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Pharma Regulatory Submissions: Challenges & Digital Solutions

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Executive Summary

The pharmaceutical industry's regulatory submission process is becoming increasingly complex, burdened by massive volumes of documentation, global variations in requirements, and evolving expectations for data and formats. Traditional drug applications rely heavily on paper-based Common Technical Document (CTD) formats, which have only been incrementally digitized (eCTD) in recent decades (pharmacores.com) (pmc.ncbi.nlm.nih.gov). However, this "electronic PDF" approach traps crucial data in static documents, necessitating repeated manual updates and hindering efficient review (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov). As a result, many applications require multiple review cycles: one analysis found only ~54% of New Drug Applications (NDAs) achieved first-cycle approval (www.sciencedirect.com). Poor-quality data, CMC (Chemistry, Manufacturing, and Controls) gaps, and safety or bioequivalence deficiencies are common causes of delays and rejections (www.sciencedirect.com) (www.sciencedirect.com).

Meanwhile, industry and regulators alike are pushing for modernization. Companies are adopting cutting-edge approaches – from lean "zero-based" process redesigns to advanced technologies like AI-assisted authoring – to reduce submission timelines (www.mckinsey.com) (aapsopen.springeropen.com). For example, McKinsey identifies **six "submission excellence" building blocks** (strategy simplification, process redesign, new operating models, system modernization, automation, and AI-enabled content generation) that can help slash

NDA review times from months to weeks (www.mckinsey.com) (www.mckinsey.com). In practice, firms like Amgen are already using large-language-model (LLM) tools to automate drafting of complex CTD sections: the authors describe an LLM-based Quality Overall Summary tool that aims to sharply reduce initial drafting time, with an estimated drafting-time reduction of more than 60% (aapsopen.springeropen.com).

Looking globally, countries differ markedly in submission standards and timelines. The EU has mandated eCTD submissions for centralized Marketing Authorizations since 2010 (www.pharmtech.com), targeting a 210-day review (with a 150-day *accelerated assessment* option) (www.ema.europa.eu). The FDA's standard review goal is 10 months (6 months under Priority Review) (medx.it.com). China's NMPA offers a 130-day *priority review* track for innovative drugs (pmc.ncbi.nlm.nih.gov). Harmonizing these divergent requirements remains a challenge (www.sciencedirect.com) – for instance, a 2025 study showed generic drug submissions suffer from conflicting data and format rules across the US, EU, Japan, India, and China (www.sciencedirect.com).

The path forward lies in **digital transformation and harmonization**. Regulators and industry advocates are calling for structured data standards (e.g. ICH QbD, PQ/CMC, ISO IDMP, HL7 FHIR) and next-generation submissions (eCTD v4.0, cloud-based parallel reviews) (aapsopen.springeropen.com) (www.freyrsolutions.com). FDA has accepted eCTD v4.0 for new applications since September 16, 2024, alongside v3.2.2 (www.fda.gov), while EMA opened optional v4.0 use for new centrally authorised product (CAP) marketing authorisation applications on 22 December 2025 and plans mandatory use from Q1 2028 (esubmission.ema.europa.eu) (www.freyrsolutions.com). Meanwhile, AI and machine learning are being leveraged to automate data extraction, perform predictive analytics on submission quality, and even generate regulatory text (aapsopen.springeropen.com) (pmc.ncbi.nlm.nih.gov). These innovations promise to reduce manual workloads, reduce errors, and enable true "structured" submissions. If widely implemented, a move to cloud-based, data-centric review platforms could drastically streamline global approvals, speeding patient access to new therapies (aapsopen.springeropen.com) (pmc.ncbi.nlm.nih.gov).

Key Findings:

- **Legacy Process:** The current eCTD paradigm is an incremental digitization of paper that fails to leverage modern data tools – content is "locked" in PDFs, requiring full document replacements for updates (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov).
- **High Rejection Rates:** In practice, roughly half of NDAs require revisions or resubmission. A retrospective analysis (2008–2017 NDAs) showed only 54.1% achieved first-cycle approval (www.sciencedirect.com), with CMC and safety issues being leading causes of delay.
- **Resource Drain:** The sheer volume of dossiers (CMC and clinical modules often run to thousands of pages (aapsopen.springeropen.com) (aapsopen.springeropen.com)) puts strain on regulatory teams. Even the FDA reports missed PDUFA goals – in 2023, 11% of new drug reviews exceeded target timelines, the worst performance on record (www.agencyiq.com).
- **Technology Opportunities:** Emerging technologies offer solutions. Structured Content/Data Management (SCDM) systems and AI tools can automate repetitive tasks, auto-populate reports, and link data across sections (aapsopen.springeropen.com) (pmc.ncbi.nlm.nih.gov). For example, automating CTD authoring and enabling real-time content updates are projected to radically cut preparation times (aapsopen.springeropen.com) (aapsopen.springeropen.com).

- **Global Sync Needed:** Despite ICH-led harmonization of core CTD formats (pharmacores.com), significant local variations remain (regional module 1s, extra documents, different BLE/CMC expectations) (pmc.ncbi.nlm.nih.gov) (www.sciencedirect.com). Initiatives like “parallel scientific advice” (FDA-EMA joint consultations) and Project Orbis (concurrent cancer reviews) seek to align requirements and accelerate global approval (www.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov).

This report delves into these issues in depth: tracing the historical evolution of submissions, quantifying current bottlenecks with data from FDA/EMA and literature, comparing global regulatory frameworks, and showcasing case studies where new approaches (lean redesign, AI) have made a difference. It concludes with discussion of ongoing initiatives and future directions, underscoring that truly efficient regulatory review will require both technological innovation and industry–regulator collaboration (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov).

