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Review Article

An Overview on Pharmaceutical Regulatory Affairs Using Artificial Intelligence

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ABSTRACT

In order to improve productivity and creativity in drug development, the integration of artificial intelligence (AI) is the main emphasis of this article, which examines potential future paths in regulatory affairs. It discusses possible issues like algorithmic bias and prejudice related to the use of AI in legal systems. The authors examine the functions of numerous worldwide regulatory organizations in monitoring healthcare AI applications. The study also highlights the need for data management and structured content in Chemistry, Manufacturing, and Controls (CMC) regulatory submissions in order to optimize procedures. In the end, it promotes cooperation between interested parties to successfully negotiate the challenges of artificial intelligence in regulatory settings, guaranteeing fair access to cutting-edge medical treatments while reducing any prejudices.

INTRODUCTION

The pharmaceutical business is seeing a sharp increase in the use of artificial intelligence (AI). It has been determined that artificial intelligence (AI) has a profound impact on drug development that could help not only patients but also industry and regulators [1] [2]. It is anticipated that the growing application of AI in the medical devices and pharmaceutical industries will solve many of the problems currently facing the pharmaceutical sector, boosting productivity and product development speed and producing creative solutions for enhancing and extending patient lives [2] [14]. Systems that currently control these items face additional difficulties as a result of this development [2] [7]. The term artificial intelligence has been widely misapplied by marketing teams worldwide in recent years. The term has become a helpful acronym for any consumer-facing technology that has low intelligence but automation-like characteristics in a variety of industries. People were unaware of the most important developments in AI at the moment due to this informal use of the phrase, which also

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led to certain misunderstandings and diminished its significance. Amazing innovation has been produced as a result of the developments in AI and machine learning (ML). There are many applications of AI-based solutions in our world, and the pharmaceutical industry has recently benefited from this trend [14]. A career in regulated industries, such as pharmaceuticals, medical devices, and so forth, is Every medicine must be safe, effective, and of genuine high quality. Based on reliable technology, decisions about the effectiveness, safety, and fine of medications should be made. Regulatory Affairs also has a very specific use case in the medical field (prescription medications, medical devices, biologics, and practical foods). The understanding, implementation, and communication of the regulatory approach both inside and outside of the company are critical to its success. Regulatory Affairs for Drug Use In order to protect public health, governments have launched a new profession called regulatory affairs, which involves regulating the safety and effectiveness of products such as prescription medications, veterinary medications, medical devices, insecticides, agrochemicals, cosmetics, and complementary therapies called regulatory affairs (RA), sometimes referred to as government affairs. At its core, the RA profession involves gathering, researching, and communicating to regulatory bodies and the general public worldwide the risks and benefits of health care goods [31] The companies who produce and promote these goods should make sure that they give the people high-quality goods for their health and well-being. Nowadays, the majority of agencies have Regulatory Affairs professionals in their departments. Companies' regulatory affairs departments are always changing and growing, and they are the ones that are least affected by mergers and acquisitions as well as by economic downturns. Global standardization has led to constant technique in regulatory filings and, consequently, in their evaluation. This division is in charge of comprehending the legal requirements for acquiring newly authorized, widely used goods.[31]

Objectives

Efficient, accurate, and safe drug development and lifecycle management processes are the main goals of using AI into pharmaceutical regulatory affairs.

1. Quicken Drug Approval and Development: Regulatory submissions can be made more efficient by using AI to automate processes like data extraction, formatting, and submission, which minimizes human labor and the possibility of mistakes.

• Predict Regulatory Outcomes: AI algorithms can forecast the possibility of new medicine approval by analyzing previous data and regulatory trends. This enables businesses to better schedule development activities and distribute resources.

2. Improving Drug Safety and Monitoring: The ability of AI to analyze real-world data sources, such as social media and electronic health records, allows for the faster and more accurate detection and reporting of adverse drug reactions (ADRs).

• Proactive Risk Assessment: AI can assist regulators and pharmaceutical businesses in taking proactive steps to safeguard the public's health by detecting possible safety signals and forecasting the probability of future safety issues.

• Personalized Risk Management: Using information from a patient's medical history, genetic composition, and other variables, AI may create customized risk management programs for each patient.

