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Review Article

Comparative Analysis of DMF Filing Procedure and Regulatory Requirements in India, Brazil, and Canada

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ABSTRACT

DMF is a confidential document that provides detailed information about the API dosage form in Pharmaceuticals. DMF is also about the drug product. This investigation comprehensively analyses regulatory requirements and Drug Master File filing procedures in India, Brazil, and Canada in three diverse pharmaceutical markets. The analysis explores distinct regulatory agencies governing Pharmaceuticals in each country, including the Central Drug Standard Control Organisation (CDSCO) in India, the Agência Nacional de Vigilância Sanitária (ANVISA) in Brazil, and Health Canada in Canada. Differences along with Commonalities in their DMF filling are explored in detail. Further, the paper outlines the steps involved in DMF filing, including documentation, submission and assessment, closure, and variation in the filling procedure are analyzed. The comparison of DMF filing procedures across regulatory frameworks emphasizes how crucial it is for companies to balance compliance with international standards with specific market demands. This review makes clear the challenges related to DMF filings and the importance of regulatory knowledge for pharmaceutical companies operating in different international markets. The DMF files from Canada, Brazil, and India have several distinctions and parallels. It is essential to comprehend the regulatory organizations, such as Health Canada, ANVISA, and CDSCO. This comparison analysis serves as a valuable resource for industry professionals seeking insight into the intricacies of DMF filing across diverse global pharmaceutical markets.

Keywords: Active Pharmaceutical Ingredient (API), CPID (Certificate Product Information Document), DIFA (Active Pharmaceutical Ingredient dossier or the DMF), MF (Master File), US Food and Drug Administration (USFDA).

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INTRODUCTION

A Drug Master File (DMF) is a formal submission to the USFDA, designed to offer confidential and comprehensive insights into the facilities available, plan of action, or materials employed in the production, processing, packaging, and preservation of various Pharmaceutical by-products for the use of humans.[1]

The contents within a DMF play a pivotal role in bolstering or supporting applications for NDA (New Drug Application), IND (Investigational New Drug) clearance, or ANDA (Abbreviated New Drug Approval).[2] A DMF is a document linked to the quality assessment of drug substances, excipients, and packaging materials, ensuring their high quality for evaluating New Drug Applications.[3] Typically, DMFs are concerned with the CMC (Chemistry, Manufacturing, and Control) aspects of a drug product, such as the drug substance, excipient, and packaging material.[4] The DMF should be submitted within 2-3 weeks of the time limit after submitting the main document. The agency is susceptible to rejecting the DMF if not submitted in the eCTD layout. Imagine a scenario in which a foreign manufacturer is looking to secure a drug marketing license in India for a product produced in another nation. In such cases, individuals who possess Drug Master Files (DMFs) in physical paper form do not have to re-submit their entire DMFs in the Electronic Common Technical Document (eCTD) format, irrespective of whether the DMF is active or has been withdrawn. The DMF's status can be checked on the FDA website.

The drug master file is provided in 21CFR314.420. The DMF comprises two sections.

Applicant's part, this has information regarding license holder assessment of quality, license applications, and amendment applications. It normally includes a brief outline of the manufacturing method and information on potential impurities originating from the isolation procedure or degradation. Restricted part This has secured information that is revealed to the respected regulatory authorities.[5] The Detailed information on individual steps of the manufacturing method such as

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reaction condition, temperature, validation, and evaluation data for certain critical steps of the manufacturing method.

DMF holds a pivotal role in assisting drug product manufacturers and in providing essential documentation for the registration and approval of drug products. Within the CMC portions of the drug application, aspects such as the drug's characteristics, purity, potency, and excellence are addressed. To shield proprietary and confidential information.[6] Making registered APIs available on websites is a valuable tool for promoting them to drug product manufacturers.[7]

The primary objective of a DMF is to aid in meeting the regulatory mandatories for Pharmaceutical products, showcasing their quality, safety, and effectiveness.

In India, pharmaceutical regulations are overseen by the Central Drugs Standard Control Organisation (CDSCO). Brazil's regulatory authority for healthcare products is the Agência Nacional de Vigilância Sanitária (ANVISA). Canada's oversight falls under the purview of the Therapeutic Products Directorate (TPD), which regulates therapeutic products within the country. Each of these regulatory bodies plays a crucial role in ensuring the safety, efficacy, and quality of pharmaceuticals within their respective jurisdictions.