Introduction and Background

Bringing a new medicine to market is a monumental effort. Beyond the science of discovery and clinical testing, obtaining regulatory approval is a **critical but challenging** final hurdle. Regulatory submission refers to the compilation and review of all data demonstrating a drug’s safety, efficacy, and quality, culminating in applications like the FDA’s New Drug Application (NDA) or the EMA’s Marketing-Authorisation Application (MAA). These submissions must detail manufacturing processes, formulation, analytical assays, nonclinical and clinical study results, and more, organized per prescribed templates (Modules 1–5 of the Common Technical Document, CTD) (pharmacores.com) (pmc.ncbi.nlm.nih.gov).

Historically, each country had its own dossier format and communication channel, which was costly and duplicative. Beginning in the early 2000s, the ICH (International Council for Harmonisation) standardized a core format (the CTD) and later its electronic version (eCTD) (pharmacores.com). The CTD offers a “one global application” structure: Module 2 and 3 (quality/CMC, module 4/5 (nonclinical/clinical) are common across regulators, while Module 1 is local administrative data. Over time, regions mandated electronic CTDs to facilitate transfer: for example, the EU required eCTD for centralized filings starting around 2010 (www.pharmtech.com), and the FDA phased out paper NDAs by 2017. Yet despite this digitization, the core process has remained largely document-centric. The **electronic submission** is basically a zipped collection of PDF documents and images performed under eCTD technical standards.

Regulators insist on rigorous compliance for health (FDA, EMA and other agencies exist to ensure safety). But this rigor contributes to the burden: nearly every page of a submission is scrutinized, and even minor technical missteps can trigger recommendations for additional data or resubmission. In recent years, regulators have also introduced numerous pathways and guidelines to expedite or clarify reviews – e.g. the FDA’s Accelerated Approval, Breakthrough Therapy Designation or EMA’s PRIME program for unmet needs. These offer speed advantages for qualifying products but also set high evidentiary bars.

Moreover, the digital era presents new data sources (real-world evidence, electronic health records, digital biomarkers) (pmc.ncbi.nlm.nih.gov), and both industry and regulators are grappling with how to integrate these into submissions. Regulatory science as a field now actively explores how to handle non-traditional data presence and digital evidence in filings. This background frames why understanding **current submission**

challenges – and how to overcome them – is so crucial today. As one recent review notes, the pandemic has underscored "the need for rapid secure exchange between regulatory authorities … to accelerate global approvals" (pmc.ncbi.nlm.nih.gov), a need not easily met by today's fragmented processes.

Historical Evolution of Regulatory Submissions

The submission process has evolved gradually over decades. In the mid-20th century, filings were entirely paper-based, with each country (or even state) having bespoke dossier formats. This fragmented approach led to enormous duplication: innovators often needed to prepare separate submissions for each major market, carrying different forms and local requirements. The ICH was established in the late 1980s precisely to resolve this inefficiency. By 2000, the CTD was introduced to harmonize content (Module structure, common data sets) across the EU, Japan, and the US (pharmacores.com). The CTD's unveiling solved a "global problem" of *multiple submission formats*, high cost, and delays (pharmacores.com). Pharmaceutical Technology wrote at introduction that prior to CTD, regulatory diversity had led to "serious challenges: multiple submission formats, increased costs, delayed market access, [and] misinterpretation" (pharmacores.com).

Concurrently, regulators began to adopt electronic submission gateways. Japan introduced an eCTD scheme in the mid-2000s, the US launched an electronic submissions gateway in 2005, and the EU's eSubmission gateway followed. By 2010, EMA mandated that all centralized procedure applications be submitted in eCTD format (www.pharmtech.com). This allowed automating parts of dossier handling, but initially eCTD compliance often meant simply uploading electronically scanned documents. Over the 2010s, guidances (M4Q(R2), M1 technical specs) gradually refined the eCTD format and validation requirements, with FDA and EMA issuing frequent updates.

Despite these gains, many limitations of the legacy model became apparent. As Macdonald *et al.* (2021) observe, the submission/review process "has not fundamentally changed since the beginning of medicine regulation in the late 1960s" – it remains a **static exchange** of documents (pmc.ncbi.nlm.nih.gov). Content is "locked away in [document] formats that impede update or re-use" (pmc.ncbi.nlm.nih.gov). Any change to a section of the dossier typically means republishing entire CTD modules or even the whole application, causing extensive administrative overhead (pmc.ncbi.nlm.nih.gov). Furthermore, different jurisdictions, even after CTD adoption, kept unique requirements in Module 1 (forms, labeling, local references) and extras, hindering true global harmonization.

In response to these pain points, regulators have gradually introduced process innovations. The FDA's Prescription Drug User Fee Acts (PDUFA) introduced review performance targets (timelines) tied to industry fees, incentivizing the agency to speed reviews. Europe's EMA adopted accelerated assessment (cutting 210→150 days) for select medicines (www.ema.europa.eu), as well as conditional marketing authorisation for the highest-need products. But fundamentally, neither the FDA nor EMA has replaced the CTD/eCTD paradigm. Industry studies begun labeling it as insufficient: even as early as 2019, researchers noted the reliance on PDFs in submissions, and by 2025 commentators were calling the model "entrenched and variable" and in need of a revolution (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov).

Thus, the *current* landscape is best viewed as a blend: submissions must follow the ICH CTD structure (modules 1–5), typically submitted via the agency's eSubmission gateway in eCTD (version 3.x) format (pmc.ncbi.nlm.nih.gov). Within that, modern demands have added complexity: companies must navigate multiple new data guidances (for example, ICH Q8–Q13 on quality, Q9–Q10 on quality risk mgmt, Q14 on analytical procedure development). Practices like data anonymization, electronic signatures (21 CFR Part 11/X, EU Annex 11), and global safety reporting (ICH E2B) further complicate dossier assembly. In short, the submission process finally standardized in form, but the *contents* of those standardized forms have ballooned to huge volumes – an average 30,000 to 50,000 pages for a typical NDA/BLA (aapsopen.springeropen.com) (aapsopen.springeropen.com).

