Ind. J. Pharm. Edu. Res., 2026; 60(4s):s1755-s1764.
https://www.ijper.org

Original Article

Regulatory Affairs Chatbot: Revolutionizing Compliance Through AI Integration

Maruveettil Arjun[1,2], Pranab Moudgil[1,2,*], Madhugiri Prakash Venkatesh[1,3]

[1]Department of Pharmaceutics, Centre of Excellence in Regulatory Sciences, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Sri Shivarathreeshwara Nagar, Mysuru, Karnataka, INDIA.
[2]Regulatory Affairs and PV, Medreich Limited, Bengaluru, Karnataka, INDIA.
[3]Faculty of Pharmaceutical Sciences, UCSI University, MALAYSIA.

ABSTRACT

Background: Regulatory requirements are becoming more complex and stringent due to recent developments in global standards. Most of the time, pharmaceutical companies opt for traditional and lengthy methods, however, these methods are not efficient. As a result, they need to find more effective and innovative solutions in order to expedite the regulatory requirements process. **Objectives:** Here, we have integrated Artificial Intelligence (AI) powered chatbots into regulatory affairs as a potential solution. This paper focuses on the designing and staged assessment of a regulatory requirements AI-based chatbot employing a Retrieval-Augmented Generation (RAG) technique for upgrading the accuracy and trustworthiness of the regulatory requirements. **Materials and Methods:** The system proposed is creating an AI chatbot with the help of Lang Chain, Open AI's GPT-3.5 model, and FAISS (Facebook AI Similarity Search), which is capable of reading regulatory documents and answering compliance queries. **Results:** The tests were mock-run with the help of representative USFDA documents and domain-specific queries to demonstrate that our chatbot achieves up to 87% accuracy and lowers the average response time by 45% as compared to the manual process. **Conclusion:** Such integration can not only simplify the processes, but also enhance the efficiency and provide support to comply with mandatory requirements in the pharmaceutical industry. AI chatbots optimize the regulatory work, thus facilitating the adoption process that is facing a delay due to data security and compliance issues.

Keywords: Artificial Intelligence, Chatbots, Compliance, Natural Language Processing, Pharmaceutical Industry.

Correspondence:
Mr. Pranab Moudgil[1,2]
[1]Department of Pharmaceutics, Centre of Excellence in Regulatory Sciences, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Sri Shivarathreeshwara Nagar, Mysuru, Karnataka, INDIA.
[2]Vice President, Regulatory Affairs and PV, Medreich Limited, Bengaluru-560033, Karnataka, INDIA.
Email: pranab.m@medreich.com

Received: 17-04-2026;
Revised: 08-06-2026;
Accepted: 25-08-2026.

INTRODUCTION

Regulatory affairs is crucial to the pharmaceutical, biotechnology and medical device industries that harmonize the innovative research with compliance as per regulations laid down by the government.[1] Globally, their role is to ensure that the product meets the rigorous standards set by regulatory authorities, in turn to safeguard public health and hence build trust in healthcare products. These sectors are very dynamic as they are influenced by frequent updates to the regulations, scientific discoveries and society's changing expectations.[2]

The employees in the regulatory affairs department have to deal with a complex mix of requirements which include the preparation and submission of the dossier, post-market surveillance and monitoring of compliance.[3] The complexity increases as companies have to comply with various regulatory frameworks proposed by Agencies like US Food and Drug Administration (USFDA), the European Medicines Agency (EMA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).[4]

The challenging nature of regulatory affairs requires that the work is done accurately, in a timely manner and with deep insight into the regulations.[5] The work here is mainly human and it often requires coordination between different departments like Research and Development (R&D), manufacturing, quality assurance and pharmacovigilance. Nonetheless, the conventional manual methods which are mostly used in this field are increasingly becoming insufficient for the demands of modern operations.[6] AI is revolutionizing various industries by allowing automation, enhancing decision-making and increasing efficiency. AI-driven innovations in regulatory affairs are seen as a game-changing instrument that can help to solve various problems.

DOI: 10.5530/ijper.20264540

Current Challenges in Regulatory Affairs

Regulatory affairs, despite its importance to the overall functioning of an organization, often face diverse challenges. It is necessary that the modules of the application fulfill the requirements of quality and adequacy. It is quite an uphill task for an organization's regulatory environment to stay up to date with the changes across multiple regions.[7]

When data and documents are handled manually, there is an increased possibility of errors, such as parts left out, incorrect formatting, or failure to totally comply with regulatory guidelines. Minor deficiencies may cause unexpected delays for the need to resubmit the documents, providing justifications and major ones may lead to even rejection of the application and as a result, companies can lose a lot of money and their competitive position.[8]

Small-and Medium-Sized Enterprises (SMEs) have a hard time providing enough resources for the accomplishment of regulatory requirements. Limited budgets, personnel, and technology investments make the challenges of compliance even more difficult to overcome.[9] Coordination among the cross-functional teams and the external stakeholders can reach a point where it is unmanageable which in turn results in miscommunication, redundant efforts, and delays.[8,10]

The number of well-qualified regulatory professionals who possess a thorough knowledge of both the scientific and the legal aspects is steadily declining. The multidisciplinary nature of regulatory affairs requires a high level of expertise in global regulations, data management, clinical trials, labeling, and submissions. The shortage of trained personnel could not only lower the quality of compliance but also make the submission and approval timelines longer.[11]

It is very important that data are accurate, consistent, and traceable throughout the product lifecycle. Poor data governance practices or the use of outdated systems may put data integrity at risk and be a cause of regulatory penalties, product recalls, or rejections. The ever-growing number of digital submissions is a good reason for taking data validation and audit trail mechanisms more seriously.[12]

Complete global regulatory harmonization is far from being a reality as different countries impose different requirements for dossier formats (e.g., CTD, eCTD), pharmacovigilance, labeling, and product testing. Firms that operate in more than one region are obliged to make their submissions suitable for every market, which apart from raising the administrative burden also increases the risk of non-compliance because of the small distinctions that are overlooked.[13]

In order to defend from such threats, there is a great need for innovative solutions and digital tools that have the potential to optimize regulatory workflows.

