WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 22, 294-308. Review Article ISSN 2277–7105

FROM DOSSIER TO APPROVAL: A COMPARATIVE REVIEW OF SUBMISSION FRAMEWORKS ACROSS THE FDA, HEALTH CANADA, AND EMA

J. Swapna[1], M. Swetha[2], B. Chandra Shekhar Reddy[3*]

[1]Student, Department of Regulatory Affairs, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya, Affiliated to Osmania University.

[2]Associate Professor, Department of Regulatory Affairs, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya, Affiliated to Osmania University.

[3]Professor & Head, Department of Pharmaceutics, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya, Affiliated to Osmania University.

Article Received on 21 Oct. 2026,
Article Revised on 11 Nov. 2026,
Article Published on 16 Nov. 2026,

https://doi.org/10.5281/zenodo.24272515

***Corresponding Author**

B. Chandra Shekhar Reddy

Student, Department of Regulatory Affairs, Sarojini Naidu Vanita Pharmacy Maha Vidyalaya, Affiliated to Osmania University.

How to cite this Article: J. Swapna[1], M. Swetha[2], B. Chandra Shekhar Reddy[3*] (2026). From Dossier To Approval: A Comparative Review Of Submission Frameworks Across The Fda, Health Canada, And Ema. World Journal of Pharmaceutical Research, 15(22), 294–308

This work is licensed under Creative Commons Attribution 4.0 International license.

ABSTRACT

Regulatory submissions serve as the formal mechanism by which sponsors demonstrate that a medicinal product meets jurisdiction-specific standards for quality, safety, and efficacy. While the United States Food and Drug Administration (US FDA), Health Canada, and the European Medicines Agency (EMA), along with national competent authorities, extensively rely on International Council for Harmonization (ICH) principles and the Common Technical Document (CTD), their legal frameworks, application routes, review management, expedited pathways, and post-authorization obligations differ. This review systematically compares these three regulatory systems for human medicinal products, focusing on investigational-stage authorization, marketing applications, dossier architecture, electronic submission, review timelines, lifecycle management, and pharmacovigilance. The FDA operates through a federal agency model utilizing IND, NDA, ANDA, and BLA pathways; Health Canada implements the Food and Drugs Act and Food and Drug Regulations via clinical trial applications and NDS/ANDS families; and the EU integrates EMA scientific coordination with European Commission decisions for centralized products and national

authority procedures for other products. Although a shared CTD core enables dossier reuse, regional Module 1, forms, labeling, administrative data, and procedural expectations remain distinct. Illustrative timelines clarify that published review targets should not be interpreted as total development-to-market durations, as clock stops, screening, sponsor response periods, and post-opinion decision steps vary. Practical examples demonstrate how a single global dossier can be adapted for three regions without presuming that approval in one jurisdiction automatically confers access to another market. The review concludes that early regulatory strategy, robust data, lifecycle-ready eCTD publishing, and region-specific planning are critical for efficient global development.

KEYWORDS: regulatory submissions; US FDA; Health Canada; European Medicines Agency; CTD; eCTD; NDA; NDS; marketing authorization; pharmacovigilance.

1. INTRODUCTION

Medicinal product regulation seeks to ensure that medicines available to patients have an acceptable benefit–risk balance and are consistently manufactured to appropriate quality standards. A marketing application is not simply a collection of study reports; it is an integrated scientific argument connecting product quality, nonclinical safety, clinical efficacy, proposed use, manufacturing controls, and risk management. In the United States, the Federal Food, Drug, and Cosmetic Act and Public Health Service Act provide the statutory foundation for drug and biological product oversight.[1,2] In Canada, the Food and Drugs Act and Food and Drug Regulations establish the legal basis for authorization and post-market controls.[3,4] In the European Union (EU), Regulation (EC) No 726/2004 as well as Directive 2001/83/EC define centralized and national authorization frameworks.[5,6]

Global development increasingly relies on harmonized scientific standards. ICH guidelines align expectations for quality, safety, efficacy, and multidisciplinary topics, while the CTD establishes a common dossier structure.[7–10] However, harmonization does not supersede regional legal requirements. Sponsors must select the appropriate legal route, fulfill regional administrative obligations, address local labeling, and submit through the designated electronic gateway. This review compares the three regulatory systems and translates their differences into practical considerations for submission planning.

