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Exploring the Adoption and Challenges of Industry 4.0 in Pharmaceutical Industries of Bangladesh

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Abstract: Industry 4.0 is revolutionizing the pharmaceutical sector by integrating advanced technologies into manufacturing processes and supply chain management. Traditional approaches to manufacturing pharmaceuticals are being challenged and has undergone a significant transformation with the advent of the Fourth Industrial Revolution. This research aims to identify key factors influencing the adoption of Industry 4.0 technologies in Bangladesh's pharmaceutical sector, the barriers they face, and provide insights to guide policy and strategic decisions for the development of this sector. In our research, we conducted a comprehensive investigation into 22 pharmaceutical companies in Bangladesh to assess their current adoption or willingness to adopt Pharma 4.0 technologies in manufacturing and validation processes. The study observed that approximately 55% of pharmaceutical companies are embracing Industry 4.0 technologies in their manufacturing process. Additionally, 50% of these companies have implemented automation in their warehouse operations and supply chain management tools. Moreover, investment by leading pharmaceutical companies in Pharma 4.0 adoption has shown a steady rise over the years. Overall, this study provides valuable insights into the landscape of pharmaceutical manufacturing in adopting Pharma 4.0 practices in pharmaceutical manufacturing which aligns with the Sustainable Development Goals (SDGs) and contributes to the vision of a SMART Bangladesh by 2041.

Keywords: *Industry 4.0, Pharma 4.0, Automation, SDG, SMART Bangladesh*

Introduction: Industrial revolution has played a pivotal role in shaping the pharmaceutical world, driving progress in drug discovery, manufacturing, regulation, and personalized medicine, ultimately improving healthcare outcomes and advancing human well-being [1]. The first revolution, the period from about 1760 to 1820, laid the groundwork for modern chemistry and pharmacology. It facilitated advancements in laboratory equipment and chemical processes, enabling the synthesis of new compounds and the development of early pharmaceuticals [2]. Second Industrial Revolution, continued in the period until the early 1940s, saw the rise of the pharmaceutical industry as we know it today. Advancements in chemical synthesis, along with improved manufacturing processes and quality control, led to the mass production of drugs [3]. This era also witnessed the establishment of pharmaceutical companies and the standardization of drug formulations [3]. Third Industrial Revolution, also called the Digital Revolution, transformed the pharmaceutical sector through computational drug discovery, bioinformatics, and personalized medicine [4]. Advances in genomics, proteomics, and data analytics enabled more precise drug targeting and personalized treatment approaches. Additionally, digital technologies enhanced drug development processes, from research to clinical trials and regulatory compliance [3]. Fourth Industrial Revolution is witnessing unprecedented innovation in the pharmaceutical sector, driven by technologies like artificial intelligence, machine learning, and big data analytics [5]. These technologies are revolutionizing drug discovery, allowing for faster and more efficient identification of potential drug candidates. Furthermore, developments in biotechnology, such as gene editing and mRNA vaccines are opening new frontiers in disease treatment and prevention [6].

Pharmaceutical companies are increasingly realizing that traditional manufacturing practices may no longer suffice to meet the demands of a rapidly evolving market landscape [1]. Challenges such as stringent regulatory requirements, increasing quality and safety standards, and the need for greater flexibility and responsiveness are driving the need for innovation and modernization in manufacturing operations [3]. Additionally, pharmaceutical companies compete for highly skilled human resources with expertise in specialized areas, such as research, development, and manufacturing. Understanding how these challenges impact the pharmaceutical industry and exploring strategies for overcoming them is essential for sustaining growth and innovation in the sector [4]. By embracing Industry 4.0 technologies, pharmaceutical companies can address these challenges and unlock new opportunities for growth and competitiveness [5]. Pharma 4.0, the next phase of pharmaceutical industry evolution, offers the potential to address these issues through automation. By leveraging digital technologies and advanced manufacturing techniques, Pharma 4.0 can enhance production efficiency, improve transparency, and reduce costs [7].

The advent of Industry 4.0 presents a paradigm shift towards fully digitized and autonomous manufacturing, with profound implications for pharmaceutical operations and regulations [8]. In this digitally-driven landscape, real-time data integration, automation, and advanced analytics will revolutionize pharmaceutical manufacturing, enabling unprecedented levels of quality and efficiency. The adoption of smart technologies, such as IoT sensors, robotics, and AI-driven analytics will optimize production

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processes, minimize human error and ensure regulatory compliance [9]. Moreover, the ability to monitor and analyze data in real-time will facilitate proactive decision-making, predictive maintenance, and continuous improvement initiatives [6,9]. In the context of Industry 4.0, quality professionals will be inundated with real-time data from multiple sources, necessitating intelligent use to enable quick and efficient decision-making [10]. Managers and quality management personnel will need to implement effective risk management strategies to improve product quality and operational efficiency, leveraging machine learning and AI capabilities to provide optimal services. Thus, there is a pressing need for the risk management team to develop plans for the proper implementation of these strategies [11].

