SUB05 Electronic Common Technical Document (eCTD)

Approximate study time: 2.5 hours

Level: Introductory/Intermediate

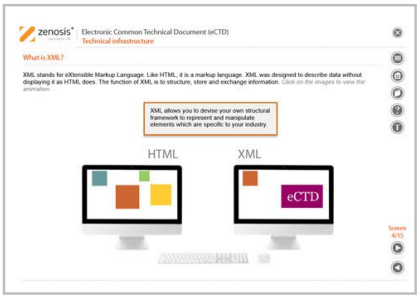
Audience: Regulatory

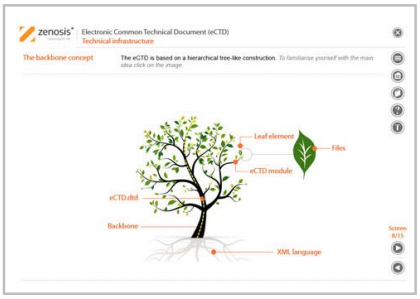
Category: Regulatory Submissions, ICT

Region: USA, Europe, Other

CPD Points: 2.5

Module outline
- Introduction
- Technical infrastructure
- Directory structure
- Creating an eCTD submission
- Special components
- Tools
- Assessment





The eCTD is mandatory for all applications for marketing approval and all subsequent related submissions in the European Economic Area, the USA and Canada. Other countries intend to make its use mandatory. The eCTD specification has been developed to facilitate the global electronic submission, review and lifecycle management of medicinal product dossiers for regulatory applications. It broadens the scope of the CTD to include information on variations, renewals and amendments, so that it is no longer a static document but is updatable throughout the life of the product. This module outlines the eCTD specification, discusses the approach to regional differences in dossiers, and provides guidance on creation of an eCTD submission. The module provides a training and reference tool that will be of particular value to those new to the use of the format.

Who will benefit from this module?

This module is an essential tool for regulatory affairs and compliance staff and specialists in data handling, knowledge management or documentation. All those involved in drug development and who contribute to regulatory submissions will also wish to familiarise themselves with its contents.

Learning objectives

- Describe the structure, requirements and functionality of the eCTD.
- Outline XML basics and the architecture of the eCTD.
- Discuss Document Type Definitions (DTDs) and schemas.
- Explain how to build an eCTD.
- Specify regional differences.
- Discuss life cycle and change management.
- List criteria that will make an electronic application technically valid.
- Initiate electronic transfer to a regulatory authority.
- Create, submit and maintain an eCTD dossier throughout the life of a drug product.

Module outline

Introduction
This session defines the eCTD and identifies advantages of using this submission format.

Technical infrastructure
This session gives information on XML specification and style sheets and describes the eCTD backbone.

Directory structure
This session looks at the eCTD hierarchy, life cycle management and structure of the five modules.

Creating an eCTD submission
This session explores the workflow around planning, creating and submitting an eCTD – particularly setting up the modules, and migrating and validating the data.

Special components
Features of the Canadian, EU, Japanese and US DTDs/schemas and the STF specification are outlined.

Tools
This session includes a case study and an eCTD checklist to assist learners when compiling an eCTD submission.

Assessment
Multiple-choice mastery assessment.