2. Methodology and Scope

This review employed a targeted analysis of primary legislation, regulatory guidance documents, ICH guidelines, and official procedural materials from the FDA, Health Canada, EMA, the European Commission, and ICH. The focus is on human prescription medicines and biologics; the principal scope excludes device, veterinary, blood, tissue, and natural health product pathways. Regulatory information was verified through November 2026. Review targets are presented as published or illustrative regulatory clocks rather than guaranteed approval times. This article provides a comparative educational synthesis and does not constitute legal advice; sponsors should consult current regional guidance prior to submission.

3. Regulatory authorities and legal architecture.

Dimension	US FDA	Health Canada	EMA / European Union
Institutional model	Federal regulator; CDER reviews most small-molecule drugs, CBER reviews many biologics.	Federal department; specialized directorates assess pharmaceutical and biologic submissions.	EMA coordinates scientific evaluation; European Commission grants centralized authorizations; national competent authorities manage national, decentralized and mutual-recognition routes.
Core legal basis	FD&C Act; Public Health Service Act; implementing regulations in 21 CFR.	Food and Drugs Act; Food and Drug Regulations.	Regulation (EC) 726/2004; Directive 2001/83/EC; related regulations and guidelines.
Typical marketing route	NDA, ANDA, BLA; supplements and amendments after approval.	NDS, ANDS, SNDS, SANDS; biologic submissions and supplements as applicable.	Centralized, decentralized, mutual recognition or national procedure, depending on product and legal eligibility.
Decision structure	FDA issues approval, complete response or other regulatory action.	Health Canada issues Notice of Compliance (NOC), NOC with conditions, or a non-compliance decision.	Centralized: CHMP scientific opinion followed by European Commission decision; other routes involve national authorities.

The term “EMA approval” is frequently used informally; however, it is more accurate to distinguish between EMA’s scientific role and the European Commission’s legal authorization decision under the centralized procedure. In decentralized and mutual-recognition procedures, national competent authorities grant national marketing authorizations following coordinated assessment.[5,6,11] This distinction matters for defining

an approval's geographic scope and identifying the authority responsible for post-authorization variations.

4. Submission pathways across the product lifecycle

4.1 United States

Before a new investigational drug is administered to humans in the United States, the sponsor generally submits an Investigational New Drug (IND) application. The IND contains nonclinical, chemistry, manufacturing and controls (CMC), clinical protocol, and investigator information. Unless a clinical hold is imposed, a study may generally proceed after the statutory 30-day period following FDA receipt.[12,13] For marketing, an NDA under section 505(b) of the FD&C Act presents evidence supporting safety and effectiveness. At the same time, an ANDA relies on the statutory abbreviated pathway and demonstrates, among other requirements, bioequivalence to a reference listed drug.[14,15] Biological products requiring licensure are submitted through a BLA under the Public Health Service Act.[2,16]

FDA review includes filing assessment, multidisciplinary scientific review, facility and manufacturing assessment, labeling negotiation, and regulatory action. Possible outcomes include approval, a complete response letter identifying deficiencies, or a refuse-to-file decision where an application is not sufficiently complete for substantive review. Post-approval changes are managed through supplements and annual reports, depending on the change's significance.[17]

4.2 Health Canada

Clinical trials of drugs in Canada generally require a Clinical Trial Application (CTA) and Research Ethics Board review. Health Canada’s default CTA review period is 30 days from receipt of a completed application; a no-objection letter (NOL) permits the trial to proceed subject to applicable requirements.[18] A New Drug Submission (NDS) is the principal route for a new drug requiring a Notice of Compliance. Generic products generally use an Abbreviated New Drug Submission (ANDS), while post-authorization changes may require a Supplement to an NDS (SNDS) or other filing category.[3,19]