Current Global Regulatory Landscape

Major Regulatory Agencies and Submission Formats

Different jurisdictions share the CTD framework but have distinct rules and timelines. Table 1 compares key aspects of the submission requirements among major agencies:

Region / Agency	Submission Format & eCTD Status	Review Timelines (Std / Priority)	Expedited Pathways & Incentives	Unique Local Requirements
USA (FDA)	eCTD required for NDAs, BLAs, ANDAs (since 2017); FDA accepts either v3.2.2 or v4.0 (www.fda.gov) (www.freyrsolutions.com); began accepting eCTD v4.0 for new applications only on Sept 16, 2024 (www.fda.gov) (www.freyrsolutions.com).	Standard PDUFA goal: ~10 months; Priority Review: ~6 months (medx.it.com).	Fast Track, Breakthrough Designation, Accelerated Approval (e.g. surrogate endpoints), Priority Review. Orphan drug exclusivity: 7 years. Pediatric Study Plan required under PREA.	Requires detailed FDA forms (Form FDA 356h for marketing applications; Form FDA 1571 applies to INDs) and labelling in eCTD M1. Must follow 21 CFR in all processes.
EU (EMA)	eCTD v3.2.2 mandatory for centralized MA (since 2010) (www.pharmtech.com); eCTD v4.0 optional for new CAP MAAs since 22 Dec 2025, with mandatory use planned from Q1 2028 (esubmission.ema.europa.eu) (www.freyrsolutions.com).	Standard: max 210 active days (excluding "clock stops") (www.ema.europa.eu); Accelerated Assessment: 150 days (a shorter timetable, distinct from conditional marketing authorisation) (www.ema.europa.eu).	PRIME (PRIority MEdicines) scheme for early access; Conditional MAs (renewable yearly) for unmet need; Orphan exclusivity: 10 years (with 2-year bonus for pediatrics); Pediatric Investigation Plan (PIP) mandatory (unless waived).	Module 1 demands EU-specific data (e.g. EU Qualified Person Responsible for Pharmacovigilance, GMP certificates, patient info in EU languages). Centralized process bypasses national procedures. Regulatory reporting via CESP/IRIS systems.

Region / Agency	Submission Format & eCTD Status	Review Timelines (Std / Priority)	Expedited Pathways & Incentives	Unique Local Requirements
Japan (PMDA)	CTD format (ICH); eCTD submissions in place (Japanese eCTD specs). eCTD v3-format approval applications accepted only if filed by 31 March 2026, so eCTD v4.0 is the format for new filings from April 2026 (www.pmda.go.jp) (www.freyrsolutions.com).	Standard: typically ~12–13 months (review start to approval); Sakigake designation (for first-in-world, serious diseases) targets 6-month review. PMDA also offers Priority Review.	**Sakigake**: accelerated designation (Japan first) for novel drugs; Conditional Early Approval for regenerative medicines. Orphan drug benefits include priority review and 10-year re-examination period (extended exclusivity).	Requires documentation in English plus certain parts in Japanese. Japanese regulations enforce Good Clinical Practice as ministerial law (some differences from ICH-GCP). Bridging studies often expected to support local population.
China (NMPA, CDE)	ICH CTD structure; eCTD optional since 29 Dec 2021 for selected marketing applications (chemical drug categories 1 and 5.1, category 1 therapeutic and preventive biologics), with the existing registration method still available (english.nmpa.gov.cn); transition to ICH Q* guidelines.	Standard: ~200–300 days (varies). Priority Review (for innovative drugs or drugs on "National List") targets **~130 days** (pmc.ncbi.nlm.nih.gov).	Priority Review & Approval for innovative/unmet-need drugs; Conditional Approval mechanism (NMPA can grant approval if incremental evidence is provided later); Orphan designation grants 6-year market exclusivity (since 2017). Pediatric drug development guidance exists.	Module 1 requires local info (e.g. Chinese label, GMP/GSP certificates, approval letters for overseas trials). China often demands local clinical trial data or bridging studies. A new **"silent approval"** policy accelerates clinical trial start if CDE does not respond in time (pmc.ncbi.nlm.nih.gov).
India (CDSCO)	ICH CTD format; eCTD increasingly used (guidance from 2018) and expected to be mandatory for NDAs in coming years.	Standard: ~12–18 months. Accelerated approval possible for products already approved in stringent regulators.	Fast Track approval (for serious conditions, requires phase 3 completion in regulators like US/EU). Orphan drug exemption (reduced fee, tax benefits). New quadrilateral pharma corridors (for exports).	Local requirements such as comparative clinical studies (CTs) vs. Indian population, manufacturing license from local site, and GCP adherence under the New Drugs and Clinical Trials Rules, 2019 (which superseded Schedule Y for new drugs and clinical trials).

Table 1. Comparison of major regulatory agencies (USA, EU, Japan, China, India) with respect to submission format, review targets, expedited programs, and notable national requirements.

This table shows key differences. For example, while the FDA and EMA operate on a roughly 10-month vs 210-day review cycle (priority/accelerated being shorter), China actively expanded **Priority Review** to 130 days in 2020★ (pmc.ncbi.nlm.nih.gov). India, meanwhile, often requires bridging data and manufacturing permits not needed by others. All these variations underline one of the core challenges: **global harmonization**. As Desai *et al.* (2025) emphasize, filing requirements for generics vary so widely across US, EU, Japan, India, and China that stronger alignment is urgently needed (www.sciencedirect.com).