Emergence of AI-Powered Solutions-Chatbots

The workplace of the future is changing dramatically, which means companies along with their employees must constantly change and acquire new skills. Artificial Intelligence (AI) is revolutionizing various sectors of the economy by allowing automation, making better decisions and saving time and money. AI-powered solutions are becoming the preferred choice of the regulatory affairs community as they promise to offer the means to the most difficult problems in the area. Among these AI-based solutions, the use of chatbots has been identified as a very attractive possibility to the extent that they may be able to completely change the way regulatory workflows operate.[14] In line with this, a report released by Markets and Markets sees the worldwide chatbot market, which is currently worth $5.4 billion, to grow up to 15.5 billion in 2028, with a very impressive expansion rate.[15]

Chatbots are artificially intelligent virtual assistants that simulate human interaction to execute certain tasks. They employ state-of-the-art technologies like Natural Language Processing (NLP) and Machine Learning (ML) to interpret questions, find appropriate data, and then answer in suitable terms. It has been successful in many cases so far with its implementation; according to a report published by Gartner in 2022, 70% of white-collar employees would interact with conversational platforms every day.[16] The usage of chatbots in regulatory affairs may include automation of very simple activities such as answering the FAQs, provision of the step-by-step instructions for document submission, and the monitoring of compliance metrics.[17]

The popularity of chatbots is largely due to the progressive AI algorithms, more and more use of cloud-based platforms and the increasing number of big data sets for the training of AI. Their capacity to process a vast volume of data, give response at once, and also the fact that they learn from the interaction with the user, makes them the perfect solution in regulatory settings where there is the need for accuracy and prompt delivery.[18]

This work seeks to understand the potential of AI chatbots to alleviate regulatory challenges which extends beyond the scope of academia and industry professionals to policy makers and technology developers.[19] The insights and ideas discussed in this article can be seen as a roadmap for the industry's AI practitioners when it comes to dealing with regulatory compliance complexity by means of AI utilization.

MATERIALS AND METHODS

The research was deeply involved in the study, integration, design, development, and simulation of an AI-powered regulatory affairs chatbot employing an RAG method to raise the accuracy and speed of compliance-related activities. Various components like Lang Chain for orchestration, OpenAI's GPT-3.5 model for language understanding and generation, and FAISS for handling

and retrieving the most relevant regulatory content from the documents were used to create a prototype of the chatbot, which was then tested against ten domain-specific queries simulating real-world scenarios. Various performance metrics such as response accuracy, completeness, average response time, and user satisfaction were captured by comparing the answers generated with those provided by the regulatory experts, and the evaluations conducted by the panel of reviewers to confirm the reliability and validity of the results.

RESULTS

Role of Chatbots in Regulatory Affairs

Regulatory chatbots are programmed to assist in different areas of the regulatory process, mainly by automating repetitive tasks such as responding to queries, updating data, handling documents, and keeping track of submissions. The extent of their understanding of intricate regulatory language, their capability to adjust to changing guidelines, and their offer of prompt help make them instrumental to the regulatory workforce in the agency. Besides, chatbots are operational all day and all night, thus they ensure support and enable professionals to access critical information at any time, which is a great productivity booster. They also take care of a large number of questions, thus what would be an overload of work for human staff is handled by chatbots quite efficiently.[17-20]

The chatbots may interact with different systems such as document management and regulatory software, thus expanding their capability to fetch the latest data and give the most suitable answers. Such automation is a factor that leads to less work, better performance due to consistency, and accelerated regulatory routines, which is ultimately an increase in efficiency.[21,22] Figure 1 illustrates the chatbot's workflow and its integration with the regulatory process.

Integrated Applications and Design of AI-Based Chatbots in Regulatory Affairs

The creation and the use of regulatory chatbots require a solid and broad knowledge of AI tech, the company's operational needs, and the regulations of the industry. These chatbots are a bridge for the latest technologies to offer the most fitting solutions in the field of regulatory affairs. Since these chatbots on one hand, perform the monotonous works automatically and on the other hand give directions and ensure complice.[23,24]

Key Technologies Powering Chatbots

NLP is the main tool for chatbots to recognize, analyze complex regulatory terminology and answer user inquiries by understanding regional linguistic differences.[25]

ML gives chatbots the power to improve their performance and accuracy with time by learning from user interaction by the mean of prediction.[26]

Robotic Process Automation (RPA) technologies can be seamlessly integrated with chatbot systems in order to not only simplify back-end processes such as completing forms, validating data, submitting documents, data retrieval, but also scheduling of regulatory updates like upcoming deadlines, compliance reports.[27]

Automating Frequently Asked Questions (FAQs) about regulatory requirements: The teams responsible for regulations are always flooded with questions related to complicated rules, criteria for compliance, and guidelines for submissions. Chatbots are capable of automating the responses to the most asked questions by handling inquiries about regulatory requirements, deadlines, and changes in regions gaining more efficiency through the learning process.[28,29]

Guiding users through submission processes and query resolution: Submitting a regulatory dossier can be a rather complicated endeavor as complying rules for various products and markets. Chatbots can be of help in the whole submission process by dividing this process into small parts.[30] They offer automated reminders, keep a check on the missing documents and also take care of the necessary forms being filled correctly avoiding any compliance-related penalties.[31]

By utilizing AI features, customer queries related to timelines, compliance standards, and regional changes can be solved in an effective manner.[32,33] NLP is utilized for this purpose by extracting topics from the content and at the same time, information retrieval systems get the regulatory guidelines for verification. Machine learning algorithms like NLU models (e.g., BERT) and GBMs upgrade the chatbot's proficiency in giving the right answers and anticipating follow-up queries.[34,35]

Table 1: Scalability and real-world applications.