Health Canada performs initial screening before scientific review. Sponsors are required to submit a complete dossier in an accepted electronic format, address screening deficiencies, and manage solicited information within the designated response period. Published performance standards vary by submission class; a standard NDS target is 300 calendar days,

while qualifying priority review submissions have a 180-day target. The Notice of Compliance with Conditions (NOC/c) policy may facilitate earlier access for serious, life-threatening, or severely debilitating conditions where evidence is promising but uncertainty persists and enforceable conditions are warranted.[20–22]

4.3 European Union / EMA

The EU offers four principal routes: centralized, decentralized, mutual recognition and national procedures. The centralized procedure is mandatory for specified categories, including many biotechnology-derived, orphan and other innovative medicines, and is available for other eligible products. The applicant submits one application to EMA; the Committee for Medicinal Products for Human Use (CHMP) conducts the scientific assessment and provides an opinion to the European Commission. A Commission decision produces a marketing authorization valid throughout the EU.[5,23]

The decentralized procedure is used when a product has not yet been authorized in an EU Member State and is not within the mandatory centralized scope. Identical applications are submitted to participating Member States, with one Reference Member State leading the assessment. The mutual-recognition procedure starts with an existing national authorization that the applicant seeks to extend to other Member States.[6,24] The centralized assessment has a maximum active evaluation timeframe of 210 days, excluding clock stops; an accelerated assessment may reduce the active review to 150 days for products of major public-health interest.[25,26]

5. CTD and eCTD: harmonized core, regional differences

The CTD organizes the application into five modules. Module 1 contains regional administrative and prescribing information; Module 2 contains summaries and overviews; Module 3 contains quality/CMC information; Module 4 contains nonclinical reports; and Module 5 contains clinical study reports.[7–10] Modules 2–5 form the harmonized scientific core, while Module 1 reflects local law and administrative needs. The eCTD adds lifecycle management by structured metadata, sequence-based submissions, hyperlinks, and technical validation.

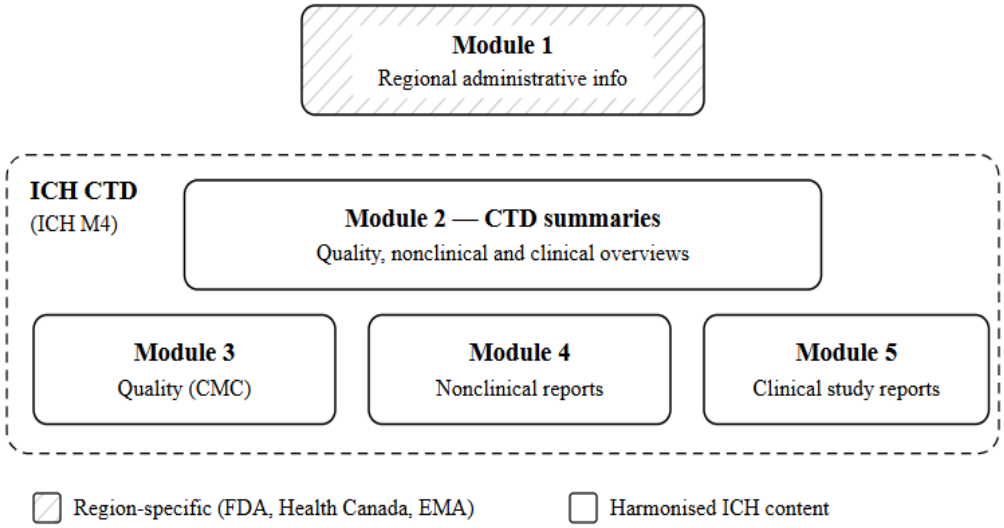


Figure 1: CTD architecture. Modules 2–5 are based on harmonized ICH content; Module 1 remains region-specific.

