIFE SCIENCES**

### **FROM CHAOS TO CLARITY - CRAFTING SUBMISSION READY DOCUMENTS FOR YOUR eCTD**

#### **PRESENTER:**

**Dr. Madelein Terblanche**

#### **WORKSHOP INTRODUCTION:**

Creating submission-ready documents is a critical step in ensuring a smooth and successful eCTD submission to SAHPRA. This workshop focuses on the practical preparation of high-quality, compliant documents that meet SAHPRA eCTD requirements. Participants will learn how to efficiently create, format, and optimize documents using Microsoft Word and Adobe Acrobat, apply proven shortcuts, and leverage templates to improve consistency, quality, and submission readiness. The session is hands-on and aimed at reducing validation errors, rework, and avoidable regulatory queries.

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#### **WHO SHOULD ATTEND THE COURSE:**

This workshop is designed for individuals involved in the preparation, formatting, publishing, or quality checking of eCTD documents, including regulatory affairs professionals, document authors, publishers, consultants, and support staff responsible for creating or managing submission content.

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#### **WORKSHOP CONTENT:**

- Overview of SAHPRA eCTD document requirements
- Creating submission-ready source documents in Microsoft Word
- Efficient use of Word styles, headings, numbering, and templates
- Building and maintaining reusable document templates for eCTD submissions

- Converting Word documents to compliant PDFs
  - PDF requirements for SAHPRA (bookmarks, links, security, file settings)
  - Adobe Acrobat shortcuts and productivity tips
  - Common document preparation mistakes and how to avoid them
  - Using templates consistently within an eCTD lifecycle
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## **WORKSHOP OUTCOMES:**

By the end of the workshop, participants will be able to:

- Create submission-ready documents aligned with SAHPRA eCTD requirements
- Use Microsoft Word more efficiently for regulatory document creation
- Apply and manage templates to ensure consistency across eCTD submissions
- Produce compliant, high-quality PDFs suitable for eCTD publishing
- Reduce validation errors, rework, and regulatory queries related to document quality