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# Integrated Assessment of U.S. Marketing Applications: A View into FDA Internal Operations

**Amy Bertha**

Senior Director, Regulatory Policy

Regulatory Affairs, Americas

Bayer

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# Agenda

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## **Integrated Assessment of Marketing Applications Overview**

Rhonda Hearn-Stewart, MD

Associate Director, Implementation for the Integrated Assessment of Marketing Applications, Special Programs  
Office of New Drugs, Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

## **Integrated Assessment Process: ORO Regulatory Project Management Perspective**

Jennifer Mercier

Director, Office of Regulatory Operations  
Office of New Drugs, Center for Drug Evaluation and Research  
U.S. Food and Drug Administration



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## **INMAZEB Case Study: Industry Perspective**

Janie Parrino, MD

Executive Director, Regulatory Affairs  
Regeneron Pharmaceuticals, Inc.

## **INMAZEB Case Study: FDA Perspective**

John Farley, MD MPH

Director, Office of Infectious Diseases  
Office of New Drugs, Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

## **Q&A**



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# Thank You

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