All things considered, the choice of these nations offers educational information on the various regulatory frameworks and practices affecting DMF submissions in various international pharmaceutical markets. This review clarifies the DMF Filling process with regulatory systems regulating three distinct pharmaceutical markets in India, Brazil, and Canada. Identifying the distinct regulatory environments and the common guidelines for DMF submissions provides important insights into the nuances of international pharmaceutical regulation.

DMF system in India

The regulatory authority of India, specifically the "Central Drugs Standard Control Organization (CDSCO)", has not issued any official guidelines for Drug Master Files (DMF). Typically, in India, a United States standard format of DMF is employed for the confidential submission of information regarding both drug substances and drug products to the relevant regulatory bodies.[8] In the USA guidelines for DMFs were instituted in September 1989 through the 'Guideline for Drug Master Files'.[9] Suppose a foreign manufacturer intends to acquire a marketing license in India for a product manufactured or produced in a country other than India. In that case, they must provide all the mandatory Chemistry, Manufacturing, and Controls (CMC) data for the drug product in the Indian CTD (*Common Technical Document*) layout to the Central Drugs Standard Control Organization (CDSCO). Suppose regulatory bodies like the US FDA, European authorities, or any other nation have granted a Drug Master File (DMF) status to foreign drug items, including drug compounds, intermediaries, and so forth.

In that case, these should be included in the application approval of the respective drug products in India. It's worth noting that India holds a prominent position with the highest number of DMFs submitted to the USFDA.[10]

Types of DMF

As the DMF system in India is followed concerning USFDA, the Types of DMF in India are the same as those of the USA.

There are mainly five types of DMF in the US

- Type I: "Manufacturing site, Facilities, Operating Procedures, and Personnel (no longer applicable)"
- Type II: "Drug Substance, Drug Substance intermediate, drug product, and material used in their preparation."

Drug Substance

Present a brief overview of the critical stages in the manufacturing and quality control of the drug intermediate or active substance.

Drug Product

Usually, comprehensive manufacturing instructions and quality control methods for finalized dosage forms are included in an IND, NDA, ANDA, or Export Application. In cases where it's impractical to incorporate this data in those applications, it should be provided in a DMF.

- Type III: "Packaging material"

Every packaging material is distinguished based on constituents, purpose, composition, and the criteria for its approval, necessitating the inclusion of the manufacturer's name and acceptance standards within the DMF.

Toxicological data related to these packaging materials are incorporated within this DMF type, or they can be cross-referenced to an additional document where available.

- Type IV: "Excipients, Flavour, Colorant, Essence, and material used in their production"

Every added ingredient is distinctly recognized and defined by its manufacturing process, testing protocols, and criteria for release. The inclusion of toxicological information regarding these materials is expected within this DMF category. Standardly, the official compendia and FDA regulations (21 CFR) are considered reliable sources for release testing, specifications, and safety criteria.

- Type V: "FDA accepted reference information"

If a holder intends to submit data and supplementary information within a DMF that doesn't fall under the purview of Types I to

IV, such credential material is applied for sterile manufacturing facilities and contract establishments handling biotech products approved by the FDA.[11]

In this context, Indiums are ordinarily presented in the English language, which serves as the established standard for regulatory submissions and documentation within the nation's Pharmaceutical and healthcare sectors.

Drug Master File (DMF) Filing Procedure in India

Assemble all relevant documentation, including Chemistry, Manufacturing, and Controls (CMC) data and other necessary information related to the drug product.

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Determine the appropriate type of DMF based on the nature of the information being submitted.

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Organize and compile all information in the format specified by the Central Drugs Standard Control Organization (CDSCO), which typically follows the Common Technical Document (CTD) format.

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Conduct internal quality control checks to verify the accuracy, completeness, and compliance of the DMF with regulatory standards.

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Submit the DMF application to CDSCO in India. Include a cover letter and the required application fees. You will receive an acknowledgment receipt upon submission.

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CDSCO will review the DMF

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During the review process, CDSCO may request additional information or clarification.

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Based on the review, CDSCO will decide whether to approve or reject the DMF application.

↓

Upon approval, you will receive a reference number. This number is essential for future drug product registration applications.

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In the event of any changes to the drug product or CMC data, ensure prompt submission of updates or amendments to CDSCO following their guidelines.