Furthermore, the implementation of Quality 4.0 will be essential for ensuring alignment with the fourth industrial revolution [12]. This will involve upgrading platforms related to Quality Management Systems (QMS) and supply chain management to transform the industry into smart factories capable of meeting the requirements of Industry 4.0 [13]. Technological advancements such as the integration of AI, sensors and enterprise-level solution platforms will play a crucial role in this transformation, replacing outdated equipment with modernized alternatives [13,14].

Our vision of becoming a "SMART" nation by 2041 encompasses a holistic transformation across various sectors, leveraging Science, Technology, Innovation, and Digitization to achieve sustainable development and prosperity [15]. This initiative aims to harness the power of technology and innovation to address key challenges and unlock opportunities for economic growth, social inclusion, and environmental sustainability [16]. Additionally, Bangladesh is on the brink of reaching its Sustainable Development Goal (SDG). SDG 3 emphasizes ensuring good health and well-being by providing access to affordable and quality pharmaceuticals is an essential component of achieving this goal [16]. Pharma 4.0, characterized by the integration of automation, data exchange, and advanced technologies in manufacturing processes (Figure 1), offers several opportunities to streamline pharmaceutical production and reduce costs and thereby meeting SDG goals [17].

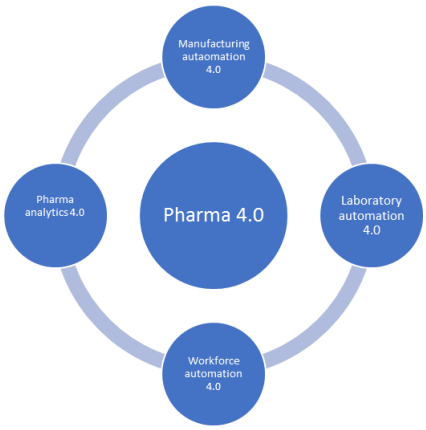

Fig. 1: Pharma 4.0 and its area in pharmaceutical industry.

Literature Review: Akbari *et al.* (2024) provides insights into the digital transformation trends within Vietnamese supply chains, focusing on adoption rates, predicted impacts, and financial investments in key Industry 4.0 technologies. Digital transformation in Vietnamese supply chains reveals that big data analytics and the Internet of Things are expected to have the greatest impact and receive the most investment in the next 5–10 years [18]. Simões *et al.* (2022) evaluated the impact of Industry 4.0 on the pharmaceutical industry, particularly in production, and explored the technological readiness of Portuguese pharmaceutical companies for implementing Industry 4.0 technologies [19]. Devansh *et al.* (2023) investigated how Industry 4.0 revolutionizes pharmaceutical manufacturing by enhancing flexibility, reducing human labor, and promoting sustainable development through advanced technologies like AI, robotics, and IoT. It highlights the potential for more efficient, cost-effective, and sustainable drug production processes [20]. Our research aims to deepen understanding of Industry 4.0 adoption in Bangladesh's pharmaceutical industry by examining the challenges encountered and the opportunities presented for its implementation. By embracing these technological advancements, Bangladesh can improve healthcare access and stimulate economic growth in the pharmaceutical industry.

Materials & Method: Our research involved the random selection of 22 pharmaceutical companies in Bangladesh, encompassing small, medium, and large enterprises, to ensure that the sample was both unbiased and representative of the entire pharmaceutical industry in the country. However, during the sampling and data collection, companies not involved in manufacturing or lacking engagement in quality management practices, as well as those without the necessary infrastructure, were excluded from the study. Data was collected from these 22 pharmaceutical companies on various aspects such as companies adopting tools of industry 4.0 in pharmaceuticals which include Big data analytics, Quality by Design (QbD) and Process Analytical Technology (PAT) approaches. Moreover, utilization of robotic process automation in warehouses, investment of pharmaceutical company in Industry 4.0 and the adoption of automated/non-automated approaches in supply chain management

were also studied. The machines observed for this study typically meet specification criteria that included seamless integration with existing systems, offering flexibility, scalability, and support for advanced automation and real-time monitoring with user-friendly interfaces. Our research design was both descriptive and exploratory, utilizing a mixed-methods approach that combines quantitative and qualitative data. Data collection methods included a survey to gather numerical data on the extent of adoption of Industry 4.0 tools like QbD and PAT. Additionally, we conducted semi-structured interviews with key stakeholders (e.g., production managers, process engineers) to gain deeper insights into the experiences and challenges related to Pharma 4.0 implication and regulatory affairs. The study also encompassed relevant company documents, including website reports, to gain a comprehensive understanding of the context and process involved in the implementation of Industry 4.0 tools. Data analysis involved a comparative assessment of adoption of different Industry 4.0 tools, including supply chain tools, automation, QbD, and robotics, which was visually represented using pie charts. Moreover, inferential statistics was utilized to show associations between the company budget and the adoption of Industry 4.0 tools over different years. However, the confidentiality of company-specific information was strictly maintained throughout the study. The outcome of this study can offer valuable insights into the opportunities and obstacles associated with embracing Pharma 4.0. This will facilitate informed decision-making and strategic planning for achieving Vision 2041 goals in pharmaceutical sector of Bangladesh.