3. Enhance Oversight and Regulatory Compliance:

• Automate Compliance Monitoring: AI can keep an eye on legal requirements and spot possible compliance problems instantly, lowering the chance of non-compliance and the fines that come

with it.

• Improve Regulatory Inspections: AI-driven technologies can help regulatory inspectors prioritize their investigations and identify high-risk locations.

4. Enhance Resource Allocation and Decision-Making:

• Data-Driven Decision Support: AI can offer data-driven insights to regulatory decision-makers in order to bolster evidence-based judgment.

• Optimize Resource Allocation: Regulatory agencies can increase their overall efficacy and optimize their resource allocation by determining where AI can automate tasks and boost efficiency.

Possibilities for using AI to pharmaceutical regulatory matters -

AI is being used more and more in pharmaceutical regulatory affairs to increase productivity, make better decisions, and simplify procedures [30]. Getting permission for new pharmaceutical medicines and making sure that approval is retained for as long as the corporation want to keep the product on the market are the responsibilities of the RA department of a pharmaceutical company. In order to make sure that the project plan accurately predicts what the regulatory authority will need before approving the product, the RA department acts as the liaison between the project team and the regulatory authority. It also acts as a channel of communication with the regulatory authority throughout the project.

RA is in charge of staying up to date on the latest laws, rules, and other regulatory information [10] [14].

1. Regulatory intelligence

Even if AI's application in RA activities is still in its early stages, automation and AI are already causing a true regulatory innovation. According to research, one important use of AI in the pharmaceutical industry is regulatory intelligence (RI) [14]. Regulatory intelligence is typically the functional group within RA responsible for analysing information from both internal and external sources, which is what pharmaceutical companies rely on. Businesses are looking for ways to use technology to maximize their capacities in order to support RI initiatives [1] [9]

2. Regulatory CMC

In regulatory affairs, Regulatory Chemistry, Manufacturing, and Controls (CMC) is another functional category. Applications for marketing or investigational authorization of pharmaceutical products must include three essential elements. Clinical, nonclinical, and quality documentation modules are the cornerstones of any program. Chemistry, manufacturing, and controls all become important factors for a company when it comes to the quality component. CMC is essential because it facilitates clinical and nonclinical research and shortens a product's time to market [11]. As previously mentioned, once the pharmaceutical product is approved, it becomes essential to carefully oversee several expedited submissions made all over the world. This includes answering questions from health authorities and making any necessary post-approval modifications to improve the manufacturing process over time, like adding a new manufacturing site. [19] Pharmaceutical companies have to deal with the complexity and pace of research and development (R&D) as well as the ongoing need to diversify their operations. One of their key priorities is to transform their CMC knowledge processes into globally networked, digitally empowered powerhouses that can innovate at scale and break new ground. Legacy methods might lead to divisional disconnects between production and research units. Throughout the medication development process, this results in scientists using laborious working methods and outdated knowledge exchange protocols. Pharmaceutical businesses and regulators engage in recurring cycles of evaluation, feedback, and response, and regulatory

documentation is based on a variety of information sources from a wide range of development processes. [12], [14], and [19]. Worldwide licensing timelines and the variety of globally registered product details will be greatly reduced by modernizing regulatory operations to enable simultaneous worldwide submissions and contemporaneous collaborative evaluations. [12] [13] [19]

3. Additional chances where applying AI to regulatory concerns can be beneficial

This research analysis also identified a number of other key areas where using AI to regulatory matters can be beneficial. [2] [5, 8, 12, 13, 14, 15] [19]: analysing new and current laws (AI notifications regarding the most recent international, regional, and national legislation); centralizing information on important regulatory changes from regulatory authorities (FDA, EMA, Health Canada, etc.)

• automatically generate regulatory documentation utilizing templates or extract data from clinical studies; • prepare regulatory intelligence and dossiers by extracting complex regulatory intelligence from unstructured material data and automated form pre-filling;

• Support regulatory and health authorities in their decision-making on CMC documents, product characteristics, and summaries.

