

Drug Master Files



For Type II, Type III, Type IV

A Drug master File (US DMF) is a submission to the US FDA that may be used to provide confidential detailed information about facilities, processes or articles used in the manufacturing, processing, packaging and storing of one or more human drugs. Typically, a DMF is filed when two or more firms work in partnership on developing or manufacturing a drug product. The DMF filing allows a firm to protect its intellectual property from its partner while complying with regulatory requirements for disclosure of processing details.

- **Guidance on DMF**
- **Drug Master File Preparation**
- **US Agent Service**
- **Annual Report Preparation.**

Role of Consultant

- Guidance on US FDA Regulatory requirements
- Guidance on GMP as per 21 CFR 820
- Guidance on Product Selection and submission procedures
- Identification of test requirements (for type II DMF and III DMF).
- Identification of testing lab (for type II DMF and III DMF).
- Identification of performance and Product Conformance requirements
- Edit and organize DMF
- Submission to US Agent.



United States Agent Services

Under the Code of Federal Regulation 807.40(b) the Food and Drug Administration requires a foreign establishment to designate a United States Agent to act as their official correspondent for DMF Filing. The following are the roles and responsibilities...

- Submitting DMF to FDA.
- US FDA DMF Agent service.
- Communicating with FDA on behalf of our client.
- Assisting clients to issue LOA (letter of authorization) to FDA.
- Assistance with DMF Annual report submission to FDA.
- Assistance in DMF Closure request submission to FDA.
- Assistance in DMF Reactivation request submission to FDA. (for closed DMF)

Fees

| DMF Type | Description | Fee |
|----------|--|-------------------|
| Type 11 | Drug substance, drug product, intermediates and material used in their manufacture | \$ 3700 - \$ 4500 |
| Type 111 | Packaging | \$ 2800 |
| Type 1V | Excipients | \$ 3600 |
| | US Agent Service | \$ 649 annually |

Service available from Bangalore, India and Chicago, USA.

Travelling from the above locations and Lodging additional