The FDA accepts the electronic Common Technical Document (eCTD) for major application types, including IND, NDA, ANDA, and BLA, with specific technical specifications and regional Module 1 requirements.[27,28] Health Canada accepts both eCTD and non-eCTD electronic-only formats for designated submission types via its Common Electronic Submission Gateway and Regulatory Enrolment Process; the appropriate pathway must be verified for each activity.[29,30] In the European Union, eCTD is the standard electronic dossier format, and regional requirements are maintained through EMA and EU eSubmission guidance.[31,32]

A global publishing strategy should maintain a single controlled scientific source dossier while generating distinct regional sequences. Regional content may include FDA forms and administrative declarations, Canadian forms and product monograph requirements, and EU application forms, summaries of product characteristics, labeling, and package leaflets. A dossier that is technically valid in one region may fail validation or be administratively incomplete in another.

6. Comparative assessment

Topic	US FDA	Health Canada	EMA / EU
Clinical trial entry	IND; generally, 30-day safety review period before proceeding unless hold.	CTA; default 30-day review; NOL if no objection.	Clinical Trial Regulation (EU) 536/2014; submission via CTIS and coordinated assessment.
New drug	NDA; BLA for	NDS; biologic product-	Centralized or national-

marketing	biological products.	specific requirements.	coordinated routes depending on eligibility.
Generic route	ANDA; sameness and bioequivalence framework.	ANDS; pharmaceutical equivalence and bioequivalence requirements.	Generic/hybrid applications under EU pharmaceutical legislation.
Standard review clock	PDUFA goal commonly 10 months from filing for standard original NDA/BLA; priority goal 6 months.	NDS performance target commonly 300 days; priority 180 days.	Centralized active assessment maximum 210 days, excluding clock stops.
Expedited access	Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review.	Priority Review; NOC/c policy.	Accelerated assessment; conditional marketing authorization; PRIME support.
Post-market safety	FAERS, periodic safety reports, REMS when required.	Canada Vigilance, periodic benefit-risk evaluation and risk communications.	EudraVigilance, GVP, RMP and periodic safety update reports.

The table summarizes high-level differences; the precise regulatory pathway depends on product type, legal basis, indication, development history, and regional eligibility. The term "review clock" does not represent the total elapsed time. Screening, validation, clock stops, advisory committee scheduling, sponsor responses, inspections, and final administrative decisions may extend the overall timeline.

7. Review timelines and expedited pathways

For the FDA, Prescription Drug User Fee Act (PDUFA) review goals are typically 10 months for standard applications and 6 months for priority review, measured from the date of filing rather than from the start of development.[33,34] Health Canada's New Drug Submission (NDS) performance standard is generally 300 days, with a 180-day target for accepted priority review applications; Notice of Compliance with conditions (NOC/c) has a separate pathway and performance target.[20–22] The EMA's centralized procedure involves a 210-day active assessment, which may be reduced to 150 days through accelerated assessment when specific criteria are met.[25,26]