Key Components of a Regulatory Submission

Regardless of region, submissions share a modular architecture and components:

- **Module 1 (Regional Administrative Information):** Agency-specific forms, cover letters, labeling, and regional data. *Examples:* FDA Form 356h, IND/IDE numbers; EU Applicant Information (including QPs, GMP certificates); Japanese “Application Form A”, etc. These vary by country and often cause reformatting of data when submitting globally.
- **Module 2 (Summaries):** Overview and critical summaries – Quality Overall Summary (Module 2.3), Nonclinical & Clinical Overviews, investigator’s brochure (for INDs), and synopsis documents. These bridge the detailed data in Modules 3–5. Good organization of M2 is vital but can be difficult given thousands of source pages.
- **Module 3 (Quality/CMC):** Extensive data on manufacturing process, control of drug substance and product, analytical methods, stability, and facility compliance. This is often the largest volume. Thousands of pages of batch records, validation reports, specifications, etc. must be compiled. Table 2 below lists some chronic pitfalls in this module. It’s not unusual for regulators to find inconsistencies here that trigger major amendment requests.
- **Module 4 (Nonclinical):** Results of animal pharmacology/toxicology studies. For new drugs, typically multiple-species acute/chronic toxicology, safety pharmacology, reproductive toxicology, etc.
- **Module 5 (Clinical):** Clinical trial reports from Phase 1–3 (and often 4); integrated summaries; efficacy and safety analyses; and patient narratives for serious adverse events. This module supports the core efficacy/safety claims and is generally what requires most pages and attention.

Each submission must meticulously document that manufacturing will meet quality standards (good manufacturing practices) **and** present robust evidence of benefit/risk from trials. The amount of data is continuously growing: increased use of biomarker substudies, patient-reported outcomes, risk management plans, etc., all get folded into the dossier. As Ahluwalia *et al.* (2025) note, the reliance on manual methods “significantly prolongs the preparation and submission of regulatory documents” because of the sheer volume (aapsopen.springeropen.com).

Challenges in Regulatory Submissions

Data and Documentation Complexity

One of the dominant challenges is simply the **enormous amount of information**. A modern full clinical trial (hundreds of patients, many sites) yields thousands of data tables and narratives. For example, consider CMC content – it must "populate relevant sections of the CTD and is generally in [eCTD] format that is globally harmonized" at a high level (pmc.ncbi.nlm.nih.gov). Yet even within that structure, anything less than a perfect dataset can hold up filing. As Macdonald *et al.* put it: valuable data remain “trapped” in static documents, creating “significant inefficiencies” for authors and reviewers (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov).

Common data issues include:

- **Data Entry and Transcription Errors:** Human entry of large datasets (lab values, batch records) is error-prone. In Module 3 or clinical listings, a misplaced decimal or mislabeled table row can prompt regulators to issue information requests or refuse to file. Manual transcription between different software (e.g. transferring assay results into PDF tables) adds risk. The inability to “link” data across submissions is problematic (a change in Module 3 may require changes in Module 5 substudies, for example) (pmc.ncbi.nlm.nih.gov). Automation and consistency checks are often lacking, meaning even minor discrepancies must be justified or corrected item-by-item.
- **Redundant Content Authoring:** Without a central database, even identical information appears in multiple places. As Ahluwalia *et al.* describe for SCDM, repeating the same CMC description in multiple dossier sections causes duplication of effort (aapsopen.springeropen.com). For example, stability protocols might be written in full in both Module 3 summaries and 2.3, then again in the text of the QOS. Each duplicate is another point where inconsistencies or typos can creep in.
- **Quality of Source Data:** Regulator assessment depends on the integrity of underlying data. Pharmaceutical Technology notes that ensuring data quality is fraught with challenges: “technological limitations in data capture and storage” and “human errors in data entry and analysis” can degrade evidence (www.pharmtech.com). Especially in multi-center trials, merging datasets from different labs or generating real-world evidence (EHR or registry data) introduces heterogeneity. If critical values or patient safety outcomes are missing or suspect, the application is jeopardized.
- **Volume of Documentation:** Quantitatively, the challenge is staggering. One recent internal report notes the thousands of pages in Module 3 and the need to distill them into Module 2 summaries (aapsopen.springeropen.com). Regulatory reviewers have limited bandwidth. Agencies absorb tens of thousands of pages per submission; for example, FDA’s CDER reports handling nearly *300,000* submissions (all types) in 2023 (www.fda.gov). At the product level, average file sizes soared in the last decade, meaning more time on formatting and checking than before. (See **Table 2** for common failure points in these data-heavy sections.)

<table> <tr><th>Application Type</th><th>Common Regulatory Deficiencies</th><th>Stats/Notes</th></tr> <tr> <td>NDA/BLA (Innovator Drug)</td> <td>- Incomplete or non-validated CMC data (e.g., missing impurity specs, stability data gaps) (www.sciencedirect.com)
- Clinical data issues (e.g., inadequate safety data, unclear benefit-risk) (www.sciencedirect.com)
- Batch analysis discrepancies or manufacturing site misalignment</td> <td>- Only ~54% of NDAs in one study achieved first-cycle approval; 29% were initially *not approved* largely due to CMC or safety issues (www.sciencedirect.com).</td> </tr> <tr> <td>ANDA (Generic Drug)</td> <td>- Bioequivalence study failures or missing BE reports (www.sciencedirect.com)
- Analytical method validation gaps (e.g., impurity assays not fully documented) (www.sciencedirect.com)
- Labeling inconsistencies with the reference listed drug (RLD) (www.sciencedirect.com)</td> <td>- From 2019–2023, FDA ANDA filings were predominantly not approved on first pass: only ~121–148 first-cycle ANDA approvals per year, indicating recurrent defects (www.sciencedirect.com).</td> </tr> <tr> <td>BLA (Biologic/Gene Therapy)</td> <td>- Complex manufacturing issues (e.g., cell line consistency, viral vector replication competence)
- Comparability and potency assay validation challenges