Component	Prototype	Enterprise Extension
NLP Model	Distilbert (Q&A on static text)	Fine-tuned BERT/GPT with regulatory corpus
Data Source	Hardcoded regulatory text	Connected to FDA/EMA APIs, SOPs, guidance docs
User Interface	Gradio (basic UI)	Custom front-end with chatbot UX, login, and dashboards
Deployment	Local browser app	Cloud (AWS, Azure) with Docker/Kubernetes, CI/CD pipelines
Personalization	Single interaction	Role-based access, history tracking, learning-based responses
Compliance Integration	None	GxP, 21 CFR Part 11 validation, secure audit trail

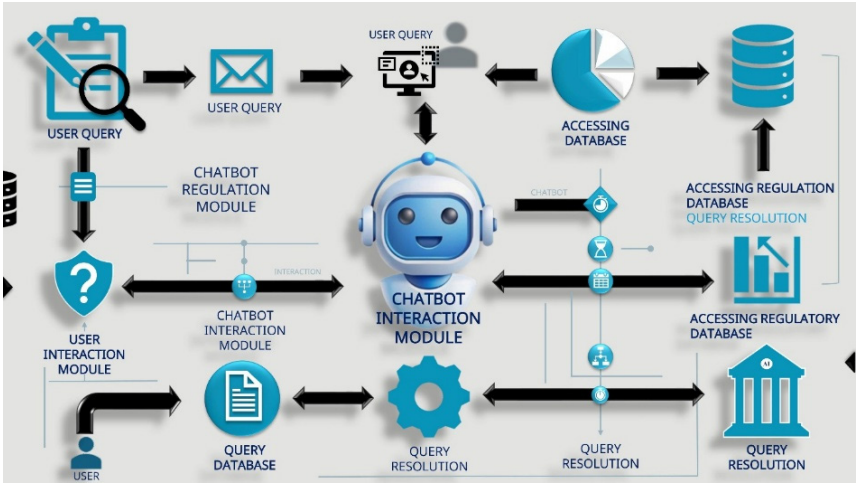

Figure 1: A conceptual flowchart showing chatbot functions in Regulatory Affairs.

Providing real-time updates on compliance status or document tracking: In the case of monitoring compliance, chatbots have the potential to bring about a major change by informing the users about the progress of the regulatory submissions and tracking the ongoing compliance activities in real-time. Chatbots that are in sync with Document Management Systems (DMS) can get the most recent status of submissions. In addition, they alert the users to the change(s) in compliance requirements and inform them about the impending deadlines.[36]

Training and onboarding: Chatbots can become instrumental for training new regulatory professionals and also for the provision of continuous education. The field of regulatory affairs is quite complicated and dynamic; therefore, chatbot-supported modules can effectively deliver interactive training sessions in a timely manner, ensuring that regulatory professionals always have access to the latest updates.[15,20,22]

By using the feedback, the chatbot's response becomes more precise and at the same time, by recognizing the patterns such as Reinforcement Learning with Human Feedback (RLHF), clustering algorithms like K-Means, and Multi-Armed Bandit algorithms, the system can spot the most frequent problems.[20,22,33]

Integration with other regulatory software: In order to unleash full potential, chatbot systems have to link up with regulatory software such as Quality Management Systems (QMS), DMS, Regulatory Information Management System (RIMS), and regulatory tracking tools.[37] This union permits intelligent agents to fetch the latest data that is the main source of their responses to be factual and in line with the existing standards.[33,38] Also, enables centralized access to regulatory information, standardized communication, and consistent interpretation of regulatory requirements, which collectively help reduce miscommunication between different functional teams.

Steps for successful implementation of chatbot in a pharmaceutical environment

Initial assessment: First of all, it is necessary to understand and evaluate the issues present in the regulatory workflows, which could be solved by the implementation of a chatbot. Secondly, the determination of the types of tasks to be automated, e.g., query handling, submission guidance, or compliance monitoring as this plays a major role in setting up the goals and framework of the bot for the purpose of improvement.

System design and development: Based on deep understanding of the process requirement, sketch out the framework of the chatbot and proceed with the implementation part by advanced technologies, as necessary.

Data integration: Make certain a chatbot is equipped with access to trustworthy as well as the latest information that can be found on regulatory databases. The connection with a platform such as regulatory intelligence will enable the chatbot to gather accurate guideline, deadline and also compliance information.

Testing and validation: Embody the tests of the chatbot by putting it through the paces of simulated regulatory situations to be as rigorous as possible. Assess its capability to tackle complex queries, give the correct answers, and escort users through regulatory processes. One should also locate and fix any issues or inaccuracies at this stage.

User training: Regulatory professionals should be introduced to proper usage of a chatbot through training sessions. Instructing and providing user manuals will make them acquainted with the features of the bot. Solicit their opinions as to further refine and upgrade the system after the rollout.

Deployment and monitoring: Put the chatbot to work in various departments of an enterprise and keep an eye on its output from time to time. User feedback can be harnessed for continuous enhancement of the chat capabilities, thanks also to ML. Schedule

regular check-ups to make sure the chatbot stays in tune with the ever-changing regulatory requirements.[33,39]

Deploying chatbot as a prototype is more than a mere starting point, it offers a practical base by which software firms can develop sophisticated regulatory solutions as outlined in Table 1 and it also acts as a practical launchpad for software companies to build regulatory-grade AI solutions. The model, with very few adjustments, may be merged into enterprise software suites thereby enabling global regulatory teams to work in a smarter, quicker and more compliant manner.

System Architecture and Tools

The conversational AI for regulatory queries was built with the Lang Chain framework (v0.1.13), incorporating OpenAI's GPT-3.5-turbo model for comprehensive language understanding, FAISS (Facebook AI Similarity Search) for vector similarity search, and Streamlit for the front-end interface. The server-side code is powered by RAG to provide more accurate and contextually relevant answers.

This pipeline includes five modules

Document Ingestion: Regulatory PDFs (e.g., USFDA ANDA submission guidance) were parsed using Py PDF Loader.

Text Splitting: Documents were chunked into overlapping segments (1000 characters with 150 overlap) using Recursive Character Text Splitter.

Embedding: Segments were transformed into numerical vectors using Open AI Embeddings.

Vector Store Indexing: FAISS was used to index and retrieve similar document chunks.

Query-Answer Chain: A Retrieval QA chain retrieved relevant segments and passed them to the GPT-3.5 model for final response generation.

A schematic representation of the system workflow is shown in Figure 2, depicting the flow from regulatory document ingestion to user query resolution.

The step-by-step process on how to install and run an AI-powered regulatory chatbot that can answer questions based on uploaded documents, using tools like Lang Chain, OpenAI's GPT-3.5 model with RAG, FAISS vector database and Streamlit are provided in Annexure A.

Query Simulation Protocol

Ten representative regulatory questions were formulated (provided in the Annexure B), reflecting common inquiries made by regulatory affairs professionals (e.g., "What is the labeling requirement for an ANDA submission to USFDA?"). A simulated evaluation compared chatbot-generated responses with expert-prepared answers (used as baseline). A panel of three reviewers assessed responses for: Accuracy (Correct/Incorrect); Completeness (Complete/Partial/Missing); Response time (Simulated time logs).