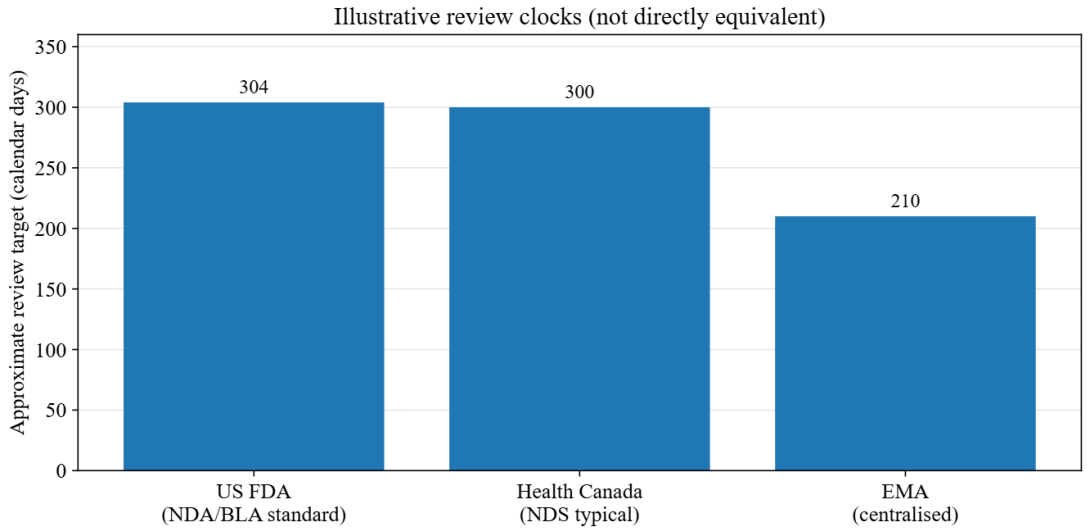


Figure 2: Illustrative standard review targets. The FDA's 10-month review period is converted to approximately 304 days for visual comparison; actual counting conventions and clock stops vary between agencies.

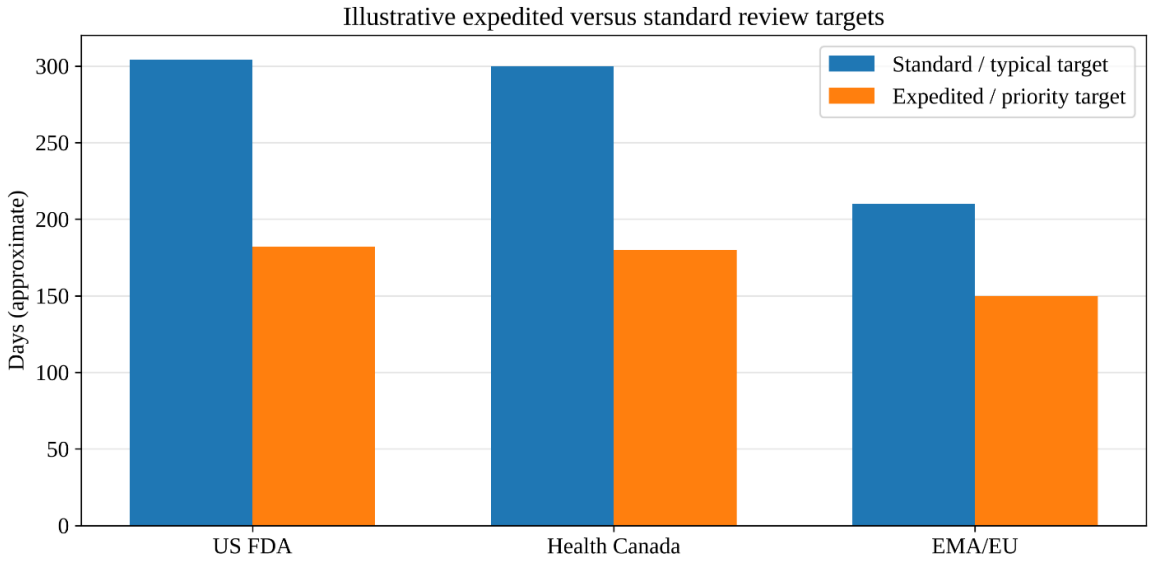


Figure 3: Illustrative regular and accelerated review targets. This comparison is indicative and does not represent a direct service-level benchmark.

FDA expedited programs serve distinct purposes and are not interchangeable. Fast Track and Breakthrough Therapy are development and review designations. Accelerated Approval is an approval pathway that may rely on a surrogate or intermediate clinical endpoint reasonably likely to predict benefit and requires confirmatory evidence. Priority Review shortens the review goal.[34–36] Health Canada's priority review is intended for drugs targeting serious, life-threatening, or severely debilitating conditions with significant therapeutic benefit.