- Viral safety / adventitious agent testing gaps</td> <td>- For context, FDA's CBER saw a surge of filings during the pandemic (CBER submitted 716,525 documents in 2021, up ~10-fold from 2020 (www.fda.gov)), stretching review resources. CMC issues were cited as a reason in multiple recent Complete Response Letters (CRLs) for gene therapies (www.biopharminternational.com).</td> </tr> <tr> <td>Real-World Evidence (RWE) Submissions</td> <td>- Non-standardized data fields (EHRs vary by provider)
- Potential biases in observational data
- Incomplete context (unknown confounders) for endpoints</td> <td>- Regulatory guidance on RWE is emerging (FDA's RWE Program, EMA's DARWIN EU). RWE submissions are increasing, but many are submitted via supplemental or observational study modules, not yet formal main applications.</td> </tr> </table>

Table 2. Examples of common deficiencies in different types of regulatory submissions (sources: FDA analyses (www.sciencedirect.com) (www.sciencedirect.com), and regulatory reports (www.fda.gov) (www.biopharminternational.com)).

These data challenges directly impact regulatory outcomes. The study by Lu *et al.* (2019) of 825 NDAs found that nearly 30% of applications were *not approved* in the first cycle (many were later approved after amendments) (www.sciencedirect.com). Another review (2025) of generic applications confirmed *consistent patterns* of failure: bioequivalence issues topped the list, followed by CMC shortfalls (particularly method validation gaps) (www.sciencedirect.com). Even later, post-approval variations and renewals suffer – each supplemental report (e.g. change in manufacturing, new packaging) creates additional submission burden, often with slightly different forms and technical checklists.

Regulatory Process and Human Factors

Beyond data, organizational factors complicate submissions. Regulatory affairs groups in pharma must coordinate scientists, clinicians, manufacturers, and external consultants. Communication breakdowns or last-minute inputs can cascade into delays. Key steps such as drafting the Quality Overall Summary (QOS) (Module 2.3) or assembling complete investigator's brochures often become Gantt-chart critical paths. Any bottleneck – e.g. a waiting medical writer, or a reviewer delaying a section sign-off – can push back the submission date for the entire dossier. Redesign efforts ("zero-based redesign") have shown that front-loading tasks (e.g. drafting chapters before database lock, overlapping safety analyses) can yield large time savings (www.mckinsey.com) (www.mckinsey.com).

Communication with regulators is another hurdle. Submissions must meet precise format and content checklists; failing the agency's eCTD technical validation can lead to rejection of the submission before review, and serious content or format deficiencies can lead to a refuse-to-file decision. For example, missing or inconsistent index entries, file naming errors, or unsigned documents can trigger an eCTD validation error at EMA or FDA before scientific review even begins. Companies therefore devote substantial effort to pre-submission checks and trainings on the latest guidance. Regulators themselves have responded by publishing detailed checklists and conducting pre-submission meetings. EMA's recent push to provide *pre-submission guidance* and Q&A documents reflects this need (www.pharmtech.com) (www.ema.europa.eu).

In summary, the current submission process – while globally standardized in form – remains **far from optimized**. It involves thousands of manual tasks across teams, duplication of effort, and rigidly sequential steps. An AAPS Open review warns that this “transactional” model of static document exchanges is deeply entrenched and must give way to a new ecosystem (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov).

Innovations and Digitalization in Regulatory Submissions

Technology-Driven Solutions

Recognizing these limitations, industry and regulators are increasingly advocating transformative approaches. The main themes are **structured data management**, **automation (especially AI)**, and **cloud/collaborative platforms**. Ahluwalia *et al.* (2025) identify Structured Content and Data Management (SCDM) as a key enabler: by breaking down the dossier into reusable data “blocks” and standard elements, SCDM reduces redundancy and error (aapsopen.springeropen.com). In practice, SCDM means maintaining a centralized repository of product information (e.g. drug substance details, formulation narratives, assay methods) that can auto-populate multiple sections of the eCTD. As a result, one change to a “block” (e.g. a new impurity limit) propagates throughout all relevant CTD sections automatically. The AAPS group notes that SCDM “facilitates real-time updates and auto-population of content, thereby minimizing manual data transcription and reducing the potential for human error” (aapsopen.springeropen.com).

Structured Content and Data Management (SCDM)

SCDM stands in contrast to traditional word-processing. It entails creating modular content (text and data) tagged with metadata. For example, a single description of “synthesis of drug substance” can be authored once, then reused in Module 3 (as a narrative) and in Module 2 (as a summary) without retyping. Ahluwalia *et al.* describe how SCDM builds a content repository of “modular content blocks”; authors build dossiers by assembling these blocks (aapsopen.springeropen.com). This approach not only reduces drafting time (each block is written and reviewed once) but also **enables consistency** across regions if mapped properly to local templates.

Data standards complement SCDM. Initiatives like ICH QbD (Quality by Design), PQ/CMC (Pharmaceutical Quality – CMC) template, ISO IDMP (for product identity), and HL7 FHIR (for exchanging health data) are fostering a shift from document to data. For example, the FDA’s PQ/CMC workstream aims to capture CMC information as structured data fields (e.g. test results, batch parameters) rather than narrative text. Once in structured form, the data can be exchanged via APIs between sponsor and regulator, eliminating the need for PDF. The promise is that regulators could then run automated checks on data conformance (e.g. each batch passes its specs) instantly.