• Examine vast volumes of data to identify trends and connections that would be impossible for people to detect otherwise; expedite the regulatory evaluation procedure for the development of new medications and expedite its release onto the market; guaranteeing adherence to technical, legal, and marketing documents (for example, helping to streamline operations by using AI to automatically check promotional content to brand guidelines and basic data sheets/SMPCS for drug products);

• improve the utilization of data standards such as IDMP, data transformation, and data purification; Automate global CMC regulatory activities (global submissions and HAs' contemporaneous collaborative reviews) through online digital processes; automate internal standard operating procedures (SOPs) by incorporating regulatory updates and revising pertinent SOPs.

The function of the department of regulatory affairs (RA) - The pharmaceutical industry's Regulatory Affairs (RA) department is in charge of securing approval for new pharmaceutical medicines or drugs and making sure that the approval process is maintained for as long as desired. Experts in regulatory affairs offer technology and strategic direction to the production, R&D, and quality control departments from the very beginning of product development. They also make significant financial and scientific contributions to the advancement of a development initiative and the business. Stay up to date on international laws, consumer practices, and rules. Verify that a company's products meet the most recent regulations.Stay informed about a company's current product line [29]. Oversee the review of audit reports and customer, regulatory, and compliance inspections. In addition to providing guidance on legal and scientific constraints and requirements, the Regulatory Affairs professional's job is to monitor the constantly evolving laws in every region where a company wants to distribute its product. They also gather and assess the scientific data that their research and colleagues are producing. An agency's regulations are legally enforceable instructions on how to interpret and adhere to the law; if regulations are not followed, many of them wind up in the FDA website's "issued warning letter" sections, which is unfair to the pharmaceutical sector. Keep a record of the registration fees paid and the accepted application when DMFs (drug master files) and other papers have been submitted. A regulatory affairs specialist can help a business

avoid issues brought on by improperly maintained records, faulty data presentation, or unsuitable scientific reasoning. In order to optimize the economical use of the company's resources, a competent regulatory affairs expert will have "right first time approaches" and will be crucial in coordinating scientific end with regulatory demands throughout the products' life [29]. Giving doctors and other medical experts accurate and comprehensive information on the items' efficacy, safety, and quality is another aspect of their job. The Department of Regulatory Affairs is also involved in the marketing concepts for drug development. Before a medication product is utilized commercially, regulatory affairs must authorize its packaging and advertising.

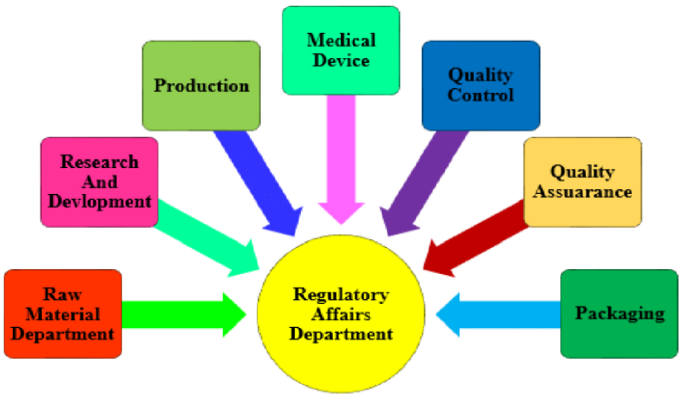

Figure 1:- Contribution of regulatory affairs in different departments

Effect on upcoming regulatory matters

Professionals in the pharmaceutical business and regulatory affairs do not operate in a vacuum, and their actions are influenced by both international trends and the laws, rules, and standards that govern the sector. Digital transformation is one of the key variables that will affect regulatory affairs in the future. The healthcare sector, especially the pharmaceutical industry, is being impacted by a number of global trends, including artificial intelligence [30]. There are numerous factors influencing the development, regulation, and value proposition of novel medicinal goods that the regulatory affairs industry must contend with.

The function of the regulatory affairs specialist and the manner in which regulatory professionals carry out their duties are also affected by this. Megatrends are worldwide patterns that could develop over a number of years and have the capacity to significantly alter society. Pharmaceutical industry and regulatory affairs professionals can navigate the future impacts on their roles and activities by understanding changes in global megatrends, such as adapting to a changing environment, becoming leaner, cleaner, and greener, unlocking the health imperative, geopolitical shifts, diving into digital, becoming increasingly autonomous, and unlocking the human dimension (Figure 2) [30].