NOC/c may be considered when promising evidence supports earlier access, subject to conditions and confirmatory obligations.[21,22]

In the European Union, accelerated assessment reduces the Committee for Medicinal Products for Human Use (CHMP) active assessment timeframe when a medicine is of major public health interest and represents therapeutic innovation. Conditional marketing authorization may be granted when complete data are not yet available, provided that the benefit of immediate availability outweighs the risk of incomplete data, subject to specific obligations.[25,37] PRIME offers early and enhanced support for medicines addressing unmet medical needs.[38]

8. Practical examples of regional submission planning

Example 1: New small-molecule medicine

A sponsor developing a new oral small-molecule medicine for a chronic inflammatory disease may utilize a common International Council for Harmonization (ICH)-aligned nonclinical and clinical program, followed by preparation of three regional marketing dossiers. In the United States, development would typically proceed under an Investigational New Drug (IND) application, culminating in a New Drug Application (NDA). In Canada, the clinical program would be supported by a Clinical Trial Application (CTA), and the marketing application would generally be a New Drug Submission (NDS). In the European Union, the sponsor would first assess centralized-procedure eligibility; if not eligible, a decentralized or national route may be considered. The same pivotal trial reports can populate Common Technical Document (CTD) Module 5, but regional Module 1, proposed labeling, risk-management documents, and administrative forms must be tailored.

Example 2: Generic immediate-release tablet

For a generic immediate-release tablet, the sponsor should not assume that a single bioequivalence package will automatically satisfy requirements in all three regions. The sponsor must confirm the reference product, strength, study design, fed or fasted conditions, dissolution expectations, biowaiver eligibility, and product-specific guidance separately. FDA Abbreviated New Drug Application (ANDA), Canadian Abbreviated New Drug Submission (ANDS), and EU generic applications share scientific concepts but differ in legal basis, reference product rules, and regional dossier requirements.[15,19,39]

Example 3: Biologic with urgent unmet need

For a biologic intended to treat a serious disease, the sponsor should engage with each regulator early, discuss clinical endpoints and manufacturing comparability, and independently assess accelerated options. FDA Breakthrough Therapy or Fast Track may facilitate development interactions; Health Canada's priority review or Notice of Compliance with conditions (NOC/c) may be relevant; EMA's PRiority MEdicines (PRIME) or accelerated assessment may be considered. The criteria and obligations differ, and granting a designation in one jurisdiction does not guarantee designation or approval in another.[34–38]

9. Post-authorization lifecycle and pharmacovigilance

Regulatory responsibility extends beyond approval. Sponsors must manage manufacturing changes, labeling updates, safety signals, periodic reports, commitments, and renewals or maintenance activities. The FDA enforces postmarketing safety reporting requirements, including 21 CFR 314.80 for approved drug products and 600.80 for biological products, and may require a Risk Evaluation and Mitigation Strategy (REMS) when necessary to ensure that benefits outweigh risks.[40,41]

Health Canada requires the reporting and assessment of adverse drug reactions under the Food and Drug Regulations and provides the Canada Vigilance system for suspected adverse reaction reporting. Sponsors must maintain safety surveillance, signal evaluation, risk communications, and compliance with any conditions attached to a Notice of Compliance with conditions (NOC/c).[3,4,42] In the European Union, EU legislation and Good Pharmacovigilance Practices (GVP) govern pharmacovigilance. The EU system includes EudraVigilance, the Pharmacovigilance Risk Assessment Committee (PRAC), risk-management plans, and periodic safety update reports.[43–45]

ICH Q12 supports a more predictable, science- and risk-based approach to post-approval chemistry, manufacturing, and controls (CMC) changes, while ICH Q9(R1) and Q10 provide complementary quality risk management and pharmaceutical quality system principles.[46–48] A global lifecycle plan should map each change to regional reporting categories rather than assume identical filing classifications.

10. DISCUSSION: strengths, limitations and strategy-related implications

The principal strength of the three regulatory systems lies in their shared scientific foundation. ICH guidelines and Common Technical Document (CTD) modules reduce

repetitive dossier authoring, support consistent evidence interpretation, and facilitate multi-region development.[7–10] Each regulator also provides mechanisms to facilitate access to important therapies, but the pathways reflect different statutes, institutional responsibilities, and public health priorities.

