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Session #368: Predicting Future Generic Drug Competition: Powering Strategic Planning Using Quantitative Methods and Modeling

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Learning Objectives

1. Discuss examples of applications of quantitative modeling and methods to strategic planning related to the timing of potential generic drug submission;
2. Summarize best practices from the experiences of success and failure;
3. Identify the developing trend in using quantitative methods and modeling for strategic planning.

Presentations & Speakers:

- Predictive Analysis of First ANDA Submission for NCEs Based on Machine Learning Methodology
  Meng Hu, PhD
  Scientific Lead, Division of Quantitative Methods and Modeling, ORS/OGD/CDER/FDA

- Product Selection Drivers for Large Generic Drug Companies
  Nicholas Cappuccino, PhD, MBA
  Vice President, Quality and Scientific Affairs, Dr. Reddy's Laboratories

- Product Selection Drivers for Smaller Generic Drug Companies
  Charles DiLiberti, MS
  President, Montclair Bioequivalence Services, LLC

Panel discussion and Q&A (30') upon conclusion of the presentation (3x15')

Panel Question 1:

What are major difference and similarities in product selection considerations for small and large firms?

Panel Question 2:

In a real world situation for product selection, how much of the decision making is based on judgmental calls as opposed to a data-driven process? How dynamic can the whole decision making process be and how likely a decision can be reversed based on new information /data?

Panel Question 3:

What is your current confidence level in using quantitative methods and modeling to support portfolio decision making and product selection?