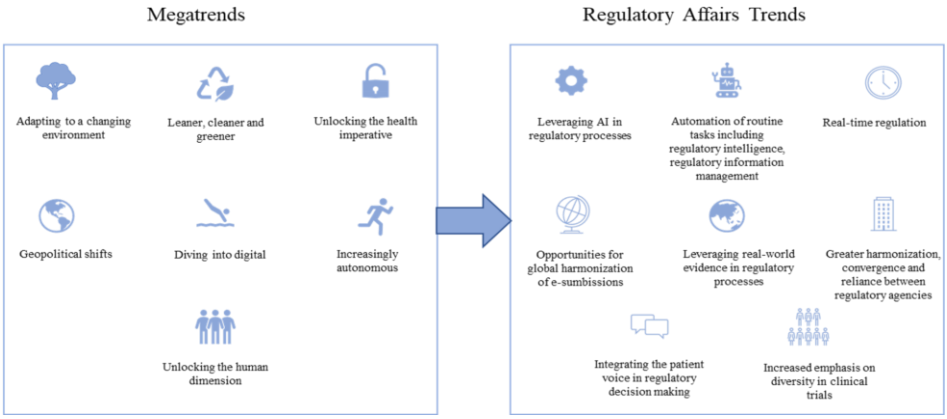

Figure 2. Trends impacting the future of regulatory affairs (modified from [12])

Issues related to the application of AI

The use of AI presents both potential and drawbacks, notwithstanding the numerous technological advancements. Assuring transparency and explainability of the deep learning models used in AI; ensuring inclusivity and equity to reduce bias; and promoting responsive and sustainable AI are some of the major issues surrounding the implementation and growth of AI, which center on data governance and ethics [12]. The following are some of these issues and possible fixes: [1] [2] [8] [12] [24] [30]

1. How to verify AI-powered programs that are continuously "learning"

When AI-based software learns while being used, how and when should it be validated? One method that has been suggested in the literature is to validate it in a staggered fashion, meaning that it is re-validated after a specific number of learning cycles. The decision of whether to use a risk-based method for validation is another. This may be predicated on the idea that systems that have learned to solve a problem entirely on their own pose more risks, necessitating a more thorough validation process than instruments that have only been optimized by machine learning approaches. Incorporating a validation against "human raters" and the final result also looks fair. In any event, debates are required to determine the best methodology for software validation that is based on AI.

2. How to set up the evaluation of intricate medical devices that use AI

Regulatory agencies are facing more and more difficulties in reviewing medical devices and software that are becoming more complicated, particularly those that use artificial intelligence (AI). To ensure appropriate expertise and to achieve and maintain the depth of knowledge necessary to regulate the increasingly complex technical products, a centralized fashion review is being considered in place of multiple organizations (such as the FDA in the US and designated Notified bodies (NBs) in the EU). This is especially important when there is a high need to understand both the technology and the disease to which the device is applied.

3. Who owns the patient's data? AI systems require data. Data is necessary for AI systems. AI systems require data in order to "learn," and in the case of many healthcare applications, patient data will be needed. Although the tools created with these data are expected to improve patient care in the future, they were most likely created for profit and to recoup their development costs. In this case, the question of who owns the data and, consequently, the tools that have been built comes up. This question cannot be answered simply; instead, stakeholders including patient organizations, legal professionals, healthcare practitioners, industry, and hospitals must work closely together and make decisions on an

individual basis based on the project's scope as well as local and national regulations.

4. Issues with data governance

Data governance issues encompass issues including obtaining informed consent for AI training data, protecting individual privacy and de-identifying data, sharing, managing, and controlling data, cyber security, and assigning intellectual property rights. To boost trust in the application of AI, strong governance and ethical frameworks will be required, and companies that depend on these systems must have well-established quality assurance and auditing procedures. In order to ensure that these technologies comply with government regulations and to communicate with regulators regarding the registration of AI-based medicinal goods, regulatory professionals will need to be comfortable describing these technologies. Such systems must be able to be incorporated into their official benefit-risk decision-making procedures.