The United States system features well-defined application types and multiple expedited programs, but sponsors must manage detailed FDA-specific technical standards, user-fee commitments, and postmarketing requirements. Health Canada offers a relatively integrated national route and published performance standards; its screening and response processes require careful administrative management. The European Union provides broad geographic reach through the centralized procedure, while decentralized and mutual-recognition routes allow national access for eligible products. The EU structure can be procedurally complex because the EMA, the European Commission, and national authorities have distinct roles.

Common causes of delay include incomplete Module 1 content, inconsistent datasets or study narratives, unresolved chemistry, manufacturing, and controls (CMC) questions, insufficient justification of specifications, inadequate bioequivalence rationale, poor labeling alignment, and delayed responses to agency questions. An effective global regulatory plan should include: (i) a target product profile; (ii) early pathway assessment; (iii) agency scientific advice or pre-submission meetings; (iv) a regional requirements matrix; (v) controlled source documents and traceable data; (vi) validated eCTD publishing and technical checks; (vii) inspection readiness; and (viii) a post-approval change and pharmacovigilance strategy.

Digital transformation is reshaping submission operations. Structured data, eCTD version 4.0, enhanced metadata, electronic clinical trial systems, and risk-based review processes may improve dossier reuse and lifecycle traceability. However, technical implementation remains regional and continues to evolve. FDA acceptance of eCTD v4.0 and ICH implementation packages illustrate the transition toward more structured electronic regulatory information.[28,49] Regulatory teams should therefore maintain version-controlled regional specifications rather than rely on static templates.

11. CONCLUSION

The US FDA, Health Canada, and EMA/EU share a harmonized scientific dossier foundation, yet each operates within distinct judicial and procedural frameworks. The FDA employs the IND, NDA, ANDA, and BLA pathways; Health Canada utilizes the CTA and

NDS/ANDS families; and the EU offers centralized, decentralized, mutual-recognition, and national procedures. The Common Technical Document (CTD) facilitates the reuse of Modules 2–5, while regional Module 1 and local legal requirements remain essential. Review timelines and expedited pathways vary and must be interpreted within their respective contexts, particularly regarding clock stops, screening, and sponsor response periods. Effective global submissions require early route selection, region-specific dossier planning, high-quality evidence, robust electronic publishing, and integrated post-authorization compliance.

12. REFERENCES

1. United States. Federal Food, Drug, and Cosmetic Act. 21 USC §301 et seq. Washington (DC): US Government Publishing Office.
2. United States. Public Health Service Act. 42 USC §201 et seq. Washington (DC): US Government Publishing Office.
3. Government of Canada. Food and Drugs Act, RSC 1985, c F-27. Ottawa: Department of Justice Canada.
4. Government of Canada. Food and Drug Regulations, RSC 1985, c F-27. Ottawa: Department of Justice Canada.
5. European Parliament and Council. Regulation (EC) No 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use. Off J Eur Union, 2004; L136: 1-33.
6. European Parliament and Council. Directive 2001/83/EC on the Community code relating to medicinal products for human use. Off J Eur Communities, 2001; L311: 67-128.
7. International Council for Harmonization. M4: Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use. Geneva: ICH, 2004.
8. International Council for Harmonization. M4Q: The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality. Geneva: ICH, 2002.
9. International Council for Harmonization. M4S: The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Safety. Geneva: ICH, 2002.
10. International Council for Harmonization. M4E: The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Efficacy. Geneva: ICH, 2002.
11. European Medicines Agency. The European regulatory system for medicines. Amsterdam: EMA, 2024.