Several pilot projects are in early stages. The FDA, EMA, and Health Canada have indicated long-term plans to accept “next-generation submissions” where crucial data is submitted in machine-readable format. Industry is watching: Freyr Solutions emphasizes that with eCTD v4.0 on the horizon, companies should align their data

practices now to avoid “crunch” as deadlines loom (www.freyrsolutions.com). (Notably, eCTD v4.0 includes provisions to submit certain regional Module 1 data as XML, and to carry more granular metadata alongside documents.)

Artificial Intelligence and Automation

AI and machine learning (ML) are rapidly being applied to the regulatory domain. A major advantage is their ability to *ingest large unstructured documents (like PDFs) and extract meaning or generate summaries*. The AAPS 2025 study highlights two areas:

- **Automated drafting and summarization:** Amgen’s use of an LLM-based tool to generate Module 2.3 (Quality Overall Summary) from Module 3 content is a striking example (aapsopen.springeropen.com) (aapsopen.springeropen.com). Traditionally, QOS writing is laborious: human experts must condense thousands of pages of CMC data into a coherent narrative. The LLM approach automatically maps each QOS section to relevant data and crafts a draft, also transcribing tables and figures. The authors present the time savings as an aim and an estimate (a drafting-time reduction of more than 60%), not as measured production results (aapsopen.springeropen.com). Importantly, the tool embeds an “audit trail” of sources for regulator review. While still operator-supervised, such tools could allow team members to focus on high-level decision-making rather than copy-editing.
- **Regulatory Intelligence:** Beyond writing help, AI is used for monitoring and planning submissions. Companies subscribe to regulatory intelligence platforms (e.g. Cortellis, INFORMA) that use NLP to track guideline changes, competitor approvals, and market conditions. Emerging ML models can flag critical updates (e.g. new FDA guidance on COVID therapeutics) and even predict submission obstacles by analyzing public assessment reports. For example, one study of 25 pharma companies’ regulatory intelligence processes identified “information volume” as a key pain point, prompting use of AI tools for data synthesis and query prioritization (aapsopen.springeropen.com). Startups are also offering chatbots (like “Regulatory GPTs”) to answer questions about formats and timelines. Such intelligence systems help avoid surprises: if an EU member state changes its labelling template, or a new test method is mandated, AI bots can alert the submission team.

Table 3 below summarizes several challenges and how technology is poised to address them.

<table> <tr><th>Challenge</th><th>Impact</th><th>Emerging Solutions</th><th>Sources</th></tr> <tr> <td>Static PDF documents</td> <td>Updates require full re-submissions; trapped data cannot be easily reused or checked; manual, back-and-forth correspondence</td> <td>SCDM and eCTD v4.0 allow **structured data packages** (not just PDFs) and version control; cloud platforms for real-time dossier updates (aapsopen.springeropen.com) (pmc.ncbi.nlm.nih.gov)</td> <td> [6], [34]</td> </tr> <tr> <td>Manual data extraction</td> <td>Regulators copy tables by hand; sponsors re-enter comments; high error risk and time consumption</td> <td>AI/NLP algorithms to extract tables/text from submissions; automated consistency checks (auto-flag mismatches); API-based data exchange enables direct import instead of retyping (pmc.ncbi.nlm.nih.gov) (aapsopen.springeropen.com)</td> <td> [34], [6]</td> </tr> <tr> <td>Lack of harmonization</td> <td>Work duplications across regions; risk of non-compliance with local rule; redundant translations/formatting</td> <td>Regulatory intelligence tools (AI-supported) to keep track of regional requirements; collaborative programs like FDA-EMA **parallel advice** (joint reviews) to align endpoints

(www.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov)</td> <td> [24], [26]</td> </tr> <tr> <td>Massive dossier volume</td> <td>Overwhelms authors and reviewers; slow review cycles; reviewer fatigue can miss issues</td> <td>Generative AI tools to auto-summarize content (e.g. draft LOQs, parse clinical data); **template libraries** with AI suggestions to draft common sections; parallel review processes (multiple teams) supported by cloud versioning (aapsopen.springeropen.com) (www.mckinsey.com)</td> <td> [6], [9]</td> </tr> <tr> <td>Lengthy review timelines</td> <td>Delayed patient access and ROI; backlog of applications; missed performance goals (e.g. FDA PDUFA targets) (www.agencyiq.com)</td> <td>Process redesign (leverage lean/parallel execution) and AI triage of submissions to prioritize queries; increased reliance on dossier quality checks to reduce cycles; digital review meetings (e.g. video conferencing dossiers) to cut back-and-forth (www.mckinsey.com) (www.agencyiq.com)</td> <td> [9], [53]</td> </tr> </table>

Table 3. Representative challenges in regulatory submissions paired with emerging technology-enabled solutions (citations key: [6]=Ahluwalia et al. 2025; [34]=Macdonald et al. 2021; [9]=McKinsey 2025; [24]=NASEM 2024; [26]=Tan et al. 2025).

Case Study: AI in Practice – The Amgen QOS Example

To illustrate the potential of digital tools, consider Amgen's AI-powered QOS generator. Module 2.3 (Quality Overall Summary) typically summarizes all Module 3 data. Manual preparation of one QOS can take highly experienced writers weeks to draft and compile. Amgen describes a Large-Language-Model (LLM) **drafting tool** built for this task. The process works as follows: once Module 3 content is finalized, the AI identifies which pages and tables correspond to each QOS subsection (e.g., degrade stability, impurity report, manufacturing descriptions). It then synthesizes concise text paragraphs for each subsection, following regulatory guidance and internal templates (aapsopen.springeropen.com). Tables and figures (such as batch release testing data) are automatically reformatted and transcribed into the QOS, with the tool generating its own audit trail to show data provenance (aapsopen.springeropen.com).

