eCTD Tutorial

October 20, 2005

Purpose: This tutorial will provide an overview of FDA's eCTD guidance document and a comprehensive discussion on preparing the five modules of an eCTD. Emphasis will be placed on ensuring the successful submission of an application and facilitating the review process.

Topic	Presenter
eCTD Guidance Overview	Gary M. Gensinger Director, Regulatory Review Support Staff Office of Business Process Support
Module 1 Overview	Bronwyn Collier Associate Director for Regulatory Affairs Office of Drug Evaluation III
Module 2 Overview	Virginia Ventura Regulatory Information Specialist Regulatory Review Support Staff
Module 3 Overview	Norman Schmuff, PhD Deputy Division Director Office of New Drug Chemistry III
Module 4 & 5 Overview	Armando Oliva, MD Associate Director for Policy Office of New Drugs
Successful eCTD preparation	Gary M. Gensinger Director, Regulatory Review Support Staff Office of Business Process Support