

Title

Effective Project Management Techniques for the Creation of Marketing Applications in eCTD Format

Summary

This presentation will provide examples of effective project best practices that have emerged from lessons learned in organizing the preparation and submission of marketing applications to the FDA in eCTD format. Discussion will focus on fundamental project management tools and techniques for effectively meeting time, cost, and quality constraints for the successful management a marketing application in eCTD format.

Learning Objectives

At the end of this lessons learned presentation, attendees should be able to do the following:

1. Recognize the vital role of best business practices and effective project management techniques and tools in the overall process of preparing your company for eCTD submissions.
2. Identify the challenges and benefits of managing an eCTD and how to ensure a successful outcome in meeting timelines, costs, and quality constraints that can affect a successful submission.

Abstract

This presentation will provide effective project best practices that have emerged from lessons learned in organizing and implementing the preparation and submission of marketing applications to the FDA in eCTD format. Discussion will focus on fundamental project management tools and techniques that are effective for meeting time, cost, and quality constraints for successfully managing a marketing application in eCTD format. Project management strategies for planning and initiation of an eCTD submission project will be presented, including a discussion of how conducting a formal kick-off meeting to launch the project and preparing a global program timeline is key for successful eCTD filing. Identification and management of critical path activities during project execution, and how to minimize their impact on timelines, will be discussed. The importance of finalizing a target product profile at project execution before eCTD preparation activities begin will be covered. An integrated project management tool will be introduced via a simple spreadsheet that transforms into a powerful tracking and communication tool used throughout the project life cycle to monitor resource allocation, control document progression, and track rate limiting steps, emphasizing that document management systems do not need to be complicated or generated through expensive software to be effective. Practical advice will be given in managing through effective communication management techniques such as using a communication plan to reduce delays and inefficiencies, especially when working with multiple internal groups or outsourced vendors. The advantages of managing the eCTD as a rolling submission will

be discussed, even when the application is not intended to be submitted in rolling units to the FDA, in order to maximize available resources, and minimize potential delays and costs for outsourcing. Applying close-out lessons learned to improve the company's approach for future submissions will be reviewed.