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Embracing Generative AI in Pharma Regulatory Affairs - An Industry Perspective

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Abstract: ***Generative AI has become a ubiquitous term across industries, and the pharmaceutical sector is no exception. This article delves into the burgeoning field of generative AI in the pharmaceutical industry, which is poised to reach a market size of USD 2258.1 Mn by 2032, according to industry analysts (1). With the pharmaceutical industry approaching a 2 trillion valuation, the urgency to harness the power of AI and Generative AI to expedite research and development processes is evident. This article explores the current state of generative AI in the pharmaceutical industry, showcasing real - world applications like ChatGPT and OrcaGPT in regulatory processes that are reported to have significantly reduced submission times. Additionally, it discusses the wide - ranging capabilities of generative AI in the regulatory context, from content generation to knowledge reuse, and highlights key considerations such as accuracy, data privacy, and ethical obligations. The industry's readiness for embracing generative AI is examined, emphasizing the need for transformational thinking, trust - building, and ROI assessment to fully realize the potential of Gen AI in Regulatory Affairs.***

Keywords: Generative AI, Pharmaceutical Industry, Regulatory Affairs, AI Applications, Data Privacy, Data Integrity

1. Current State of Gen AI in Pharmaceutical Industry

The pharma industry is looking for various use cases that can be enabled through Gen AI and will significantly **reduce cycle time, make information readily available, and assist Regulatory staff to perform activities faster and smarter.** A study in J of Med Sciences has demonstrated benefits of Gen AI tool ChatGPT in Regulatory Submission Process. The study analyzed the impact of AI on submission of new drug applications to the US Food and Drug Administration (FDA) and found that the use of AI reduced submission time by upto 60%**. (2).** A medical device company has illustrated an AI tool ***OrcaGPT***, to assist regulatory research **(3).** The tool is a chatbot that can answer regulatory queries faster. It extracts information from regulatory guidance and provide summarized view of obligations and requirements, which helps to create a checklist for managing quality and compliance.

2. Gen AI Capabilities in Regulatory Context:

Keeping in view the underlying capability of generative AI of learning patterns from existing data and use that knowledge to generate original content that aligns with ~~the~~ learned patterns, Gen AI tools can enable:

a) **Regulatory Content Generation**: There is a potential saving of efforts in regulatory content generation from large data sets e. g., stability data sets to create content for stability reports of product and substance. It can create content for Clinical study Reports (CSRs) from Table, Listing and Figures (TLFs).
b) **Summarization and Abstraction:** Along with content generation, abstraction and summarization leveraging Gen AI seems to be of high value in regulatory context. Abstraction and summarization of regulatory guidance enables faster regulatory intelligence gathering.
c) **Translation:** Faster translation of local and regional labels can overall reduce cycle time of label implementation as it can understand prescriptive label components required in different countries.
d) **Compliance Management**: It can enable compliance by comparing the documents for any change, e. g., deviations in labels. It can enable content reuse strategy by creating documents faster with known standardized structure and content like PBRER (Periodic Benefit Risk Evaluation Report), PSUR (Periodic Safety Update Report), CCDS (Core Company Data Sheet), SmPC (Summary of Product Characteristics), ICD (Informed Consent Document). Quality documents like SOPs (Standard Operating Procedures) and policies/procedures also fall in such category.
e) **Regulatory Knowledge Reuse**: A well – trained models on health authority queries and their responses can help in repurposing the responses for similar new HA (Health Authorities) queries with certain degree of curation. Based on approved regulatory plans and strategies it can assist in development of new plans and strategies that will require further deep analysis and evaluation from Regulatory experts.
f) **Knowledge Management**: Gen AI tools like ChatGPT as regulatory knowledge bot can assist in various regulatory tasks and help reducing manual efforts and significantly reduce time and bring efficiency. It can help in building regulatory knowledge. However, to get maximum value of Gen AI, the responsibility lies with the user. It depends on the profile of the user, the right context and specificity of question asked, ability to verify, validate, decide, and use appropriately.

Industry is in process of evaluating various use cases of Gen AI in Pharma regulatory considering its growth and sustainability.

3. Key Considerations

- **Accuracy:** Percentage of accuracy of model and effort on curation plus cost verses value is a concern
- **Lack of Regulations –** on validation and usage
- **Increasing Investment in Data privacy and Security**: To get maximum value from Gen AI capability, companies need to expose their databases for which they must invest highly on data privacy and security.
- **Investment in Building Capabilities**: With high demands of Gen AI, both sponsors and service providers are investing highly in resources and training.

- **Increasing Collaborations and Partnerships**: Industry partnerships are the key to making use of Gen AI successful. Increasing partnerships with startups and technology giants like Microsoft can help companies to achieve their milestones faster.
- **Ethical and Moral Obligations**: With low accountability and explain ability and bias information can cause regulatory risk.
- **Regulatory Insight**: Access to real - time databases and limited knowledge with cutoff due to non - public and redacted documents may need further evaluation for its real value of getting intelligence at right time.

In conclusion, the pharmaceutical industry is on the cusp of a transformative journey with generative AI. The forecasted market growth underscores the industry's recognition of the immense potential in harnessing AI technologies. Real - world examples of reduced submission times and enhanced regulatory processes demonstrate the tangible benefits of Gen AI. However, stakeholders must consider critical factors such as accuracy, data privacy, and ethical implications as they navigate this evolving landscape. Industry players are proactively preparing for this paradigm shift, focusing on building capabilities, ensuring data security, and fostering a culture of transformation. To maximize the value of Gen AI, it is essential to evaluate ROI comprehensively, factoring in regulations, cost - efficiency, and data integrity. The pharmaceutical industry stands at the intersection of innovation and responsibility, poised to leverage generative AI for the betterment of healthcare and the acceleration of drug development.

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