5. Algorithmic social bias that uses inaccurate traits or inadequate datasets to discriminate and mislead learning It has been said that the issue of bias is particularly difficult. Bias occurs when the system's results disadvantage some people or groups. Despite the fact that bias and discrimination have long existed in civilizations and cultures, there is worry that AI technology could exacerbate existing issues and make them worse. Although bias is frequently unintended, it can be produced at many phases of the data science and machine learning process. The selection of the data set, the training dataset itself, the techniques employed, the application dataset, and even society at large can all contain bias [30].

Name Of Regulatory Authorities with Their Country [28]

Country	Name of Regulatory Authority
USA	Food and Drug Administration (FDA)
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
India	Central Drug Standard Control Organization (CDSCO)
Canada	Health Canada
Europe	European Medicines Agency (EMEA)
Denmark	Danish Medicines Agency
Costa Rica	Ministry of Health
New Zealand	Medsafe - Medicines and Medical Devices Safety Authority
Sweden	Medical Products Agency (MPA)
Netherlands	Medicines Evaluation Board
Ireland	Irish Medicines Board
Italy	Italian Pharmaceutical Agency
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)
Ukraine	Ministry of Health
Singapore	Centre for Pharmaceutical Administration Health Sciences Authority
Hong Kong	Department of Health: Pharmaceutical Services
Paraguay	Ministry of Health
Sweden	Medical Products Agency (MPA)
Thailand	Ministry of Public Health
China	State Food and Drug Administration
Germany	Federal Institute for Drugs and Medical Devices

Malaysia	National Pharmaceutical Control Bureau, Ministry of Health
Pakistan	Drugs Control Organization, Ministry of Health
South Africa	Medicines Control Council
Sri Lanka	SPC, Ministry of Health
Switzerland	Swissmedic, Swiss Agency for Therapeutic Products
Uganda	Uganda National Council for Science and Technology (UNCST)
Brazil	Agencia Nacional de Vigiloncia Sanitaria (ANVISA)
Japan	Ministry of Health, Labour & Welfare(MHLW)
International Organizations	
World Health Organization (WHO)	
Pan American Health Organization (PAHO)	
World Trade Organization (WTO)	
International Conference on Harmonization (ICH)	
World Intellectual Property Organization (WIPO)	

CONCLUSION

Faster access to safe and effective therapies is the future objective of the pharmaceutical industry's digital transformation and AI technology adoption. The application of AI in regulatory issues could expedite the time to market for patients in need as well as the submission and approval procedures. It may also make it possible to execute MA dossier changes in real time and effectively after approval. All parties must now more than ever collaborate to create a unified risk-based regulatory framework that fully utilizes AI technology in order to accomplish this goal. Organizations will need to undergo significant organizational and business process change, as well as ongoing professional development and new methods of operation, in order to fully utilize AI technologies. Because of stringent regulatory standards and a lack of a unified regulatory framework for more AI integration into RA operations, the application of AI technology solutions in regulatory affairs is still in its infancy. To guarantee pharmaceutical product safety, data integrity, and compliance, industry must adhere to stringent regulatory criteria. A significant revolution in RA procedures is currently taking place, as seen by recent developments in worldwide harmonization and alignment of data standards, digital innovations, and strategic stakeholder alliances. Once accomplished, this will drastically alter the tedious physical labor and repetitive tasks currently involved in regulatory processes. Interestingly, one important application of AI in regulatory matters is currently regulatory intelligence. As one of the most risk-averse and heavily regulated industries, healthcare is anticipated to gradually but safely embrace digital change on a worldwide scale [27]. Numerous elements, most notably the rise in AI solutions and digital transformation, will influence the future of RA professionals; for this reason, a flexible and ongoing learning mindset will be crucial.

REFERENCES

1. MJ et al, 2019. A Study on the Application and Use of Artificial Intelligence to support Drug Development. Clinical Therapeutics. Volume 41, Issue 8, August 2019, Pages 1414-1426 (Internet) Available from: < https://doi.org/10.1016/j.clinthera.2019.05.018 > (Accessed Lamberti 15 May 2023)
2. Belkum SV, 2018. Artificial intelligence in clinical development and regulatory affairs – Preparing for the future. Regulatory Rapporteur 15(10):17-21 (Internet) Available from: < https://www.researchgate.net/publication/328

139493_Artificial_intelligence_in_clinical_development_and_regulatory_affairs_-_Preparing_for_the_future > (Accessed 15 May 2023)

