

# **eCTD Tutorial**

*Friday, April 22, 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.

<b>Topic</b>	<b>Presenter</b>
eCTD Guidance Overview	Gary M. Gensinger Director, Review Technology Staff Office of Information Management
Module 1 Overview	Bronwyn Collier Associate Director for Regulatory Affairs Office of Drug Evaluation III
Module 2 Overview	Stephen Wilson, PhD Deputy Division Director Division of Biometrics II
Module 3 Overview	Norman Scmuff, PhD Deputy Division Director Office of New Drug Chemistry III
Module 4 Overview	Stephen Wilson, PhD Deputy Division Director Division of Biometrics II
Module 5 Overview	Armando Oliva, MD Associate Director for Policy Office of New Drugs