Results and Discussion: In our study, we conducted a comprehensive investigation into 22 pharmaceutical companies in Bangladesh to assess their current adoption or willingness to adopt Industry 4.0 technologies in manufacturing and validation processes. Our study encounters various aspects, including the extent of adoption, encountered challenges and barriers, anticipated benefits, and future outlook. After analyzing the data, it has been found that Approximately 55% of pharmaceutical companies are embracing process analytical technology (PAT) and the quality by design (QbD) approach in their formulation development and process validation efforts (Figure 2). This indicates a significant recognition within the industry of the importance of data-driven, quality-focused methodologies in ensuring the reliability and efficacy of pharmaceutical products. PAT and QbD represent a proactive stance on quality, emphasizing the integration of rigorous analytical techniques and design principles from the very beginning of the drug development process. Furthermore, around 27% of these companies are transitioning their facilities into QbD designs. This shift highlights their dedication to embedding quality principles into the very infrastructure of their operations, ensuring that quality is built into every stage of production rather than merely inspected at the end. However, despite these advancements, approximately 18% of companies are still adhering to traditional methods of drug manufacturing and production. This adherence to older practices could indicate a potential gap or reluctance to fully embrace modern, efficient approaches. These companies may benefit from exploring and integrating more contemporary methodologies to enhance their competitiveness in an increasingly technology-driven pharmaceutical landscape.

Fig. 2: Companies adopting QbD approach in manufacturing and quality control.

The findings from the survey conducted across 22 pharmaceutical companies reveal that approximately 50% of these companies have embraced automation in their warehouse processes (Figure 3). Some automation technologies followed by these pharmaceuticals include barcode scanning and robotics, digital inventory management, automated shipment and transportation. Automated systems in warehouse increase the efficiency of handling products and equipment, while also reducing manual errors and boosting overall productivity.

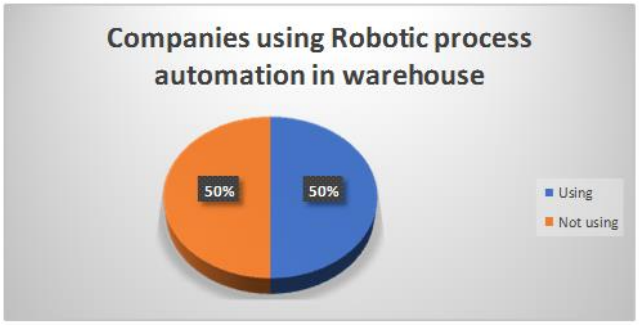

Fig. 3: Companies using Robotic process automation in warehouse.

The investment of a reputed pharmaceutical company in Pharma 4.0 adoption has shown a steady rise over the years, increasing from 0.1 billion taka in FY 2010-11 to 4.5 billion taka in FY 2020-21 (Figure 4). This substantial increase reflects the company's commitment to embracing advanced technologies and digital transformation in its operations. This dramatic rise in investment not only underscores the company's commitment to integrating the latest technological advancements but also reflects its strategic focus on digital transformation within its operations. By significantly increasing its investment, the company is signaling its dedication to enhancing its operational efficiency, adopting innovative technologies, and maintaining a competitive edge in the rapidly evolving pharmaceutical landscape. Hence, the substantial financial commitment of leading companies highlights the proactive approach to staying at the forefront of industry developments and embracing the future of pharmaceutical manufacturing and management.

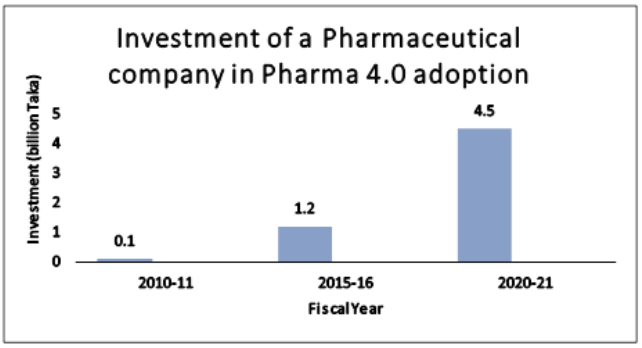

Fig. 4: Investment of a reputed pharmaceutical company of Bangladesh in Pharma 4.0 adoption.