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Drug Product Registration

Closure of DMF

If a holder wishes to conclude the DMF, they must submit a formal request to the DMF personnel, detailing the closure. The regulatory authority retains the right to cease a DMF if it lacks an annual update including the names of authorized individuals responsible for updating DMF data and a record of any alteration made since the last annual report. In such cases, the holder will be notified by the FDA about the agency's plan to close the DMF.[12]

DMF system in Brazil

Brazil, the largest nation in the South American region, is overseen by the regulatory authority ANVISA, which stands for 'Agência Nacional de Vigilância Sanitária'. This name is originally in Portuguese and translates to 'National Health Surveillance Agency' in English. On January 26, 1999, it was officially renamed "Brazilian Health Surveillance Agency". Brazil has emerged as the second-largest pharmaceutical market among developing economies, and it anticipates annual economic growth rates ranging from 7% to 10% until 2020, as reported by Afonso *et al.*, in 2015. ANVISA's vision is to establish itself as a respected and integral component of the Brazilian Unified Health System, exemplifying nimbleness, modernity, transparency, and adherence to domestic and international standards in health surveillance and regulation.[11,13]

Regulatory submission process

Over the preceding 5 years, ANVISA has continuously revised its regulations and formulated various guidelines. The updated submission process for Active Pharmaceutical Ingredients (APIs) under ANVISA's regulatory framework is detailed, beginning with the preparation of required documents, followed by their submission to the regulatory authority, the conduction of a comprehensive review, and the final approval of the API. This systematic process is designed to streamline the submission and evaluation of API dossiers in alignment with ANVISA's evolving regulatory guidelines, as shown in Figure 1. The main challenge in successfully submitting a regulatory file to ANVISA is closely associated with the limited familiarity that Biopharmaceutical companies have with the process. ANVISA's website is currently accessible in two languages: English and Portuguese i.e., The native

language of Brazil. Nevertheless, the version written in English lacks comprehensive content and fails to include all relevant information found in the Portuguese edition. To improve our understanding of the ANVISA process, we draw a comparison between the registration procedure and a more familiar system used by the FDA.[12,14]

Closure of DMF

In the Brazilian context, closing a Drug Master File (DMF) entails informing the regulatory body of Brazil, ANVISA (Agência Nacional de Vigilância Sanitária), and adhering to prescribed protocols to formally conclude or terminate the DMF submission once its original objectives have been met.

DMF system in Canada

A DMF (Drug Master File) is a documentation source offering details regarding particular processes or elements employed in the production, processing, and packaging of a Pharmaceutical product. The DMF serves as an effective means to convey information to Health Canada. Pharmaceutical manufacturers have the privilege to cite the DMF to substantiate their NDSs (New Drug Submissions), ANDSs(Abbreviated New Drug Submissions), SNDS (Supplements to New Drug Submissions), SANDS (Supplements to Abbreviated New Drug Submissions), NCs (Notifiable Changes), NPN (New Product Number) applications, and CTAs (Clinical Trial Applications). It's worth noting that DMFs can be referenced by multiple pharmaceutical manufacturers.[14]

Types of DMFs

A revised version was published in the year 1994 in the name of 'CANADIAN DMF' which contains 2 parts,

The applicant's part and,

The restricted part, and is of 4 types,

Type 1-"Active Substance Master File (ASMF)"

For pharmaceuticals: API in the manufacturing of a drug substance.

For biologics: includes process intermediates, vaccine antigens, and excipients of biological origin.

Type 2-"Container Closure System MasterFile (CCSMF)"

Type 3-"Excipient Master File (EMF)"

comprises information related to an excipient, coating ingredients, colorants, flavors, and other additives.

Type 4-"Dosage Form Master File (DFMF)"

Covers information related to dosage form and their intermediates.

Need for Filing DMF

Secrecy

DMF enables pharmaceutical companies to send regulatory bodies in confidence, comprehensive data regarding the manufacturing procedures, quality assurance measures, and specifications of Active Pharmaceutical Ingredients (APIs) without sharing this data with rival companies or the general

