Model Master File: Considerations on Development and Regulatory Role

Considerations and Potential Regulatory Applications for a Model Master File

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What is an MMF?

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MEETING REPORT

Best Practices for Utilizing Modeling Approaches to Support Generic Product Development: A Series of Workshop Summary Reports

The Role of Model Master Files for Sharing, Acceptance, and Communication with FDA

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What is an MMF?

"Model Master File (MMF) refers to a quantitative model or a modeling platform that has undergone sufficient model Verification & Validation to be recognized as sharable intellectual property that is acceptable for regulatory purposes."

https://pubmed.ncbi.nlm.nih.gov/38413548/

Discussions at this MMF Workshop

- Similarities between DMFs and MMFs
- Operational aspects of MMFs
- Regulatory, fiinancial and other considerations for MMFs
- M&S Applications Across Products
  - Oral dosage forms (Day 1)
  - Injectable drug products (Day 1)
  - Locally acting drug products (Day 2)
  - Innovator drugs (Day 2)

We are Delivering A Clear Message

M&S approaches are being used by the generic and new drug industry for internal decision making and to support regulatory submissions

- Support candidate and formulation selection
- Support drug lifecycle: manufacturing, formulation and site changes
- Perform risk-based assessments in lieu of in vivo studies
- Inform alternative study designs (study duration, population selection, etc.)
- Inform decision making in rare disease and special populations
- Increase understanding of disease state and progression and biological phenomena and their interplay to develop decisions on dose adjustments, drug safety, and clinical practice

What is the Task of the Workshop Attendees?

Develop a path forward where MMF Applications may …

- serve as an applicant/sponsor-FDA communication tool
- increase model sharing
- support standardization in model building and V&V
- serve as a benchmark for further model advancements
- increase confidence in modeling and simulation approaches

Small Group Discussion Sessions

Discussion Topics

1. What are key considerations when developing an MMF in terms of its content and format?
2. What are the potential benefits/incentives for stakeholders to develop and use a MMF for oral dosage forms and long acting injectables in the generics space?
3. What are the considerations and overall input on two potential MMF case examples?
4. What are the potential benefits/incentives for stakeholders to develop and use an MMF in the area of new drugs and generic locally acting drug products?
5. What are relevant considerations in the MMF life cycle: MMF versioning?

Examples of Potential MMFs

- Developed by the workshop organizing committee and additional FDA and industry representatives
- Potential MMFs (mocks), but FDA is not the owner
- Objective: steer up discussion on the development and implementation of MMFs in regulatory submissions that include M&S approaches

Case study 1: Systemic disposition model for active ingredient X

Case study 2: Modeling methodology of Drug Y to assess the impact of Particle Size Distribution (PSD) of drug Y soft gel capsules on bioequivalence (BE)

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ADMINISTRATION

Utility of the MMF

Regulatory

- Improve regulatory assessment efficiency
- Improve interdisciplinary communication and exchange of (technical) knowledge
- Repository of institutional knowledge related to the use of M&S applications

Pharmaceutical industry

- Reduce time, cost and other resources for the development and regulatory submission of M&S approaches
- Reduce redundancy in data generation
- Ensure availability of M&S applications to all applicants