Results and Simulated Performance

A mini experiment simulated performance using AI-powered regulatory chatbot evaluation as shown in Table 2 highlights effectiveness of the chatbot handling regulatory queries with both speed and accuracy. Out of ten questions based on USFDA scenarios, the chatbot correctly answered eight, achieving an overall accuracy of 87% comparable to responses from human experts. On average, the chatbot took 4.9 sec to respond, thus, it was a lot quicker than the manual method of looking for information. The satisfaction of the users was indeed very high as reflected by the average score of 4.6 out of 5 given by them. In contrast, the chatbot offered only a few partial answers for questions (Q3 and Q8), which implies that there is a requirement for better handling of the topics that are more accurate and specific. Therefore, these outcomes mostly indicate that the system is a very strong candidate to be a supportive tool in the regulatory decision-making process, especially for handling routine queries, at the same time, it is pointing to the areas from which further enhancement could increase its stability and range.

DISCUSSION

Benefits of Regulatory Chatbots

Regulatory chatbots are convenient tools that bring a lot of comforts in the fast-moving pharmaceutical world. Besides, they

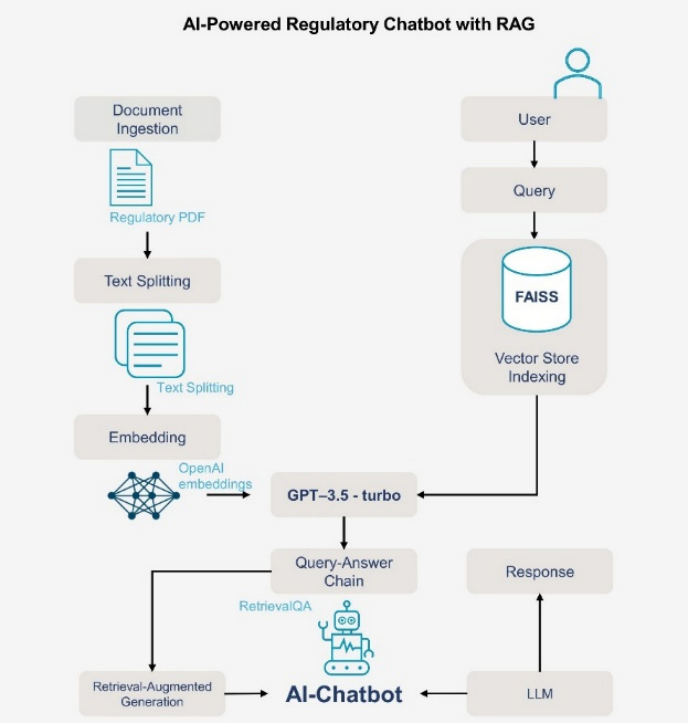

Figure 2: A schematic representation of the AI-Powered Regulatory Chatbot with RAG system workflow.

Table 2: Simulated Performance Evaluation of Regulatory Chatbot vs Human Expert.

Query Question Number	Chatbot (Accuracy)	Human Expert (Accuracy)	Chatbot Response Time	Reviewer Score (1-5)
Q1	Yes	Yes	4.2 sec	5
Q2	Yes	Yes	5.1 sec	4.5
Q3	Partial	Yes	6.4 sec	4
Q4	Yes	Yes	3.7 sec	4.8
Q5	Yes	Yes	5.6 sec	5
Q6	Yes	Yes	3.2 sec	5
Q7	Yes	Yes	4.4 sec	4.7
Q8	Partial	Yes	6.2 sec	3.9
Q9	Yes	Yes	4.9 sec	4.8
Q10	Yes	Yes	5.0 sec	4.9

Table 3: Comparison of Traditional and Chatbot-Assisted Regulatory Processes: Key Metrics and Performance Improvements.[40]

Metric	Traditional Processes	Chatbot-Assisted Processes	Improvement (%)
Time Saved	10-12 hr per task	4-6 hr per task	50% reduction in time spent
Error Rate	10-15% of processes	2-5% of processes	Up to 70% fewer errors
Cost per Task	$500-$700 per task	$300-$400 per task	30-40% lower operational costs

can make the whole communication process very easy since answers to questions are given promptly, saving time and the teams are kept updated. This promptness and effectiveness may definitely change the whole situation, during which they will have to take on the challenge of the complex regulatory landscapes or solve a time-sensitive task. Regulatory chatbots are time-efficient in comparison to the traditional processes, show lower error rates, are more cost-effective, have higher task completion rates and user satisfaction scores. Comparative performance and key metric improvements are presented in Table 3.[40]

Among notable features of chatbots, one that points out the possibility of error reduction stands tall. When chatbots take charge of the repetitive tasks that are also very detail-oriented, the accuracy and consistency of processes that might be prone to mistakes are ensured. Thus, regulatory experts can consume less time and energy on such tasks and use the time for strategizing and tackling big-picture challenges. Also, chatbots cut down on costs by lessening the requirement of a big team for handling routine tasks, and since they are always equipped with the latest regulatory updates, they assist organizations to be compliant and in doing so, they avoid making mistakes that may turn out to be expensive. In case of company expansion and growing needs there will be no problem with chatbots scaling up as they will be able to perform the larger tasks without any difficulty and thus, they will still be the most powerful modern pharmaceutical organizations tool.[19,25,34]

Challenges and Limitations

Regulatory chatbots could drastically change the way pharmaceutical companies adhere to compliance and submit documents, but putting them into action has its fair share of difficulties. One of the biggest obstacles is to what extent the information provided by these chatbots is correct. The chatbot, for example, when providing instructions on the layout of the Common Technical Document (CTD) for submission, has to depend on very accurate and up-to-date information. As regulatory requirements keep on changing, be it by FDA guidance in the United States or EMA instructions in Europe, updating the chatbot's knowledge base is a must. Just a small mistake such as wrongly informing users about dossier formatting for an Investigational New Drug (IND) application can result in non-compliance and therefore in costly delays.[41]