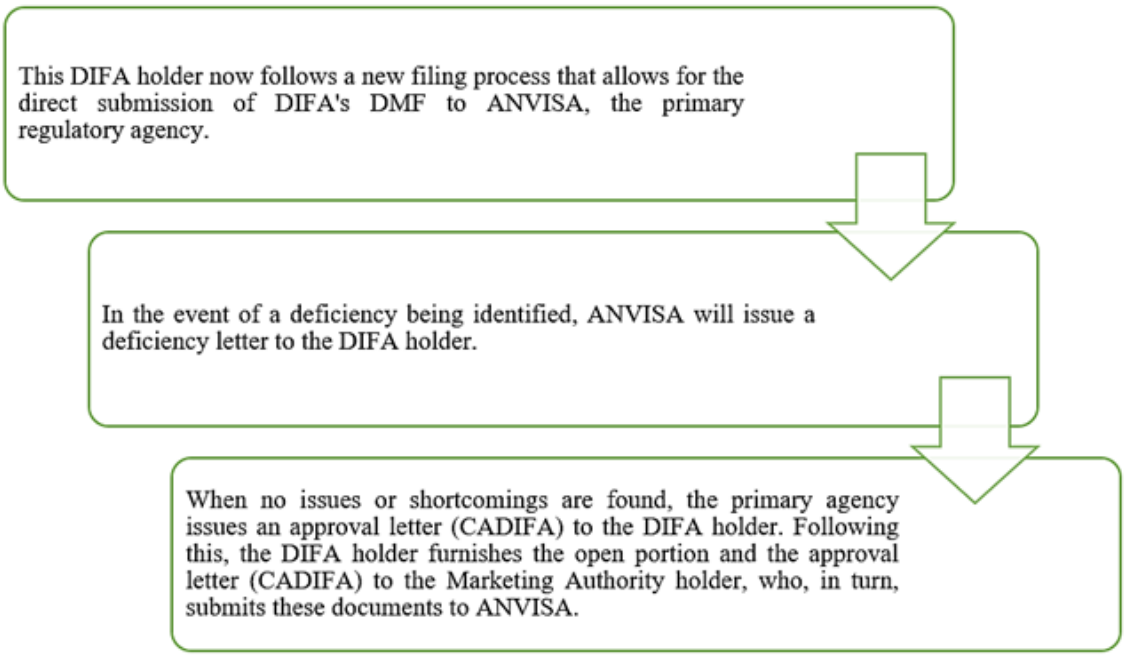

Figure 1: Flowchart illustrating the updated API regulatory framework submission procedure.

public. This guarantees regulatory compliance while safeguarding confidential information.

Regulatory Compliance

DMF submissions are required by several regulatory bodies. Submitting a DMF proves that the drug's Active Pharmaceutical Ingredient (API) is produced by Good Manufacturing Procedures (GMP) and other legal requirements.

Global Market Access

Having a DMF can make the registration procedure easier in some nations for pharmaceutical businesses looking to market their goods abroad. DMF files are accepted as supporting documentation by a large number of regulatory bodies across the globe for evaluating the efficacy, safety, and quality of pharmaceutical good.

Quality Control

Submitting a DMF shows a dedication to both regulatory compliance and quality control. It enables stakeholders and regulatory bodies to confirm that the API used in pharmaceutical goods satisfies set quality requirements and standards.

Canadian DMF Filling System

Type I ASMFs and Type IV Dosage Form Master Files consist of two distinct sections:[9]

The sections labeled *'Restricted Part'* and the applicant's *Part'* are shared with the applicant, usually integrated into the applicant's drug submission or CTA (Clinical Trial Application), along with the accompanying Letter of Access (LoA).

In the case of Type I ASMFs, the *'Applicant's part'* includes information considered non-confidential for the applicant by the ASMF Holder, whereas the *'Restricted part'* contains information marked as confidential by the ASMF Holder. Health Canada deems an MF incomplete if both sections are not submitted. For the MF registration, different electronic documents are required for attachment like the MF name with a signed cover letter MF agent authorization letter if applicable, MF application form, Fees form, Certificate of suitability (CEP), and Letter of Acess (LOA).

For *'Type I ASMFs'* and *'Type IV Dosage Form Master Files'*, additional electronic documents are required which include Applicant and the Restricted Parts as a Copy of the *'Quality Overall Summary (QOS)'* in Word format, Certified Product Information Document (CPID) in Word format, if applicable.

Table 1: DMF filing Procedures in India, Brazil and Canada.

