SAAPI Workshop

Behind the XML Curtain: Unpacking the Secrets of eCTD 3.1 Specification Engine

08 September 2026

Course Overview

Stop trusting the green tick. Learn to read the backbone yourself.

A four-hour, practitioner-level deep dive for regulatory affairs professionals who publish, validate, and troubleshoot eCTD submissions — and are tired of the publishing tool being a black box. SAHPRA-anchored, with FDA and EU for contrast.

Who it's for

Publishers, RA specialists, and eCTD leads who already submit dossiers but want to move from *following the wizard* to *understanding the file* — the people who get the 2 a.m. "why is this document in the wrong place?" call.

What you'll walk away able to do

- Read a raw leaf and predict exactly how it renders — before you submit
- Trace a document's lifecycle across sequences and know precisely what the reviewer sees
- Diagnose a validation failure at the layer it breaks, not by trial and error
- Speak za-regional.xml, us-regional, and eu-regional fluently — and know what ports between them
- Walk into eCTD v4.0 / RPS conversations already understanding the shift

Module	The promise
Architecture	Why the folder tree is just scaffolding - and the backbone is the building
Anatomy of index.xml	Dissect the leaf until it holds no more secrets
Lifecycle *(the core)*	Master the four operations and the one pointer that binds them- nothing is ever truly deleted
Regional & SAHPRA	Home turf: the za-backbone, the specifics that quietly sink SA submissions, and how other regions compare
eCTD v4.0 & RPS	The paradigm shift, demystified - decoupling document from placement
Integrity & validation	Four validation layers, real-world failures, and a debug workflow that works with any tool
Case study	Hunt a planted defect in a live three-sequence trace - then take the reference sheet home

The takeaway

By the end, the backbone stops being something your software generates and becomes something you command. Two short breaks, one hands-on defect hunt, and a reference sheet you'll actually keep.