3. Paul D et al, 2021. Artificial intelligence in drug discovery and development. Drug Discov Today. 2021 Jan;26(1):80–93 (Internet) Available from: < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7577280/#sec0005title > (Accessed 16 May 2023)
4. Hunter J, 2016. Adopting AI is essential for a sustainable pharma industry. Drug Discov. World Winter, 2016 (Internet) Available from: <https://www.ddwonline.com/media/32/adopting-ai-is-essential-for-a-sustainable-pharma-industry.pdf > (Accessed 16 May 2023)
5. Kamiński R, 2021. AI in Pharma. What does Artificial Intelligence bring to the pharmaceutical industry? 2 Mar 2021 (Internet) Available from: < https://nexocode.com/blog/posts/ai-in-pharma/ > (Accessed 16 May 2023)
6. ISO/IEC 22989:2022(en) Information technology — Artificial intelligence — Artificial intelligence concepts and terminology (Internet) Available from: < https://www.iso.org/obp/ui/#iso:std:iso-iec:22989:ed-1:v1:en:term:3.1.3 > (Accessed 28 May 2023)
7. US FDA, 2023. Artificial Intelligence and Machine Learning (AI/ML) for Drug Development (Internet) Available from: < https://www.fda.gov/science-research/scienceand-research-special-topics/artificial-intelligence-and-machine-learning-aiml-drugdevelopment > (Accessed 05 Jun 2023)
8. ICMRA Informal Innovation Network. Horizon Scanning Assessment Report – Artificial Intelligence 6 Aug 2021 (Internet). Available from: < https://www.icmra.info/drupal/sites/default/files/2021-08/horizon_scanning_report_artificial_intelligence.pdf> (Accessed 05 Jun 2023) Mayer M et al, 2019. Potential Use of Artificial Intelligence for Regulatory Intelligence:
9. Biopharmaceutical Industry's Views. Therapeutic Innovation & Regulatory Science. 2019, Vol. 53(6) 759-766 (Internet) Available from: < https://journals.sagepub.com/doi/pdf/10.1177/2168479018812778 > (Accessed 28 May 2023)
10. Hägglöf I, Holmgren Å, 2013. Chapter 20 – Regulatory Affairs. Drug Discovery and Development (Second Edition). 2013, Pages 285-301 (Internet) Available from: < https://doi.org/10.1016/B978-0-7020-4299-7.00020-2 > (Accessed 08 Jun 2023)
11. Antonelli S, Craig M. CMC regulatory strategy. RF Quarterly. 2022;2(3):31-40. Published online 30 September 2022. (Internet) Available from: < https://www.raps.org/news-andarticles/news-articles/2022/9/cmc-regulatory-strategy > (Accessed 08 Jun 2023)
12. Chisholm O, Critchley H. Future directions in regulatory affairs. Front Med (Lausanne). 2023 Jan 9;9:1082384. Available from: < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9868628/ > (Accessed 08 Jun 2023) 13. Ahluwalia K et al, 2022. The Future of CMC Regulatory Submissions: Streamlining Activities Using Structured Content and Data Management. Journal of Pharmaceutical Sciences 111 (2022) 1232-1244 (Internet) Available from: < https://doi.org/10.1016/j.xphs.2021.09.046 > (Accessed 08 Jun 2023)
13. Sushma JK et al, 2023. Regulatory Innovation in Artificial Intelligence for Accelerated

