IJBPAS, August, 2025, 14(8): 4725-4732

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

MALPRACTICES IN REGULATORY SUBMISSION

KAVYA K*, KRUTHIKA B T, JOSHI V AND ABHISHEK B V

Dept. of Pharmaceutics & Regulatory Affairs, Sri Adichunchanagiri College of Pharmacy, ACU, B.G Nagara, Karnataka,571448, India

***Corresponding Author: Kavya K: E Mail: kkavya5214@gmail.com**

Received 10th April 2024; Revised 4th May2024; Accepted 7th Sept. 2024; Available online 1st Aug. 2025

https://doi.org/10.31032/IJBPAS/2025/14.8.9374

ABSTRACT

Malpractice in regulatory submissions can compromise product efficacy, safety, and integrity, negatively impacting health and legal situations. Common types of submissions include clinical trials, changes to information, marketing applications, and post-approval commitments. The FDA has tightened submission conditions, with 32% of trial data showing serious problems with data compliance. To optimize submissions, companies should maintain extensive regulatory knowledge, stay updated on regulations, guidelines, and standards, and participate in meetings and discussions before filing. Collaboration between senior management and submission teams is crucial, as unrealistic deadlines can increase risk. Ensuring regulatory submissions is a complex process that requires extensive knowledge, effective communication, and a commitment to avoiding malpractice.

Malpractice, characterized by actions that defy standards, bias, and public opinion, is influenced by weak legislative frameworks, disproportionate company influence, and lack of initiative. Implementing a structured SOP and staying updated on regulations can help companies navigate the complex process of regulatory submissions, improving their chances of success.

Keywords: Malpractices, Regulatory Submissions, Optimization, SOP's

INTRODUCTION:

Any action, inaction, or custom that departs from the set rules is referred to as **"Malpractice"** or which

- Promotes prejudice
- Harms the public's opinion of qualifications
- Violations, attempts to discredit, or anything else that would call into question the reliability of any

certification, assessment procedure, or outcome

- Harms the position, authority, and reputation of any centre or awarding body, as well as the standing of any officer, representative, or employee of one of these institutions.

Among other things, malpractice is giving controlled assessments using prohibited methods and going against instructions.

- **The following are types of malpractices:**

1. A breach in security
2. Deception
3. Inadequate assistance
4. Improper management
5. Fabrication and manipulation of information

Illustrations of misconduct

- Often instances emerge deliberately to give individuals an unfair advantage during the evaluation procedure.
- When a person follows the rules carelessly, inattentively, or forgetfully, certain things happen.
- Things get worse because of the intricacy of the problems the corporation is dealing with, the unreliability of the information at hand, and the authorities' ignorance of corruption.
- Weak legislative and regulatory environments have been caused by national regulatory frameworks that usually rely on self-regulation at crucial decision points, a lack of oversight, and insufficient funding.
- Companies may have an excessive level of influence over laws and regulations due to their unequal access to resources and a high degree of autonomy over crucial decision points. Therefore, maximizing profits goes against moral precepts and compromises the objectives and outcomes of public health.
- Insufficient initiative in combating corruption.

Regulations

'Regulations' means the list of documents. They include instructions and procedures for setting up access and conducting controlled evaluations.

Regulator

An establishment tasked by the government with developing and managing national certificate standards **[1]**.

Regulatory submissions

Regulatory agencies will only accept submissions of new medications and medical techniques if the data is high-quality and pertinent. The regulatory filing process is a crucial stage in the creation of novel drugs and medical treatments **[2]**.

The submission's result will decide whether or not a drug can proceed from clinical trials to commercial release **[3]**.

The phrase "malpractice in regulatory submissions" refers to unethical, unlawful, or erroneous acts committed when submitting data and documentation to regulatory bodies in order to obtain permission for products like chemicals, medications, or medical devices. These acts may compromise the products' efficacy, safety, and integrity as well as have detrimental effects on one's health and legal situation.

Common type of regulatory submissions:

- ✓ Requests for Applications for Clinical Trials
- ✓ Changes to the Information on Chemistry, Manufacturing, and Controls (CMC)
- ✓ Marketing applications
- ✓ Requirements for Changes to Submissions
- ✓ Making Use of a third-party Services
- ✓ Agency Questions Addressed During the Examination
- ✓ Submission of the Post-Approval Commitment **[4]**.

Objectives:

- ✓ To illustrate common malpractices in regulatory submissions, Identify the challenges organizations face in complying with diverse regulatory frameworks and how these challenges can lead to unethical practices.
- ✓ To understand a comprehensive framework or action plan that organizations can adopt to mitigate the risk of malpractices in regulatory submissions

RESULTS & DISCUSSIONS:

Smaller or newly established biotechs have historically found it difficult to navigate the complex regulatory filing processes, but this has recently become more difficult. The conditions for submissions have tightened, and candidates are now expected to submit a substantial amount of data and accompanying documentation **[3]**.

