

Course Title

Busting the Myths of eCTD: eCTD Basics

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Course Overview

The electronic Common Technical Document (eCTD) is often perceived as complex, restrictive, and difficult to manage. Many of these perceptions are based on **myths carried over from paper-based submissions or early electronic formats**.

This course demystifies eCTD by **busting common myths**, explaining *why* eCTD works the way it does, and showing how its structure, navigation, and lifecycle principles actually **support clarity, reuse, and efficient regulatory review**.

The session focuses on **foundational eCTD concepts**, using simple explanations and practical examples especially relevant to **SAHPRA submissions**.

High-Level Course Outline

1. Introduction & Common eCTD Myths
2. eCTD Navigation & Structure
3. Document & File Requirements
4. Building the eCTD
5. Lifecycle Management
6. Attributes & Content Reuse
7. Future Direction

Course Objectives

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

- Identify and correct common **eCTD myths and misconceptions**
- Understand how eCTD evolved from paper and why those changes matter

- Apply basic eCTD rules for documents, structure, and lifecycle
- Appreciate how good eCTD practice reduces rework and review burden

Who Should Attend

This course is designed for **pharmaceutical and life sciences professionals involved in regulatory submissions**, whether directly or indirectly, who want to better understand eCTD fundamentals and avoid common submission errors. This can include but is not limited to: eCTD Publishers and Submission Specialists, Regulatory Operations and eSubmission Teams, Dossier Compilation and Publishing Staff, Regulatory Affairs Consultants, eCTD Publishing Vendors and Service Providers.

Target Level

- **Beginner to Intermediate** - Suitable for first-time eCTD users and those wanting to strengthen fundamentals