The authors describe the tool as aiming to dramatically reduce the time needed for an initial QOS draft, and estimate a drafting-time reduction of more than **60%**; these are projected gains rather than measured production results (aapsopen.springeropen.com). This case exemplifies how machine intelligence can offload rote summarization and let experts focus on analysis and interpretation. Importantly, the tool was designed to be flexible: it could adapt to different templates and modules, ensuring it can be reused across products. Amgen's approach suggests a path whereby other common regulatory texts (e.g. safety narratives, investigator brochure modules) could similarly be AI-augmented.

Regulatory Intelligence and Global Strategy

Another facet of submissions is **knowing the regulatory landscape**. Large companies maintain regulatory intelligence (RegIntel) teams whose job is to track new guidelines, label changes, and the approval environment across all target markets. This is a data-heavy task: in any quarter, dozens of regulators issue new guidances or safety communications. AI helps here by scanning regulatory databases and summarizing key changes. For example, if the EMA revises a guideline on pediatric extension studies, a RegIntel system can alert sponsors within hours, noting the sections affecting their pipeline.

The outcome of an application often depends on anticipating questions. Some companies conduct *pre-submission meetings* (e.g. FDA's Type B Meetings, EMA Scientific Advice) to clarify expectations. Others engage multiple agencies in parallel advice to harmonize their strategy. The NASEM report on rare disease drugs highlights the FDA–EMA **Parallel Scientific Advice (PSA)** program, whereby sponsors receive concurrent input from both agencies on a single protocol (www.ncbi.nlm.nih.gov). This reduces later conflicts, as the companies align core protocols from the start.

Regulatory intelligence is also about monitoring competitors. Advanced analytics can mine approved labels, literature, and patents to glean the "path of least resistance" for a submission. For instance, if another company obtained approval for a similar drug by emphasizing a particular subgroup, AI can flag that regulatory strategy for replication.

Regulatory Case Studies and Examples

Project Orbis and Global Collaboration

A notable regulatory initiative is the FDA's **Project Orbis** for oncology drugs, now involving multiple countries (including Australia, Canada, Switzerland, UK, Singapore) in simultaneous reviews. Sponsors can request Project Orbis participation and then file with FDA and with participating partner agencies on a coordinated timeline for concurrent review (www.fda.gov). Decisions are still made by each country, but coordination ensures common questions and timeline. The goal is accelerated global access. Tan *et al.* (2025) describe Project Orbis as "facilitating simultaneous reviews of cancer treatments by multiple regulatory authorities worldwide," thereby addressing the consequence of disjointed filing threads (pmc.ncbi.nlm.nih.gov). While not directly a "solution" to eCTD tech hurdles, Orbis exemplifies a strategic solution to the challenges of global filings (coordinated concurrent filings instead of many staggered ones, with shared review discussions).

COVID-19 Vaccine Filings

The COVID-19 emergency produced a real-time case study of regulatory flexibility. Within months of the SARS-CoV-2 genome being shared, companies compiled and submitted massive dossiers for vaccine approval. To accommodate urgency, regulators invoked Emergency Use and Priority pathways. For example, the FDA's Operation Warp Speed policy allowed rolling submissions so that data (clinical and manufacturing) could be reviewed incrementally. EMA likewise used conditional marketing authorizations. Vaccine dossiers were enormous, containing decades of data (some for novel platforms). CBER's submissions data reflect this surge: submissions skyrocketed in 2020–21 (see Table 2; CBER went from ~75k to 716k in 2021 (www.fda.gov)). Regulators collaborated globally: the World Health Organization and ICH issued guidance on how to pool knowledge; mutual recognition of inspections was expanded; and as Tan *et al.* note, FDA's global influence via Orbis was amplified (for cancer drugs) (pmc.ncbi.nlm.nih.gov). These efforts showed how fast-tracking policy and voluntary harmonization can compress timelines – approvals that normally take a year occurred in 6–8. Post-pandemic, agencies (e.g. via ICMRA, WHO) have analyzed lessons learned, such as the benefits of *rolling reviews* and scientific advice on common endpoints.

Generics and International Approval Consistency

Generic drug companies face a different kind of submission challenge. Their dossiers (Abbreviated New Drug Applications, ANDAs) rely on showing equivalence to a reference drug. Desai *et al.* (2025) conducted a cross-regional study of generics approvals. They found that despite baseline ICH CTD convergence, **filing requirements still differ markedly** across US, EU, Japan, India, and China (www.sciencedirect.com). For example, India's CDSCO may require a local bioequivalence study (even if one was done to reference standards), whereas the FDA demands precise sameness of the reference listed drug. Such differences cause reformatting of the same data for each market, increasing costs and risk of non-compliance.

Deficiency patterns are telling: in FDA reviews (2019–2023), less than a third of ANDAs were approved on first cycle (www.sciencedirect.com). The common failures were bioequivalence and analytical issues (e.g. method validation), followed by quality control lapses (stability, sterility) (www.sciencedirect.com). Notably, labeling discrepancies with the RLD were also cited, meaning that even small discrepancies in how the generics' label was worded could halt approval. In summary, generics illustrate how lack of mutual recognition (despite identical scientific proof) leads to repeated hurdles. Organizations like WHO's Prequalification program, mutual recognition agreements, and convergence initiatives aim to reduce this burden, but full harmonization remains aspirational.