According to a recent FDA inspection, there were serious problems with data compliance in 32% of the trial data that were presented. The FDA does not receive submissions that are turned down because they do not meet the requirements for research data; rather, the FDA Electronic Submissions Gateway and the FDA Electronic Document Rooms are the first steps in the formal FDA review process **[2]**.

Causes for Malpractices in Regulatory Submission

Regulatory submissions can be challenging no matter how big the company is or where the product is in the development process. The process of preparing a regulatory request for approval involves multiple steps, and mistakes are inevitable.

Malpractices in submissions include:

National values: Certain national submission requirements those from the US and Europe- might be difficult to remember

and comprehend. Manufacturers should be aware that updates or modifications to foreign rules may result in changes to submission requirements.

Absence of strategies for regulation: Before submitting their work, manufacturers must get in touch with the relevant authorities, plan a suitable course of action that starts with the offset, and obtain guidance and support for the necessary data. Robust regulatory approaches will be based on several essential principles, such as the needs of the target market, the competitive environment, an unfulfilled medical need, possible first-in-market prospects, and the first target indication.

Contradicting data: Recognized agencies such as the FDA have noted that businesses frequently omit details regarding the circumstances under which their products are supposed to be utilized. Another problem that occurs when different subject matter experts write different sections of the submission is an uneven narrative.

According to a recent FDA inspection, there were serious problems with data conformity in submissions containing research data. The FDA Electronic Submission Gateway does not even forward the submission sequence to the FDA electronic document rooms, where the FDA Review process is formally initiated when a submission is rejected due to noncompliance with study data! Resubmitting applications that have been denied can be expensive, cause delays in the marketing clearance process due to earlier and stricter deadlines, and prevent patients from receiving innovative, life-saving treatments.

Minimal to negligible past submission experience: Employees with submission processing experience are typically difficult for employers to keep on board. It is important to consider the risk that the submitting teams won't be able to adjust to changes in business strategy, including the launch of new adventures or combo products **[4]**.

A lack of narrative exists for product placement: When it comes to product advertising, businesses typically don't provide regulatory reviewers with enough context or an accurate picture of their offerings. If you include a detailed narrative with your proposal, the regulatory reviewer will understand it better. For example, the eCTD submission document should contain important messaging about the product's position in the market. Since the concept is presented in bits and pieces by several SMEs, it is easy to miss the coherent narrative as a whole.

Protocols for document control that lack precision and clarity: Setting up the various documents needed for submission is crucial. Using established templates ensures homogeneity between components. Submission teams may face extra

difficulties in maintaining a procedure for updating data that becomes available after the fact and performing sufficient data verification. Errors in submissions can be decreased by implementing strict version control and planning for last-minute modifications.

Unachievable submittal deadline: Unrealistic timelines that raise risk might arise when senior management sets aggressive target submission dates without first contacting the submission team. To ensure that upper management is aware of what is possible within a specific timeframe, the project manager must collaborate with the submission team to create a realistic timeline based on preset assumptions.

Weariness from often approaching: Filing regulations is a time-consuming procedure. It often takes several months of rigorous labour with strict deadlines to finish a large proposal. It takes years of laborious work to compile the information required to support a product's approval. Good product portfolios can open fresh, interesting business options, but managers need to be aware that pursuing market leadership or competitive advantage can also increase the risk of staff fatigue **[5]**.

Optimizing the Regulatory submissions:

Optimizing the Regulatory submissions is necessary to successfully obtain approval for biologics, medical devices, and prescription drugs. By putting best practices into practice and being proactive, life science companies can improve their chances of clearance and become more adept at negotiating the regulatory environment.

Proper preparation and organization of the paperwork is necessary for a successful submission. To maintain uniformity, regulatory agencies offer standards and norms that need to be adhered to. Efficient document management systems promote cooperation and version control; a focus on precision, coherence, and conciseness enhances the readability of the contribution.

Extensive regulatory knowledge: Maintaining up-to-date regulatory intelligence is essential. Keep abreast of any changes to the regulations, guidelines, and standards that affect the target markets. To find out about expectations and trends in regulation, use trade associations, actively participate in regulatory groups, and attend conferences. Companies that have a solid grasp of the regulatory landscape are better equipped to foresee challenges and take proactive steps to resolve them before submission.

Meetings and discussions before filing: Meetings and consultations with regulatory bodies before submission may prove to be quite advantageous. Before applying, you can use these conversations to seek clarification on the requirements and answers to any questions you may have. By

taking advantage of these chances, you could improve the quality of your application, speed up the review process, and boost regulatory confidence.

Preliminary creation of systems for control: It is imperative to have a strong regulatory strategy in place from the beginning of the product development process. Make that the company's objectives and the features of its products comply with all relevant laws. To speed up the approval process, identify possible accelerated programs, regulatory paths, and special designations.

Arranging and gathering documentation: Follow the guidelines and templates that the regulatory bodies have provided to guarantee consistency and thoroughness. Sufficient and orderly documentation is necessary for submission to regulatory agencies.