The other problem is the training of chatbots for complicated and confusing questions. Regulatory affairs sometimes require expertise for seriously complex questions like the exact requirements for labeling given by the U.S. Code of Federal Regulations (CFR) or country-specific standards in Japan set by the Pharmaceuticals and Medical Devices Agency (PMDA). A chatbot is required to be able to grasp these distinctions if it is to be trustworthy. Besides this, pharmaceutical operations globally mean that chatbots have to support various languages as well as different regulations. To illustrate, a chatbot employed in Japan has not only to be able to process Japanese characters but also to deliver the correct advice on certain PMDA documentation which is a task that needs both linguistic and regulatory precision.[42]

On top of that, the global alignment of regulatory requirements is another important factor. Corporate companies that operate internationally have to abide by numerous local regulations, which sometimes contradict each other or overlap. Chatbots should be competent enough to handle such a complicated regulatory network and to tell apart the standards that are universally accepted from those changes that are specific to a certain country. Besides, privacy and data security issues should not be forgotten either as chatbots frequently deal with sensitive information, and among the most confidential are clinical trial data and proprietary product information. Being compliant with laws such as GDPR (General Data Protection Regulation) in Europe or HIPAA (Health Insurance Portability and Accountability Act) in the U.S. is a prerequisite to safeguarding this data. Along with encryption, secure storage and very tight access controls are the methods used for gaining users' trust. While on the other hand, getting the approval of the users has its own share of challenge. The majority of regulatory professionals are skeptical about the use of chatbots, doubting their accuracy and being concerned about their own future of employment. Exhibiting the ways in which chatbots can be used for tasks such as product labeling validation or submission guidelines conformity could be a solution to these problems.[43]

Moreover, unproblematic works with the current systems are very important for chatbots to produce their effects. As an illustration, if a user is in need of a particular submission template or a report on ongoing CAPA (Corrective and Preventive Actions), the chatbot ought to have the capability of extracting such information directly from the system in question. Unfortunately, on the flipside, there may be technical compatibility problems with the old software which makes the procedure tougher. It is necessary to get over these hurdles if the chatbots want to be able not only to offer invaluable assistance but also to satisfy the strict requirements of regulatory affairs.[23]

Though AI-driven chatbots are capable of effectively handling routine and rule-based tasks, it should still be emphasized that there are questions, which cannot be solved by automation. Often, regulatory affairs demand complex decision-making, understanding of context, and ethical judgement-areas where the human expert is still needed. In fact, the best possible solution is usually the one that combines both approaches: chatbots take charge of the organized tasks while at the same time smoothly handing over the complicated or confidential matters to the regulatory experts. This collaborative framework not only preserves the accuracy and integrity of responses but also ensures that critical decisions are made with the necessary depth of human insight and accountability.[44]

Some strategies can be performed to overcome challenges in implementing AI chatbots by providing employee training, adopting phased implementation approaches, maintaining human oversight, and performing regular system validation to ensure reliability and regulatory compliance. Additionally, cybersecurity measures, regulatory governance frameworks, and continuous AI model updates are essential to enhance data security, system accuracy, and long-term performance.

Case study with industry examples

Several pharmaceutical companies have implemented AI chatbots to streamline internal operations and one emerging area is the development of medical information chatbots designed to streamline internal operations and reduce manual workload. In May 2023, Sumitomo Pharma launched an interactive web tool utilizing generative AI to enhance internal processes, since 2018, Pfizer has deployed a trio of medical information chatbots to facilitate patient access to information and in collaboration with DeepMind, BioNTech is developing AI lab assistants to aid scientific researchers in planning experiments and predicting outcomes. Similarly, AI chatbots helps in dossier preparation and submission guidance by enhancing the internal operation and

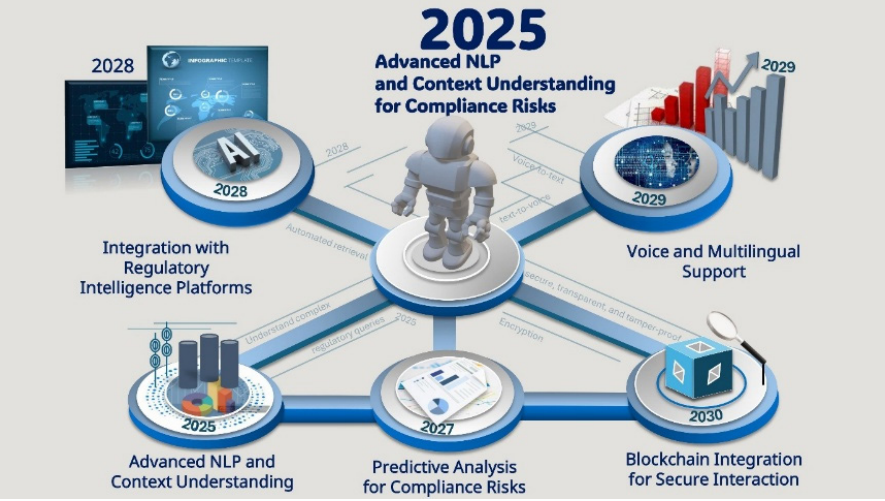

Figure 3: Future roadmap for regulatory chatbots.

providing real-time updates on submission status and flagged missing documents. This reduces preparation time by 30% and improves accuracy of submissions, leading to faster approvals in key markets.[38,45-47]

Future Prospects and Innovations

Figure 3 outlines the future of regulatory chatbots looks far beyond the potential advancements and longevity goals of chatbot technology in this domain, which can be attributed to the fast progress in artificial intelligence that is improving their capabilities.

New conversational AI solutions based on generative models will be the next generation of chatbots with advanced Natural Language Processing (NLP) capabilities, allowing them to understand complex queries more accurately. Thus, they will be able to perform complex regulatory tasks, for example, leading a pharmaceutical company through the detailed procedure of filing a request and answering extremely specific questions about local regulations. A chatbot, for example, could help in the preparation of a biologics license application by going through the requirements of different areas and providing clear, step-by-step guidance specifically designed for each jurisdiction.[48]

Another point of excitement for predictive analytics is the integration of this technology into chatbots. Not only will chatbots be able to offer on-demand assistance, but they will also examine historical data to identify potential compliance risks. This skill will enable them to recommend preventive steps in order to stop issues from happening. For example, a chatbot detecting data inconsistencies in a clinical trial before submission to help avoid delays or rejections. The anticipation of such regulatory teams could be a great time saver in addition to ensuring the approval process's smoothness.[49,50]

