

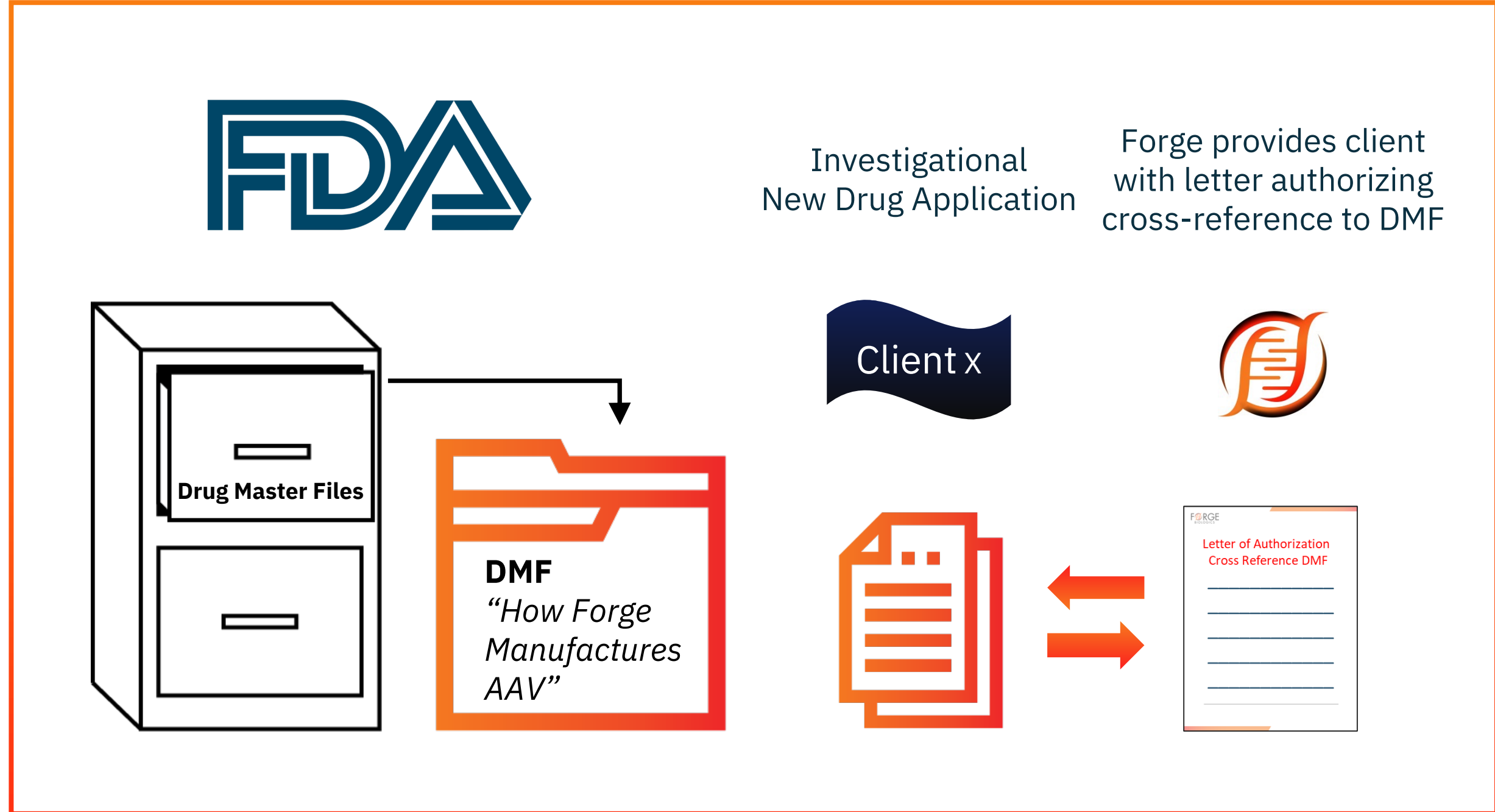
# The Role of a Drug Master File in Multi-Program Data Sharing and Review Efficiency

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## What is a Drug Master File?



## What are the types of Drug Master Files?

- Type II**
  - Intermediates, DS, or DP
- Type III**
  - Packaging materials
- Type IV**
  - Excipients
- Type V**
  - Information not captured in other DMFs
  - Allowed for some ANDAs but not BLAs (2025)

## Ex US Drug Master Files

| Region                                  | Use                 |
|---|---------------------|
| Canada (Health Canada) Drug Master File | Similar to US       |
| EU (EMA) Active Substance Master File   | Supports MAA        |
| Japan (PMDA) Drug Master File           | Supports MAA        |
| South Korea (MFDS) Drug Master File     | Support CTA and MAA |

## Referencing Drug Master Files streamlines application approvals

**PreCheck Program**  
*Type V DMF required*

**GOAL**

- Strengthen US drug manufacturing
- Improve efficiency of Agency review

**SOLUTION**

- FDA should consider allowing reference of DMFs for BLA/MAA
- DMFs reduce redundant reviews

**Plausible Mechanism Pathway (Baby KJ)**  
*Site for vetted processes*

**GOAL**

- Support bespoke treatments for rare diseases
- Improve efficiency of Agency review

**SOLUTION**

- Sponsors reference DMFs for platform processes which encourages use of a platform approach

## Client case studies show the advantages of referencing Drug Master Files

**Client A**

**PROGRAM**

- Advanced therapy medicinal product manufactured at facility participating in PreCheck program
- Phase III IND

**DMF REFERENCE**

- Module 3 of Phase III IND references Type II DMF
- PreCheck facility's Type V DMF is referenceable for BLA

**OUTCOME**

- Reduced authoring timelines enable quicker access for patients
- Saves sponsor time and money
- Enables a more efficient IND review by Agency
- Referencing Type V DMF provides a faster and smoother transition from IND to BLA

**Client B**

**PROGRAM**

- Target is a rare disease
- Characterized natural history
- Defined clinical endpoints

**DMF REFERENCE**

- Module 3 of sponsor's IND references facilities and analytics sections of CDMO's DMF

**OUTCOME**

- Reduced authoring timelines enable quicker access for patients
- Saves sponsor time and money
- Enables a more efficient IND review by Agency
- Supports use of Plausible Mechanism Pathway, may support future platform technology designation

**Client C**

**PROGRAM**

- Advanced therapy medicinal product
- Accelerated clinical program allows quick path to BLA readiness

**DMF REFERENCE**

- Module 3 of sponsor's IND references CDMO's DMF
- Sections of CDMO's DMF are shared with sponsor as program moves to pre-BLA
- CDMO's DMF is fully shared with sponsor as program moves to BLA

**OUTCOME**

- Sharing of vetted information shortens BLA process and supports accelerated clinical program

**Platform Technology Designation**  
*High value opportunity*

**GOAL**

- Enable data sharing across multiple developers
- Reduce the burden of regenerating historical data

**SOLUTION**

- Sponsors reference DMFs for mature platform processes and controls
- Expands the scope of DMFs

**Final Rule BLA**  
*Unrealized potential*

**GOAL**

- Improve efficiency of regulatory review of BLAs

**SOLUTION**

- Agency allows BLAs to mimic 2025 codification of framework permitting NDAs to reference Type V DMFs