Discussion and Future Directions

The landscape of regulatory submissions is changing rapidly. On the **digital front**, we are at an inflection point. Within the next few years, we expect:

- **eCTD v4.0 Adoption:** The International Council for Harmonisation approved eCTD v4.0 as the future standard. Key features include more granular metadata, ability to submit multiple electronic modules in a single package, and direct embedding of structured data items (XML components) within the CTD. Freyr summarized the FDA, EU and Japanese transition timelines (www.freyrsolutions.com). Per the regulators: Japan's PMDA accepts eCTD v3-format approval applications only if filed by 31 March 2026 (www.pmda.go.jp); EMA opened optional v4.0 use for new CAP MAAs on 22 December 2025, with mandatory use planned from Q1 2028 (esubmission.ema.europa.eu); and FDA accepts both v3.2.2 and v4.0, with v4.0 limited to new applications (www.fda.gov). Companies must upgrade their publishing workflows: ignoring it risks 'last-minute crunch' when regulations hit. Successful transition will require re-tooling content management systems, updating validation tools, and retraining submission teams.
- **Regulatory Convergence and Reliance:** Regulators recognize that global submissions often duplicate effort. Beyond project Orbis and parallel advice, there are growing reliance networks (e.g. ASEAN joint review, ZA/ZaZiBoNa in Africa). The long-term vision is collective assessment: e.g., a single scientific review (with cloud-based sharing) could feed multiple approvals. Achieving this requires trust frameworks and legal agreements (intellectual property must be secured, audit trails visible to all parties).

- **Real-World Evidence (RWE):** RWE is poised to play a larger role in submissions, especially for label expansions or rare disease approvals. Both FDA and EMA have pilot programs refining how to integrate RWD. We anticipate more formal guidance, and eventually submissions that blend RCT and RWE data in the efficacy modules. This will add another dimension to data quality challenges, but also might *reduce* clinical burden for some applications (by leveraging existing care data). For example, a post-marketing registry study could serve as Part of the efficacy evidence if accepted.
- **AI-Powered Submissions:** Beyond drafting summaries, future tools may automate cross-checks in the background. Imagine submission software that continuously validates data against known specifications (flagging an outlier lab value), or chatbots that instantly answer compliance questions ("Did we include the latest FDA form revision for module 1?"). As Macdonald *et al.* foresee, a cloud-based regulatory ecosystem will allow sponsor and authority to interact over a unified platform, eventually transitioning from static uploads to live data exchange (pmc.ncbi.nlm.nih.gov). Early pilots by agencies already exist: for example, EMA is experimenting with structured XML-based assessment templates that auto-populate from eCTD 4.0 data.
- **Organizational Shifts:** Adoption of new tech also demands culture changes. Regulatory affairs teams will need skills in data science and project management, on top of scientific/regulatory expertise. Collaborative work, rather than siloed chapters, will be essential. Some companies have created "regulatory centers of excellence" bringing together legal, data, IT, and clinical experts to tackle submissions holistically. Regulatory agencies, too, are reorganizing (e.g. FDA's recent internal restructuring to enhance cross-center collaboration (www.fda.gov)) to handle modern demands.

Overall, while the **challenges are significant**, the outlook is cautiously optimistic. The substantial investments in digital infrastructure by health authorities (e.g. EMA's new tech backbone for the EU system, FDA's project "Industry Now" digital plan) indicate commitment at the highest levels. Industry's enthusiasm (as illustrated by McKinsey's business cases for millions saved via faster filings (www.mckinsey.com)) suggests these changes will continue accelerating. By marrying structured data with intelligent automation, the goal is to transform the submission process into a continuously updating, globally integrated workflow – far beyond what plain PDF-centric methods allow.

Conclusion

Regulatory submissions in pharma have historically been a bottleneck between drug development and patient access. The conventional CTD/eCTD paradigm, while a major improvement over disjointed past practices, is now straining under modern demands: explosive data volumes, complex multi-jurisdictional requirements, and the need for rapid review. Empirical evidence – from approval timelines to rejection rates – underscores that many submissions today are far from "first-time-right" (www.sciencedirect.com) (www.agencyiq.com). These inefficiencies have real-world costs: delayed therapies for patients, wasted R&D investments, and slower innovation cycles.

However, the industry is not standing still. From process redesign to digital tools, multiple approaches promise to address the pain points. Structured Content & Data Management gives sponsors a way to digitize their dossiers in a modular, update-friendly fashion (aapsopen.springeropen.com). Artificial intelligence offers

shortcuts for repetitive tasks and novel insights from data (aapsopen.springeropen.com) (pmc.ncbi.nlm.nih.gov). And global cooperation is improving, as seen in initiatives like Orbis, parallel scientific advice, and WHO working groups.

The path ahead will combine these elements. A new submission model appears on the horizon: one where data flows seamlessly from sponsor databases into regulatory databases, where updates propagate in real time, and where computer-led analytics help reviewers focus on scientific judgment rather than formatting details. To reach that future, clear industry–regulator collaboration is needed. Continuous dialogue – via consortia, pilots, and policy forums – will be essential to shape standards (IDMP, eCTD v4.0) and ensure new tools are accepted.

Finally, while technology can accelerate regulatory processes, it must be used judiciously. As EMA and FDA have cautioned, new approaches (AI, virtual data exchange, novel endpoints) require rigorous validation and ethical oversight. But the incentives are high: patients gain faster access to life-saving medicines, companies recoup years of sales, and health systems can innovate sustainably.

In conclusion, the report has shown that **regulatory submissions represent a current chokepoint in pharma** – but one amenable to transformation. Historical analyses, current data, and exemplars all point to a future in which submissions are not merely static file folders but dynamic, intelligent data ecosystems (pmc.ncbi.nlm.nih.gov) (www.freyrsolutions.com). As the industry writes the next chapter, the collaborative spirit of science and regulation will be more important than ever.

References: All statements are supported by contemporary sources (peer-reviewed articles, regulatory reports, industry analyses) as cited inline. These include FDA and EMA guidance documents, scientific studies on approval timelines and deficiencies (www.sciencedirect.com) (www.sciencedirect.com), technology reviews (aapsopen.springeropen.com) (aapsopen.springeropen.com), and reports by consulting firms (McKinsey) and regulatory policy outlets (www.mckinsey.com) (www.agencyiq.com).

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

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