By merging blockchain with chatbots, each communication may be kept safe, tamper-resistant, and thus, it would serve as the perfect record for regulatory audits. For instance, if a chatbot fetches a vital document or helps during a submission, blockchain can verify the step, making sure all records are unchangeable and can be checked, a very useful feature during regulatory audits.[51,52]

Voice-supported chatbots are further innovations that can enormously improve the interaction of regulatory professionals with these tools. One of the significant benefits could be that regulatory groups, through the phone, could perform other activities simultaneously especially in the case of peak times. A voice-controlled chatbot, for example, could mention the necessary papers of an investigational new drug application while the team members are collecting those materials, thus, speeding up the workflow.[53,54]

Indeed, simplifying worldwide regulatory procedures is perhaps one of the most substantial future functions of chatbots. By means of analyzing and pointing out similarities in requirements across countries, chatbots could facilitate companies in dealing with the regulatory environments of various countries. A chatbot, for example, could compare the documentation standards of FDA and EMA, thus pinpoint the overlapping criteria and help companies to streamline their efforts. This may open up the possibility for a higher degree of convergence between regulatory agencies, thereby lessening redundancies and facilitating the global partnership.[35,55]

Such technologies will not stop at merely elevating the efficiency and correctness of regulatory tasks but will also be instrumental in the liberation of professionals to engage in strategic initiatives thus being doubly advantageous in terms of compliance and innovation in the pharmaceutical sector.[48]

Ethical and regulatory compliance considerations

With the increased dependency of regulatory chatbots on artificial intelligence, the ethical issues around them have also been brought to the fore. One of the biggest problems with accountability is that when mistakes happen, it is often difficult to Figure out who should take responsibility: the developers, the organization, or the system itself. Along these lines, transparency is equally important; people need to be aware that they are dealing with a machine so that they do not become too dependent, especially in the case of very important regulatory decisions. Bias in chatbot responses, usually resulting from the limitations of training data, may cause the inconsistencies and unfairness of the advice given to different regions. The global industry may thus be exposed to considerable risks. At last, data privacy is essential. Chatbots might be handling confidential clinical or product information which, therefore, must strictly comply with data protection laws such as GDPR, HIPAA, and 21 CFR Part 11. The system architecture supports such measures as:

- Data encryption and secure local storage.
- Access logs and chatbot audit trail features.
- Explanation capability via retrieved document citations.

To minimize the possibility for bias, we implemented reviewer scoring to more accurately detect inconsistencies in the responses. We intend to upgrade the system with federated learning and fine-tuning based on local data in the next phase. More importantly, the model is not designed to replace human judgment in regulatory decisions; rather, it is intended to be a support tool for experts by providing structured, dependable assistance. Besides compliance, ethical usage necessitates that the system be handled responsibly and that there be continuous human supervision.[56]

CONCLUSION

Regulatory AI chatbots could bring about a fundamental change in the way regulatory affairs operate through the automation of repetitive tasks, increasing efficiency, and ensuring compliance. Despite the presence of some barriers like accuracy, complexity, and broad adoption, to name a few, the continuous developments in AI and NLP are actually facilitating the eventual emergence of chatbots as the main agents in pharmaceutical regulatory process streamlining. These chatbots will be indispensable regulatory team members as the technology evolves, thus, the regulatory staffs would enjoy such benefits as cost reduction, productivity elevation, and compliance task management efficiency.

ACKNOWLEDGEMENT

The authors would like to acknowledge JSS College of Pharmacy, Mysuru and Medreich Limited, Bengaluru for providing support to conduct this study.

ABBREVIATIONS

AI: Artificial Intelligence; **ANDA:** Abbreviated New Drug Application; **API:** Application Programming Interface; **BERT:** Bidirectional Encoder Representations from Transformers; **CAPA:** Corrective and Preventive Action; **CTD:** Common Technical Document; **CFR:** Code of Federal Regulations; **CI/CD:** Continuous Integration / Continuous Deployment; **DMS:** Document Management System; **EMA:** European Medicines Agency; **eCTD:** Electronic Common Technical Document; **FAISS:** Facebook AI Similarity Search; **FDA:** Food and Drug Administration; **GDPR:** General Data Protection Regulation; **GPT:** Generative Pretrained Transformer; **HIPAA:** Health Insurance Portability and Accountability Act; **ICH:** International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; **IND:** Investigational New Drug; **LMS:** Learning Management System; **LIMS:** Laboratory Information Management System; **ML:** Machine Learning; **NLP:** Natural Language Processing; **NLU:** Natural Language Understanding; **PMDA:** Pharmaceuticals and Medical Devices Agency; **PV:** Pharmacovigilance; **Q&A:** Question and Answer; **QMS:** Quality Management System; **R&D:** Research and Development; **RAG:** Retrieval Augmented Generation; **RIMS:** Regulatory Information Management System; **RLHF:** Reinforcement Learning with Human Feedback; **RPA:** Robotic Process Automation; **SOP:** Standard Operating Procedure; **SME:** Small and Medium sized Enterprise; **UI:** User Interface; **USFDA:** United States Food and Drug Administration.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

Institutional Review Board (IRB) approval is no required for this study.

AUTHOR CONTRIBUTION

Maruveettil Arjun: Conception and design, acquisition of the data, analysis and interpretation of the data, drafting of the article. **Pranab Moudgil:** Critical revision of the article for important intellectual content, final approval of the article, provision of study materials or patients. **Madhugiri Prakash Venkatesh:** Critical revision of the article for important intellectual content, final approval of the article, administrative, technical, or logistic support.

SUMMARY

This research highlights the real, world applicability of AI, guided regulatory affairs chatbots in streamlining compliance while improving the quality and promptness of the responses in pharmaceutical regulatory workflows. The presented method outperformed the manual process with respect to accuracy and time when it combined retrieval, augmented generation with domain, specific regulatory documents. The results indicate the potential of these chatbots in alleviating the heavy workload associated with operations without compromising on the strictness of regulations, as they can be used as decision, support tools. This study sets the stage for widespread implementation of reliable AI, powered solutions in regulatory affairs.