Generation of solid data and evidence: The foundation of any effective regulatory filing is accurate data. Set strict criteria for data collection, processing, and validation to guarantee the accuracy and dependability of your data.

Conversations and responses following the submission: Take the initiative and maintain open lines of communication with regulatory agencies during the assessment process. Respond to inquiries, provide clarifications as needed, and provide further information upon request. To guarantee a seamless review procedure, keep lines of communication open and foster goodwill among regulatory bodies. Well-thought-out and organized responses demonstrate commitment, scientific rigor, and initiative **[6]**.

Recognizing the regulatory environment

Identifying Authorities: Requirements differ between regulatory agencies in different places. Developing a customized submission strategy requires a thorough understanding of the peculiarities of regulatory organizations like the FDA, EMA, and others **[7]**.

Components of a product: Every product has requirements and challenges, whether they be prescription drugs or medical equipment. A customized approach Is required to ensure regulatory success while overcoming challenges particular to a product **[8]**.

SOP for Monitoring and Reporting Regulatory Submissions

This SOP's objective is to give the entire business a standardized operating procedure for keeping track of and informing itself of regulatory filings. Along with providing efficient management of regulatory submissions and accurate and timely reporting on submission statuses and milestones, its goal is to uphold compliance with regulatory requirements.

Scope of the SOP's

All employees engaged in regulatory operations, such as regulatory managers, regulatory associates, and other pertinent staff members in charge of monitoring and disclosing regulatory submissions, are subject to the terms and circumstances of this SOP.

Responsibilities:

Regulatory Affairs Department:

- To oversee the reporting and monitoring procedure for regulatory filings.
-To ensure that all applicable laws and procedures are followed while supplying regulatory information.
-To assist, guide, and furnish the staff members engaged in the process with the required materials.

Regulatory Submissions Tracking Team:

-Every regulatory submission application, supplement, modification, and continuing report be closely watched and updated.
-For each rule that is proposed, keep an accurate and current tracking system.
-Make sure all required paperwork is completed and submitted on schedule **[9]**.

CONCLUSION:

In conclusion, ensuring regulatory submissions is a complex process that requires extensive knowledge, effective communication, and a commitment to avoiding malpractices.

Organizational integrity, industry standards, and public safety are all seriously threatened by malpractice in regulatory filings. The complexity of nation-specific legislation, the lack of strong regulatory laws, uneven data processing, and ignorance of the submission process are a few of the numerous causes of these immoral activities. These components come together to produce a setting in which taking shortcuts and cheating might be seen as acceptable, even enjoyable.

To reduce the rate of malpractice, regulatory bodies play a critical role. Increasing surveillance, enforcing compliance requirements more strictly, and working to harmonize international legislation are some tactics to lower the likelihood of unethical behavior. Furthermore, promoting transparency and accountability in the workplace would aid in reducing the stress that frequently results in malpractice.

ACKNOWLEDGEMENT:

The author wants to acknowledge the management of Sri Adichunchanagiri College of Pharmacy for their valuable support.

CONFLICT OF INTEREST:

The authors declared that there is no conflict of interest

REFERENCE:

[1] Suspected Malpractice Policies and Procedures Contact us - we are open to giving advice to centres. Click here for details of our email. Twitter@JCQcichttps://www.jcq.or

g.uk/wpcontent/uploads/2023/02/Malpractice_Feb23_v1.pdf

[2] Price C. The Importance of Quality Data for Regulatory Submissions. PharmTech 2024.

[3] Understanding regulatory submissions and the role of regulatory CMC project management NewsMedical2024https://www.newsmedical.net/whitepaper/20210617/Understanding-regulatory-submissions-and-the-role-of-regulatory-CMC-project-management.aspx

[4] Common types of Regulatory Submissions | Freyr - Global Regulatory Solutions and Services Company n.d. https://www.freyrsolutions.com/blog/common-types-of-regulatory-submissions.

[5] Carino S, Hadidi R. Common Regulatory Submission Pitfalls and Ways to Avoid Them. Integrated Project Management Company 2024. https://www.ipmcinc.com/insights/commonregulatory-submission-pitfalls/.

[6] Optimizing Regulatory Submissions: Strategies for Successful Approval. BioBostonConsulting 2024. https://www.biobostonconsulting.com/post/optimizing-regulatory-submissions-strategies-for-successful-approval.

[7] Creating a Regulatory Submission Roadmap: Timelines and Milestones. BioBostonConsulting 2024.https://www.biobostonconsulting.com/post/creatinga-regulatory-submission-roadmap-timelines-and-milestones.

[8] SOP for Regulatory Submissions Tracking and Reporting - SOP Guide for Pharma. SOP Guide for Pharma n.d. https://www.pharmasop.in/sop-for-regulatory-submissions-tracking-and-reporting/#google_vignette

[9] Regulatory Submission - Data Analysis & Review | Quantitate n.d. https://www.quanticate.com/regulatory-submission.