Around 27% companies adopt automated systems in inventory management, order processing and other supply chain tools. However, 23% pharmaceuticals prefer non-automated approaches which may offer flexibility, human judgment, and cost-effectiveness (Figure 5). Around half of the companies (50%) adopt a hybrid approach, combining automated systems for routine tasks with human intervention for complex decision-making and personalized customer interactions. This data may create some confusion regarding whether to categorize this approach under automated or non-automated methods. It could potentially complicate the interpretation of our findings on the adoption of Industry 4.0 tools in inventory management. However, this helps to leverage the benefits of both approaches effectively. This hybrid model allows companies to harness the efficiency of automation while maintaining the adaptability and nuanced understanding that human involvement provides.

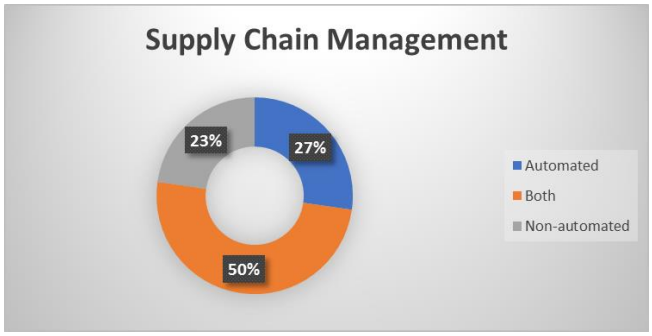

Fig. 5: Companies adopting automated, non-automated or both approaches in Supply Chain Management.

Most of the pharmaceuticals (50%) face challenges in implementing Industry 4.0 due to inadequate infrastructure, skill gaps, high costs, regulatory complexities and low awareness. The lack of precedent within pharmaceutical companies regarding the integration of new technologies can create regulatory uncertainties, which may deter investment in such innovations. Moreover, 10 out of 22 companies confirmed the shortage of data scientists, computational and systems engineers, IT specialists, and AI experts. Overcoming these hurdles requires investment in digital infrastructure, skills development programs, and financial support to incentivize technology adoption.

In summary, the findings illustrate a clear trend towards modernizing and automating processes within the pharmaceutical industry. However, there remains a significant portion of companies that still rely on traditional methods, suggesting that there is room for further innovation and adaptation. The shift towards digital and automated systems is a key driver of increased efficiency and productivity in the industry, reflecting a broader commitment to leveraging technology for operational excellence. Industry 4.0 transforms pharmaceutical manufacturing by improving flexibility, reducing human labor, and fostering sustainable development. Technologies like AI and robotics contribute to more efficient, cost-effective, and sustainable manufacturing processes. This finding aligns with Devansh *et al.*'s (2023) observation that explores the role of Industry 4.0 in promoting sustainable development within the pharmaceutical industry. Moreover, successful adoption of Industry 4.0 and its related technologies presents both challenges and opportunities for pharmaceutical companies, highlighting Simões *et al.*'s (2022) findings but in the context of Bangladesh.

Conclusions: Pharmaceutical companies are transitioning from traditional approaches to Pharma 4.0, which represents the integration of advanced technologies and digitalization into all aspects of the pharmaceutical industry. It is also clear from our study that companies that embrace these technologies can gain a strategic advantage by delivering high-quality medications more efficiently, accelerating drug development timelines and meeting the evolving needs of patients and healthcare providers. Our findings can inform policymakers, industry stakeholders, and academia about the opportunities and challenges associated with advancing towards Pharma 4.0 in the country.
Industry 4.0 technologies in the pharmaceutical sector is crucial for ensuring the provision of quality medications and pharmaceuticals in the healthcare sector, which in turn contributes to achieving SDG 3 targets related to ensuring healthy lives and promoting well-being for all. Thus, the integration of Industry 4.0 principles and technologies in the pharmaceutical sector can indeed enable a smart government to foster a smart economy, ultimately contributing to the vision of a SMART Bangladesh by 2041. However, this study focused solely on pharmaceutical companies within Dhaka division. While the results are comprehensive and significant, their generalizability to the country as a whole need to be considered. Additionally, some of the emerging technologies explored in this study are relatively new, which constrains a deeper understanding of their long-term impact and associated costs. Future research should consider investigating whether variations in impact and investment exist across different industrial contexts, company sizes, and locations throughout Bangladesh. Such studies could reveal important nuances in Industry 4.0 adoption and further enhance our understanding of digital transformation in the pharmaceutical sector. Expanding surveys to a broader population would contribute valuable insights to this evolving field.

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