REFERENCES

1. Kearney SJ, Lowe A, Lennerz JK, Parwani A, Bui MM, Wack K, *et al.* Bridging the Gap: The Critical Role of Regulatory Affairs and Clinical Affairs in the Total Product Life Cycle of Pathology Imaging Devices and Software. Front Med (Lausanne) 2021;8:765385.
2. What is Regulatory Affairs? | Regis College [Internet]. 2024 [cited 2025 Jan 28];Available from: https://www.regiscollege.edu/blog/health-sciences/what-is-regulatory-affairs
3. Basak P, Das R, Mallick S, Ray J. review on vital role of regulatory affairs in pharmaceutical industry. International Journal of Research in Pharmaceutical Sciences 2024;15(4):56-67.
4. Patil N, Ranjan A, Gaurav, Mukherjee D, Panda BK, Diksha, *et al.* Navigating Biosimilar Regulatory Pathways in Emerging Markets: Insights from BRICS Nations. Applied Drug Research, Clinical Trials and Regulatory Affairs 2025; 10.
5. Bottoms A. Understanding Compliance with Laws and Regulations: A Mechanism-Based Approach. In: Financial Compliance. Cham: Springer International Publishing; 2019; 1-45.
6. Ahluwalia K, Abernathy MJ, Beierle J, Cauchon NS, Cronin D, Gaiki S, *et al.* The Future of CMC Regulatory Submissions: Streamlining Activities Using Structured Content and Data Management. J Pharm Sci 2022;111(5):1232-44.
7. Ten Key Regulatory Challenges of 2024 [Internet]. [cited 2025 Jan 28];Available from: https://kpmg.com/us/en/articles/2023/ten-key-regulatory-challenges-2024.html
8. Regulatory Compliance Challenges in 2024 | 360factors [Internet]. [cited 2025 Jan 28];Available from: https://www.360factors.com/blog/regulatory-compliance-challenges/
9. Regulatory Affairs Updates: Navigating Challenges with Expertise-Proventa International [Internet]. [cited 2025 Jan 28];Available from: https://proventainternational.com/regulatory-affairs-updates-navigating-challenges-with-expertise/