	India 	Brazil 	Canada 
Health Authority	Central Drug Standard Control Organisation (CDSCO).	Agência Nacional de Vigilância Sanitária (ANVISA).	Health Canada.
Establishment	The CDSCO in India was established in 1940.	Established on January 26, 1999, the agency is administratively and financially independent, managed by a 5-member board of directors.	Created as the "Department of Health" in 1919-in the wake of the Spanish flu crisis-what is known as Health Canada today was formed in 1993.
DMF	In India, a DMF (*Drug Master File*) is a detailed submission that includes information, documentation, and data on the manufacturing, processing, quality, and safety of a Pharmaceutical ingredient or component. The DMF serves as a confidential document filed with the CDSCO to support pharmaceutical product registration, approval, or licensing. It provides critical information about the quality and safety of the ingredient and its compliance with regulatory standards.	In Brazil, a DMF (*Drug Master File*) is a comprehensive document that includes information and data on the quality, manufacturing, and safety of a Pharmaceutical ingredient, excipient, or component. It is submitted to ANVISA as part of the regulatory process for pharmaceutical products. The DMF helps demonstrate compliance with regulatory standards and provides essential information to support the approval and drug registration of products in Brazil.[10,11]	DMF (*Drug Master File*) is a reference that provides details about specific processes or components used in the manufacturing, processing, and packing of the drug.[16]

Types of DMF	Type I: 'Manufacturing site, Facilities, Operating Procedures, and Personnel (no longer applicable)' Type II: 'Drug Substance, Drug Substance intermediate, drug product, and material used in their preparation'. Type III: 'Packaging material' Type IV: 'Excipients, Flavour, Colorant, Essence, and material used in their production' Type V: 'FDA accepted reference information'.[3]	No Types	Type 1-'Active Substance Master File (ASMF)',Type 2-'Container Closure System Master File (CCSMF)'Type 3-'Excipient Master File (EMF)'Type 4-'Dosage Form Master File (DFMF)'.
Letter of authorization	LOA required	LOA required	LOA required
Mandatory	No	No	No
Language	English	Portuguese, English, and Spanish.	English
Submission of DMFs	eCTD format	eCTD format	eCTD format
Fees	No fees	The official fees for medicinal products in Brazil range from 585,72-157,416 reais for new drugs. For medical devices, the fees range from 702,86-49,641.20 reais.	The revised fee structure increases the cost of filling a new master file registration by $1,379 (Canadian), and cost of filling an update by $599, and the cost of filling a letter of access by a$196.[17]
Updating	Not annually	When requested by ANVISA.	Bi-annually
Approval timeframe	Takes several weeks to months, depending on the complexity changes.	Takes several weeks to months.	A few months.

For Type II CCSMF (*Container Closure System Master File*) and Type III EMF(*Excipient Master File*), it is permissible to include multiple components within a single MF, as long as those components share similarities. In a single MF, a maximum of 50 components are accepted. Any additional components beyond this limit should be submitted in a new MF.

Closure of DMF

If an owner wishes to withdraw a DMF, they must formally notify Health Canada in writing and provide a roster of the Canadian Customers dependent on their DMF. Health Canada reserves the right to close a DMF that has not received updates for five years.

Comparison of DMF filing

The comparison highlights significant differences in regulatory approaches, such as Brazil's multilingual requirements, Canada's structured fee system for updates, and India's adoption of the USFDA standard for DMF filings despite the absence of official domestic guidelines as shown in Table 1. The rationale for this comparative analysis lies in the growing globalization of the pharmaceutical industry, where regulatory compliance is critical for market access.

CONCLUSION

The detailed analysis of Drug Master File (DMF) filing processes and regulatory requirements in India, Brazil, and Canada highlights the crucial role DMFs play in simplifying the drug product application process. By structuring and presenting essential information, DMFs are key to securing Marketing Authorization (MA) by demonstrating the quality, safety, and efficacy of medicinal products. The primary goal of DMFs is to ensure compliance with regulatory standards for pharmaceutical products. The distinct regulatory frameworks, documentation requirements, and submission procedures in each country reflect varied approaches to safeguarding the safety and effectiveness of pharmaceuticals.

The scope of DMF filing could be enhanced by exploring recent advancements in pharmaceutical regulations, such as the adoption of digital signatures, electronic submissions,

blockchain technology for data integrity, and harmonization initiatives led by global organizations like the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Incorporating qualitative research techniques, such as interviews with pharmaceutical professionals, regulatory experts, and stakeholders involved in DMF submissions could provide valuable outcomes.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DMF: Drug Master File; **CDSCO:** Central Drug Standard Control Organisation; **ASMF:** Active Substance Master File; **ANVISA:** Agência Nacional de Vigilância Sanitária; **QOS:** Quality Overall Summary; **MA:** Marketing authorization; **EMF:** Excipient Master File; **CEP:** Certificate of Suitability; **CCSMF:** Container Closure System MasterFile; **CTA:** Clinical Trial Application; **LoA:** Letter of Access, **CTD:** Common Technical Document; **CCSMF:** Container Closure System Master Fil; **CDER:** Centre for Drug Evaluation and Research; **EMF:** Excipient Master File; **DFMF:** Dosage Form Master File; **TPD:** Therapeutic Products Directorate; **CPID:** Certified product information document.

