

## GENERIC DRUGS: BENEFITS AND CHALLENGES

- Brief overview of pharmaceuticals in the U.S. healthcare system
- Economic impact of generic utilization in the U.S.
- Generic Drugs: Quality and Equivalence Issues
  - FDA mandated drug product quality considerations
    - Inactive ingredients
    - Manufacturing standards
    - FDA facility inspection requirements
  - Therapeutic equivalence determinations
    - Scientific approaches to bioequivalence
      - Use of bioequivalence for brand and generic drugs
    - Special considerations
      - Narrow therapeutic index drugs
      - Highly variable drugs
      - Anticonvulsants
      - Anticoagulants
      - Immunosuppressants, etc.
      - Topicals
      - Nonabsorbed oral products
- Challenges
  - Complex products/dosage forms
    - Drug-device combinations
    - Biologics
    - Complex active ingredients
    - Liposomal/nanotechnology
  - Product recalls
  - Globalization of the supply chain
- Summary