10. Scrutiny and Divergence: 2023 Regulatory Challenges [Internet]. [cited 2025 Jan 28];Available from: https://kpmg.com/us/en/articles/2022/ten-key-regulatory-challenges-2023-scrutiny-divergence.html
11. Ali F, Neha K, Ilyas A, Ali H. Introduction, Challenges, and Overview of Regulatory Affairs. In: Global Regulations of Medicinal, Pharmaceutical, and Food Products. Boca Raton: CRC Press; 2024.3-13.
12. Ullagaddi P. Safeguarding Data Integrity in Pharmaceutical Manufacturing. J Adv Med Pharm Sci 2024;26(8):64-75.
13. Beierle J, Algorri M, Cortés M, Cauchon NS, Lennard A, Kirwan JP, *et al.* Structured content and data management-enhancing acceleration in drug development through efficiency in data exchange. AAPS Open 2023;9(1):11.
14. Dr. Nagaraju Ellaturu VandanaMNM, M. Rajalakshmi DrTLKDrSB. Ai-Driven Solutions for Supply Chain Management. Journal of Informatics Education and Research 2024;4(2).
15. On-Demand Brilliance: Elevate Training with AI Chatbots [Internet]. 2024 [cited 2025 Jan 28];Available from: https://www.infoprolearning.com/blog/on-demand-brilliance-elevate-training-with-ai-chatbots/
16. The Rise of Chatbots [Internet]. 2024 [cited 2025 Jan 28];Available from: https://www.meegle.com/en_us/topics/ai/the-rise-of-chatbots
17. What are Regulatory Chatbots? | Freyr-Global Regulatory Solutions and Services Company [Internet]. [cited 2025 Jan 28];Available from: https://www.freyrsolutions.com/what-are-regulatory-chatbots
18. Shrivastav A. How chatbots changing with Generative AI: Everything explained here [Internet]. 2023 [cited 2025 Jan 28];Available from: https://www.kellton.com/kellton-tech-blog/generative-ai-chatbots-gamechanger-or-doomslayer-to-intelligent-conversations
19. AI for regulatory compliance: Use cases, technologies, benefits, solution and implementation [Internet]. [cited 2025 Jan 29];Available from: https://www.leewayhertz.com/ai-for-regulatory-compliance/
20. Top Benefits of Using Chatbots for Employee Training in 2025 [Internet]. [cited 2025 Jan 28];Available from: https://www.edstellar.com/blog/chatbot-for-employee-training
21. Top AI Chatbot Development Services for Businesses [Internet]. [cited 2025 Jan 28];Available from: https://ossisto.com/blog/chatbot-development-services/
22. Chatbots For Employee Training [Internet]. [cited 2025 Jan 28];Available from: https://eggheads.ai/chatbots-for-employee-training/
23. Urbani R, Ferreira C, Lam J. Managerial framework for evaluating AI chatbot integration: Bridging organizational readiness and technological challenges. Bus Horiz 2024;67(5):595-606.
24. Rane NL, Choudhary SP, Rane J. Artificial Intelligence, Natural Language Processing, and Machine Learning to Enhance e-Service Quality on e-Commerce Platforms. International Journal of Artificial Intelligence and Machine Learning 2024;4(2):67-82.
25. Patra B, Kumar M. Natural Language Processing in Chatbots: A Review. Turkish Journal of Computer and Mathematics Education (TURCOMAT) 2020;11(3):2890-4.
26. CHIDIOGO C. NWOKEDI, CHIDINMA A. NWAFOR. Enhancing customer service and user experience through the Use of Machine Learning Powered intelligent chatbots. World Journal of Advanced Research and Reviews 2024;23(2):181-91.
27. Kitsantas T, Georgoulas P, Chytis E. Integrating Robotic Process Automation with Artificial Intelligence for Business Process Automation: Analysis, Applications, and Limitations. Journal of System and Management Sciences 2024;
28. Huang MH, Rust RT. Artificial Intelligence in Service. J Serv Res 2018;21(2):155-72.
29. Madhavan N. Revolutionizing user Engagement: The Impact of AI-Assisted Chat Interactions. 2024;13(7):12625.
30. Haley C. Document Review or Chatbot: Which Generative AI e-Discovery Solution Is Right for You? | Relativity Blog [Internet]. 2024 [cited 2025 Jan 28];Available from: https://www.relativity.com/blog/document-review-or-chatbot-which-generative-ai-e-discovery-solution-is-right-for-you/
31. Shukla VK, Mittal MK. Artificial Intelligence in Drug Regulatory Submissions in India. Applied Drug Research, Clinical Trials and Regulatory Affairs 2022;9(1):58-68.
32. Ezekiel Onyekachukwu Udeh, Prisca Amajuoyi, Kudirat Bukola Adeusi, Anwulika Ogechukwu Scott. AI-Enhanced Fintech communication: Leveraging Chatbots and NLP for efficient banking support. International Journal of Management and Entrepreneurship Research 2024;6(6):1768-86.
33. Using Chatbots In Pharma: What You Need to Know-Springs [Internet]. [cited 2025 Jan 29];Available from: https://springsapps.com/knowledge/using-chatbots-in-pharma-what-you-need-to-know
34. Role of NLP in Compliance Document Management-Akitra [Internet]. [cited 2025 Jan 29];Available from: https://akitra.com/role-of-nlp-in-compliance-document-management/
35. Kadam R, Das S. The Future of Regulatory Intelligence with Conversational AI [Internet]. 2022 [cited 2025 Jan 28];Available from: https://www.appliedclinicaltrialsonline.com/view/the-future-of-regulatory-intelligence-with-conversational-ai
36. Ayodeji A. Artificial Intelligence in Enhancing Regulatory Compliance and Risk Management [Internet]. 2024 [cited 2025 Jan 28];Available from: https://www.researchgate.net/publication/381045225_Artificial_Intelligence_in_Enhancing_Regulatory_Compliance_and_Risk_Management
37. Integrating QMS with ERP, LMS, and LIMS Can Boost Compliance [Internet]. [cited 2025 Jan 28];Available from: https://amplelogic.com/integrating-qms-with-erp-lms-and-lims-can-boost-compliance-and-efficiency-by-70-percent-in-2025/
38. Internal AI chatbots for pharma-streamlining internal processes-Digitalya [Internet]. [cited 2025 Jan 28];Available from: https://digitalya.co/blog/internal-ai-chatbots-for-pharma-streamlining-internal-processes/#h-7-the-future-of-ai-chatbots-in-streamlining-internal-operations
39. Step-By-Step Chatbot Implementation Process [Internet]. [cited 2025 Jan 28];Available from: https://chisw.com/blog/how-to-build-a-chatbot/
40. Johnson L. AI chatbot ranking vs traditional methods: A comprehensive comparison [Internet]. BytePlus2025 [cited 2025 May 28];Available from: https://www.byteplus.com/en/topic/380667?title=ai-chatbot-ranking-vs-traditional-methods-a-comprehensive-comparison
41. Revolutionizing Pharma: The Power of AI and Chatbots in Clinical Trials and Beyond [Internet]. [cited 2025 Jan 29];Available from: https://www.psychiatrictimes.com/view/revolutionizing-pharma-the-power-of-ai-and-chatbots-in-clinical-trials-and-beyond
42. Kim J, Min M. From RAG to QA-RAG: Integrating Generative AI for Pharmaceutical Regulatory Compliance Process. 2024 [cited 2025 Jan 29];Available from: http://arxiv.org/abs/2402.01717
43. Vakulenko I. Navigating Compliance in Chatbot Deployment for Regulated Industries [Internet]. 2024 [cited 2025 Jan 28];Available from: https://www.kommunicate.io/blog/compliance-in-chatbot-deployment/
44. Nagar G. Leveraging Artificial Intelligence to Automate and Enhance Security Operations: Balancing Efficiency and Human Oversight. International Journal of Scientific Research and Management (IJSRM) 2018;6(07):78-94.
45. Operation of a Chat Tool Using Generative AI in Dedicated Environment | Sumitomo Pharma [Internet]. [cited 2025 Jan 28];Available from: https://www.sumitomo-pharma.com/dx/dx03/chat-ai.html?utm_source=chatgpt.com
46. Meet the New Digital Assistants Transforming Patient Medical Information | Pfizer [Internet]. [cited 2025 Jan 28];Available from: https://www.pfizer.com/news/articles/meet_the_new_digital_assistants_transforming_patient_medical_information
47. DeepMind And BioNTech Are Building AI Lab Assistants To Advance Science-The Innovator [Internet]. [cited 2025 Jan 28];Available from: https://theinnovator.news/deepmind-and-biontech-are-building-ai-lab-assistants-to-advance-science/
48. What Is a Chatbot? | IBM [Internet]. [cited 2025 Jan 29];Available from: https://www.ibm.com/think/topics/chatbots
49. Predictive Analytics Examples, 12 Use Cases [Internet]. [cited 2025 Jan 29];Available from: https://www.qlik.com/us/predictive-analytics/predictive-analytics-examples
50. Transforming Customer Experience with Predictive Analytics: Leveraging AI for Personalized Support [Internet]. [cited 2025 Jan 29];Available from: https://www.researchgate.net/publication/386139462_Transforming_Customer_Experience_with_Predictive_Analytics_Leveraging_AI_for_Personalized_Support
51. Adel K, Elhakeem A, Marzouk M. Chatbot for construction firms using scalable blockchain network. Autom Constr 2022;141:104390.
52. Mechkaroska D, Domazet E. Blockchain-Integrated Chatbot. In: Conference: 9th International Congress ICICT 2024At: London, UK. 2024.
53. Voice Chatbot-IBM watsonx Assistant [Internet]. [cited 2025 Jan 29]; Available from: https://www.ibm.com/products/watsonx-assistant/voice
54. Miller A. Voice AI and Voice Chatbots: Shaping the Future of Contact Centres [Internet]. 2024 [cited 2025 Jan 29]; Available from: https://indatalabs.com/blog/ai-voice-chatbots
55. Using AI based chatbots to seek answers to regulatory questions-Pharmavibes [Internet]. 2023 [cited 2025 Jan 29]; Available from: https://www.pharmavibes.co.uk/2023/11/06/using-ai-based-chatbots-to-seek-answers-to-regulatory-questions/
56. Coghlan S, Leins K, Sheldrick S, Cheong M, Gooding P, D'Alfonso S. To chat or bot to chat: Ethical issues with using chatbots in mental health. Digit Health 2023; 9.

Cite this article: Arjun M, Moudgil P, Venkatesh MP. Regulatory Affairs Chatbot: Revolutionizing Compliance Through AI Integration. Indian J of Pharmaceutical Education and Research. 2026;60(4s):s1755-s1764.