

SAAPI Workshop

Green Tick Guaranteed:

Outsmarting eCTD Validation Hurdles the Smart Way

Wednesday, 15 April 2026

Course Overview

Achieving a successful eCTD validation outcome is a critical step in the regulatory submission process in South Africa. Submissions that fail technical validation can lead to **sequence rejection, regulatory delays, and unnecessary rework**, ultimately impacting approval timelines.

This course provides a practical overview of the **South African eCTD validation criteria** and how submissions are assessed against the **SAHPRA eCTD specification and validation rules**. Participants will gain insight into common validation errors, understand the rules that trigger them, and learn how to prevent these issues during compilation and publishing.

Using practical examples, the course explains how to **interpret validation messages, apply correct lifecycle management, structure documents appropriately, and ensure compliance with SAHPRA regional requirements**. The focus is on equipping participants with the knowledge needed to prepare submissions that **pass validation the first time — achieving the coveted green tick**.

Foundational concepts of the Validation Criteria were **covered in the “Busting the Myths of eCTD: eCTD Basics” course**, and participants who have completed that course **do not need to attend this session**.

Learning Objectives

By the end of this course, participants will be able to:

- Understand the **SAHPRA eCTD validation framework and technical validation process**

- Identify **common validation errors and warnings** encountered during submission
- Interpret validation reports and determine **how to resolve validation failures**
- Apply correct **lifecycle operations, document structure, and metadata requirements** to avoid validation issues
- Implement **best practices during eCTD compilation and publishing** to ensure submissions pass validation successfully

Who Should Attend (Industry)

This course is designed for **industry professionals responsible for compiling, publishing, or managing eCTD submissions to SAHPRA, basic level.**

Participants should have **basic familiarity with eCTD concepts**

Date and Time: 15 April 2026 - 09h00 to 13h00

Register online: www.saapi.org.za

Registration Fees: SAAPI Members: R1600.00 | **Non-Members:** R1900.00

Contact: info@saapi.org.za for more information