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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Integrated Assessment of Marketing Applications
Overview
Rhonda Hearns-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
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
Thank You

Amy Bertha
Senior Director, Regulatory Policy
Regulatory Affairs, Americas
Bayer

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