SUMMARY

This investigation provides a comprehensive analysis of Drug Master Files (DMFs) and regulatory procedures in the pharmaceutical markets of India, Brazil, and Canada. It highlights the pivotal role of DMFs as confidential repositories of accurate information essential for regulatory compliance and market approval. Through an in-depth examination of regulatory frameworks and DMF filing procedures, the paper elucidates the distinct regulatory landscapes in each country while also identifying commonalities shared across diverse pharmaceutical markets. Additionally, the paper outlines the DMF filing procedures, encompassing documentation, submission, assessment, closure, and variation. Through a comparative analysis of DMF filing procedures across these countries, the review identifies both differences and similarities, enhancing understanding of global pharmaceutical regulation and emphasizing the importance of adherence to regulatory guidelines and best practices for compliance and market access. It highlights the significance of findings for pharmaceutical professionals, regulatory experts, and researchers engaged in drug development and market authorization processes, underscoring the role of regulatory compliance in maintaining the integrity of pharmaceutical products.

REFERENCES

1. Drug Master Files: Guidelines|FDA [Internet]. [cited 2025 Jan 21]. Available from: https://www.fda.gov/drugs/guidances-drugs/drug-master-files-guidelines
2. Kota V, Sravanti L, Bandla R, Kumar R, Juturi R. Filing of DMF in the US, EU, and India, and its comparative review. International Journal of Drug Regulatory Affairs [Internet]. 2021;9(1):22-32. Available from: https://www.ijdra.com/index.php/journal/article/view/453
3. Ensor, Frederick. Drug Master Files Guidance for Industry DRAFT GUIDANCE. [cited 2025 Jan 21]; Available from: https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances
4. Shailaja P, Sunil K, Pushpalatha V, Snehlatha G, Ashok KS, Scholar R. A Review on DMF Filing in EU, USA and Australia. IJFMR - International Journal for Multidisciplinary Research [Internet]. 2022;4(5). Available from: https://www.ijfmr.com/research-paper.php?id=713
5. Agarwal P, Badjatya JK. DMF FILING IN US, EUROPE AND CANADA. International Journal of Drug Regulatory Affairs [Internet]. 2015;3(4):9-17. Available from: https://www.ijdra.com/index.php/journal/article/view/172
6. Kumar P, Mangla B, Singh S, Rana A. DRUG MASTER FILE: GLOBAL REGULATORY ISSUES AND CHALLENGES. [cited 2025 Jan 21]; Available from: www.ejbps.com
7. Singh SS, Kumar P, Mangla B, Singh S, Rana A. DRUG MASTER FILE: GLOBAL REGULATORY ISSUES AND CHALLENGES [Internet]. 2018. Available from: www.ejbps.com
8. Spk Y. Pharmaceutical Drug Regulatory Affairs Journal Filing of DMF in US, Canada and Europe Pharmaceut Drug Regula Affair J.
9. Patel R, Girase KR, Rao VT, Patel AA, Patel RJ. Assessment of Regulatory requirements and filing procedure of Drug Master File for Brazil, Europe and South Africa. International Journal of Drug Regulatory Affairs. 2022;10(2):14-27.
10. Huynh-Ba K, Beumer Sassi A. ANVISA: an introduction to a new regulatory agency with many challenges. AAPS Open. 2018;4(1).
11. Draft Guidance Document: Master Files (MFs) - Procedures and Administrative Requirements - Canada.ca [Internet]. [cited 2025 Jan 21]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/drug-products/draft-guidance-document-master-files-procedures-administrative-requirements.html
12. Gurram I, Kavitha MVS, Reddy N, Nagabhushanam M V. Drug Master File Filing in US, Europe, Canada and Australia. Journal of Pharmaceutical Research. 2017;16(2):160.
13. Canada H, Products H, Branch Therapeutic Products Directorate F. Guidance Document: Master Files (MFs) - Procedures and Administrative Requirements, mf-guide-ld-fm-eng.pdf. 2008.
14. Health Canada - Canada.ca [Internet]. [cited 2025 Jan 21]. Available from: https://www.canada.ca/en/health-canada.html

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