U.S. FOOD & DRUG ADMINISTRATION

Clearing the Path for Modeling and Simulation in Drug Applications

Robert Lionberger

May 2, 2024

CRCG Workshop: Considerations and Potential Regulatory Applications for a Model Master File

Workshop Goal

- Modeling and simulation makes drug product development and regulatory assessment more efficient
  - Patient access to both innovative and affordable medicine
- Prepare for a future where it is more common for applications to FDA to include modeling and simulation

Model Master File Advantages

- Reusable
  - Efficient product development and application assessment
  - Don’t duplicate review
- Scalable
  - More model submissions in the future
- Support an “Eco-system” for model development
  - Models are not just for applicants with “in-house” expertise
- Consistency
  - FDA assessment questions are consistent across applicants
- Support Innovative Approaches
  - Regulatory risk of using novel approaches

Scale of the Generic Drug Program

- Nearly 1000 generic drug application submissions per year
- Modeling and Simulation is more useful for generic drug development because generic drug development relies on the established safety and efficacy of an approved product
- Efficiency is essential!

Scale of the Generic Drug Program

- Many reference listed drugs have multiple ANDA submissions
- Consistency is essential!
  - Modeling and simulation should be evaluated similarly for all applicants
  - FDA also evaluates NDA (b2) submissions that build on safety and efficacy of an approved product

Lower the Risk to Innovation

- Inclusion of a modeling approach in application to FDA has some risk of unexpected questions
  - Pre-ANDA product development meetings and Model Integrated Evidence pilot
  - Model Master Files can build confidence that the approach has been documented appropriately and has been used

Summary

- Today we will dig deeply into how the MMF concept can contribute to a wide range of drug applications and use cases
- Remember the major goal
  - Modeling and Simulation make drug product development and regulatory assessment more efficient
  - Patient access to innovative and affordable medicine


FDA
U.S. FOOD & DRUG
ADMINISTRATION