Medication. JCLMM 1/11 (2023), 1971-1979 (Internet) Available from: < View of

14. Regulatory Innovation in Artificial Intelligence for Accelerated Medication (jclmm.com) > (Accessed 09 Jun 2023)
15. Taylor N, 2019. Regulatory Intelligence: How AI will change regulatory operations. Pharma IQ 24 Sep 2019 (Internet) Available from: < https://www.pharma-iq.com/businessdevelopment/articles/regulatory-intelligence-how-ai-will-change-regulatory-operations > (Accessed 10 Jun 2023)
16. Apprentice.io. What is Pharma 4.4, and How Can You Implement It. Linkedin 31 Oct 2022 (Internet) Available from: <https://www.linkedin.com/pulse/what-pharma-40-how-can-youimplement-apprentice-io> (Accessed 10 Jun 2023)
17. Algorri M et al, 2020. Transitioning Chemistry, Manufacturing, and Controls Content With a Structured Data Management Solution: Streamlining Regulatory Submissions. Journal of Pharmaceutical Sciences. Volume 109, Issue 4, April 2020, Pages 1427-1438 (Internet)Available from: < https://doi.org/10.1016/j.xphs.2020.01.020 > (Accessed 11 Jun 2023)
18. The International Council for Harmonisation of Technical Requirements for
19. Pharmaceuticals for Human Use (ICH). ICH Standards, CTD (Internet) Available from: <https://www.ich.org/page/ctd> (Accessed 12 Jun 2023)
20. Beierle J et al, 2023. Structured content and data management-enhancing acceleration in drug development through efficiency in data exchange. AAPS Open. 2023;9(1):11. Available from: <doi: 10.1186/s41120-023-00077-6> (Accessed 12 Jun 2023)
21. International Society of Pharmaceutial Engineering (ISPE). Pharma 4.0™ (Internet) Available from: < https://ispe.org/initiatives/pharma-4.0 > (Accessed 13 Jun 2023)
22. Reinhardt IC et al, 2021. Industry 4.0 & the future of the pharmaceutical industry. Pharmaceutical Engineering. (Internet) Available from: < https://ispe.org/pharmaceuticalengineering/march-april-2021/industry-40-future-pharmaceutical-industry > (Accessed 13 Jun 2023)
23. O'Brien J et al, 2021. Strengthening regulatory systems for medicines in a changed world: where do we go from here. BMJ Glob Health. 2021 Jan;6(1):e004680. Available from: <doi:10.1136/bmjgh-2020-004680 > (Accessed 13 Jun 2023)
24. EMA, 2020. Network Strategy to 2025. (Internet) Available from: < https://www.ema.europa.eu/en/documents/report/european-union-medicines-agenciesnetwork-strategy-2025-protectingpublic-health-time-rapid-change_en.pdf > (Accessed 15 Jun 2023)
25. Coeckelbergh M, 2019. Ethics of artificial intelligence: Some ethical issues and regulatory challenges, Technology and Regulation, 2019, 31–34 (Internet) Available from: < https://doi.org/10.26116/techreg.2019.003 > (Accessed 28 May 2023)
26. EU AI Act: first regulation on artificial intelligence. European Parliament, 14-Jun-2023 (Internet) Available from: < https://www.europarl.europa.eu/news/en/headlines/society/20230601STO93804/eu-ai-actfirst-regulation-on-artificial-intelligence > (Accessed 16 Jun 2023)
27. What is artificial intelligence and how is it used? European Parliament, 29-Mar-2021 (Internet) Available from: < https://www.europarl.europa.eu/news/en/head

lines/society/20200827STO85804/what-isartificial-intelligence-and-how-is-it-used > (Accessed 16 Jun 2023)

28. Askin S et al, 2023. Artificial Intelligence Applied to clinical trials: opportunities and challenges. Health Technol (Berl). 2023;13(2):203-213 (Internet) Available from: < doi: 10.1007/s12553-023-00738-2 > (Accessed 16 Jun 2023)
29. Priyanka S Bandgar et al 2020. Review On Regulatory Affairs In Pharmaceutical Industries
    JETIR January 2020. Volume 7 (71-72) (Internet)
30. Mr. Pritam R Salve Mr. Vaibhav A Jadhav 2022. Review On Regulatory Affairs and New Drug Approval Process In India. International Journal of Research Publication and Reviews. Volume 3. Issue 7. 1290-1298 July 2022.
31. Alise Rivare Artificial Intelligence and Digitalization In Pharmaceutical Regulatory Affairs 2023 (Internet)
32. Dinesh Kawade et al 2021. An Review Of Regulatory Affairs In Pharmaceutical Industries. JETIR June 2021. Volume 8. Issue 6 (a391-a408)
33. Artificial Intelligence –Transforming Regulatory Affairs by DLRC Group (Internet Available at: https://www.dlrcgroup.com/wp-content/uploads/2023/09/Whitepaper-Artificial-Intelligence-%E2%80%93-Transforming-Regulatory-Affairs-2023.pdf.

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