SUB04 Preparing Submissions in the Common Technical Document (CTD) Format

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

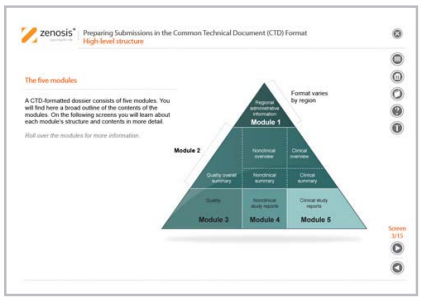
Audience: Regulatory

Category: Regulatory Submissions

Region: USA, Europe, Other

CPD Points: 1.5

Module outline
- Introduction
- High-level structure
- Fine structure and format
- Using the CTD
- Conversion tools
- Assessment



The CTD is the internationally recognised standard format for submissions to medicines regulatory authorities. In the European Economic Area, the USA and Canada, the CTD, in its electronic format (eCTD), is mandatory for all applications for marketing approval and all subsequent related submissions. The CTD is accepted in many other countries, being mandatory for new prescription medicines in some. This module explains the rationale for the CTD and provides guidance on its structure and formatand the ways in which it is used.

Who will benefit from this module?

Regulatory affairs and compliance staff, and all those involved in drug development and who contribute to regulatory submissions, will find the module an invaluable introductory training course and/or a useful reference tool. Specialists in data handling, knowledge management or documentation will also wish to familiarise themselves with its contents.

Learning objectives

- Explain the rationale for the CTD, and describe the ways in which it is used.
- Identify regional differences in regulatory requirements for information in a CTD-formatted submission.
- Describe the structure of the CTD.
- Access guidance on detailed structure and content of the CTD.
- Outline formatting requirements for a CTD dossier.

Module outline

Introduction
This session introduces you to the nature of the Common Technical Document (CTD), a global standard designed by the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) The composition of a regulatory submission team is outlined.

High-level structure
In this session you will become more familiar with the five modules of the CTD.

Fine structure and format
You will be given access to guidelines that specify in detail the structure of each module of the CTD and the relationship between their sections and the documents that make up a dossier. Recommendations are also given on how to segregate and paginate documents and how to format pages, tables of contents and cross-references.

Using the CTD
Different ways in which you can use the CTD in practice are described.

Assessment
Multiple-choice mastery assessment.