12. US Food and Drug Administration. Investigational New Drug (IND) application. Silver Spring (MD): FDA.
13. US Food and Drug Administration. Investigational New Drug Application: guidance for industry. Silver Spring (MD): FDA.
14. US Food and Drug Administration. New Drug Application (NDA). Silver Spring (MD): FDA.
15. US Food and Drug Administration. Abbreviated New Drug Application (ANDA) forms and submission requirements. Silver Spring (MD): FDA.
16. US Food and Drug Administration. Biologics License Applications (BLA) process. Silver Spring (MD): FDA.
17. US Food and Drug Administration. Changes to an approved NDA or ANDA. Silver Spring (MD): FDA.
18. Health Canada. Guidance document for clinical trial sponsors: clinical trial applications. Ottawa: Health Canada.
19. Health Canada. Guidance document: management of drug submissions and applications. Ottawa: Health Canada, 2025.
20. Health Canada. Guidance on management of drug submissions and applications: review. Ottawa: Health Canada.
21. Health Canada. Guidance document: priority review of drug submissions. Ottawa: Health Canada.
22. Health Canada. Guidance document: Notice of Compliance with Conditions (NOC/c). Ottawa: Health Canada.
23. European Medicines Agency. Pre-authorization guidance. Amsterdam: EMA; updated 2026.
24. European Commission. Authorization procedures: national authorization procedures. Brussels: European Commission.
25. European Medicines Agency. Accelerated assessment. Amsterdam: EMA.
26. European Medicines Agency. Guideline on the scientific application and practical arrangements necessary to implement the centralized procedure. Amsterdam: EMA.
27. US Food and Drug Administration. Electronic regulatory submission and review. Silver Spring (MD): FDA.
28. US Food and Drug Administration. Electronic Common Technical Document (eCTD) v4.0. Silver Spring (MD): FDA, 2026.

29. Health Canada. Filing submissions electronically: preparation of regulatory activities in eCTD format. Ottawa: Health Canada.
30. Health Canada. Regulatory Enrolment Process (REP): guidance for industry. Ottawa: Health Canada.
31. European Medicines Agency. eSubmission: electronic application forms and eCTD submission guidance. Amsterdam: EMA.
32. European Medicines Agency. EU electronic application forms and eCTD guidance. Amsterdam: EMA.
33. US Food and Drug Administration. Prescription Drug User Fee Act (PDUFA) review goals summary. Silver Spring (MD): FDA.
34. US Food and Drug Administration. Expedited programs for serious conditions—drugs and biologics: guidance for industry. Silver Spring (MD): FDA, 2014.
35. US Food and Drug Administration. Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review. Silver Spring (MD): FDA.
36. Health Canada. Policy statement: priority review and advance consideration under NOC/c. Ottawa: Health Canada, 2026.
37. European Medicines Agency. Conditional marketing authorization. Amsterdam: EMA.
38. European Medicines Agency. PRIME: priority medicines. Amsterdam: EMA.
39. European Medicines Agency. Guideline on the investigation of bioequivalence. Amsterdam: EMA.
40. US Food and Drug Administration. Postmarketing adverse drug experience reporting for human drug and biological products. 21 CFR §§314.80, 600.80.
41. US Food and Drug Administration. Risk Evaluation and Mitigation Strategies (REMS). Silver Spring (MD): FDA.
42. Health Canada. Canada Vigilance Program. Ottawa: Health Canada.
43. European Medicines Agency. Good pharmacovigilance practices (GVP). Amsterdam: EMA; updated 2026.
44. European Medicines Agency. EudraVigilance: electronic reporting of suspected adverse reactions. Amsterdam: EMA.
45. International Council for Harmonization. Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management. Geneva: ICH, 2019.
46. International Council for Harmonization. Q9(R1): Quality Risk Management. Geneva: ICH, 2023.

47. International Council for Harmonization. Q10: Pharmaceutical Quality System. Geneva: ICH, 2008.
48. International Council for Harmonization. eCTD v4.0 Implementation Guide, version 1.7. Geneva: ICH, 2026.
49. International Council for Harmonization. E6(R3): Good Clinical Practice. Geneva: ICH, 2025.