Regulatory Gaps/Challenges for Regulation of Next-Generation Influenza Vaccines

• General Principles
  – Clinical development and evaluation of a next-generation vaccine will follow the same general pathway as for other vaccines
  – Design of trials will depend on the proposed indication and the characteristics of the specific product under development
Regulatory Gaps

• **Product-specific challenges**
  – Assays to measure vaccine potency/stability
  – Determination of vaccine formulation, dosage, and schedule

• **Evaluation of vaccine response**
  – Defining/demonstrating cross-protection
  – Determination and measurement of appropriate immunological response

• **Clinical trial design**
  – Definition of the indication
  – Placebo-controlled vs. comparative efficacy
  – Non-inferiority/superiority
  – Number of clinical trials
  – Challenge studies

• **Safety**
  – Product specific issues
  – Risk mitigation
  – Vaccine-associated enhanced respiratory disease