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THE PHARMACEUTICAL REVOLUTION: THE POWER OF INDUSTRY 4.0

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Abstract

Industry 4.0 is nothing but the 4th Industrial Revolution which will change the production processes. The implementation of Industry 4.0 in the pharmaceutical sector will make the manufacturing of complex drugs easier The implementation of Industry 4.0 in the pharmaceutical sector will make the manufacturing of complex drugs easier. The arrival of Industry 4.0 and its advanced technologies such Artificial intelligence (AI), Robotics, Machine learning (ML), the Internet of Things (IoT), and Big data analytics in manufacturing processes is referred to as industry 4.0. Industry 4.0 the potential to completely transform medication research, production, and supply chain activities in the pharmaceutical sector, resulting in more productivity, reduced prices, and better quality. Real-time monitoring of manufacturing processes. The application of these technologies has to dramatically increase the agility, efficiency, flexibility, and quality of the industrial production of medicines. How these technologies are deployed on the journey from data collection to the hallmark digital maturity of Industry 4.0 will define the next generation of pharmaceutical manufacturing. Achieving the benefits of this future requires a vision for it and an understanding of the extant regulatory, technical, and logistical barriers to realizing it.

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Introduction

Industrial revolution 4.0 is the new cyber-physical technology to improve system intelligence. The Research & Developmant stage of developing a new drug or drug can be very long and costly compared to traditional products, so applying Industry 4.0-related technology to the drug development process could bring significant benefits to the biomedicine and pharmaceutical industry. The Fourth Industrial Revolution, or Industry 4.0, is the integration of cutting-edge technologies into manufacturing processes to create intelligent factories. Examples of these technologies include the Internet of Things (IoT), artificial intelligence (AI), and big data analytics. Industry 4.0 goal to increase production, lower costs, and increase efficiency by giving machines the ability to attact with people and other machines in real-time. Industry 4.0 is changing how medicines are produced, distributed, and consumed in the pharmaceutical sector. Pharmaceutical businesses are using cutting-edge technologies to improve product quality, decrease waste, and expedite production processes. Pharmaceutical businesses are now able to create customised medications that are catered to the unique needs of patients thanks to Industry 4.0 [1].

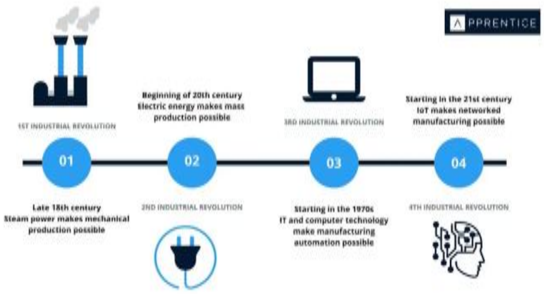

Figure: 01 Industrial revolution

Industrial revolution: 1

Industry 4.0 represents the future, while Industry 1.0 marks the beginning stage of the contemporary pharmaceutical sector. The use of herbal or botanical preparations as medicine has been a part of human civilization throughout history. However, in the last two hundred years, there have been significant developments in the processing and formulation of these materials for medical purposes. In Industry 1.0, the handling of materials derived from plants, minerals, and animals shifted from basic hand tools to industrial machinery capable of processing larger volumes of medicines through crushing, milling, blending, and pressing. In the 19th century

[2], the larger-scale production of pharmaceuticals began to develop from two main sources: individual pharmacies and the dye and chemicals sector, utilizing machinery powered by non-electrical means. The transition from laboratory-scale drug production to large-scale manufacturing catalyzed the formation of the pharmaceuticals industry in the 19th century, an industry that has experienced significant expansion over the past hundred years [3].

Industrial revolution: 2

The second industrial revolution was made possible by the advent of electricity and the development of early electronic machines and assembly lines that utilized pre-set controls. Implemented fundamental automation and process controls that enabled manufacturers to establish essential process parameters. In the pharmaceutical manufacturing sector, this was evident through the implementation of electronic machinery for crushing, milling, blending, and tablet pressing, facilitating larger-scale production and, crucially, enhanced monitoring of processes and quality. Nevertheless, the process controls were typically confined to predetermined and static configurations, which permitted only the observation of process performance and the use of passive control strategies. Advancements in Industry 2.0 have directly resulted in the creation of machines like contemporary tablet presses, which are capable of consistently manufacturing more than one million tablets each hour [4].

Industrial revolution: 3

The third industrial revolution was made possible by computers and communication technologies, including networked computing, the internet, and wireless communications. These technologies facilitate a greater level of automation in processes and equipment, which in turn has led to concepts such as continuous manufacturing and active control in pharmaceutical production. For instance, continuous manufacturing a method that transfers materials produced in each process step directly and continuously to the subsequent step for further processing has seen widespread adoption in various other industries. However, the pharmaceutical industry has been relatively slow to embrace continuous manufacturing for a number of reasons [5] .However, to fully realize the benefits of PAT and Q b D, further technological advancements are essential to gain deeper insights into processes and provide real-time analytics, which would enable broader implementation of real-time release testing with high levels of product quality assurance, particularly for biotechnology products [6].

Industrial revolution: 4

Fourth industrial revolution unites advanced manufacturing technologies, creating integrated, autonomous, and self-organizing systems that function independently of human intervention. The invaluable experience gained from the automated and digital realm of Industry 3.0 is driving a transformative shift towards Industry 4.0 in pharmaceutical manufacturing. While Industry 3.0 focused on rapid advancements in individual operations and tools, Industry 4.0 delivers significant improvements in entire manufacturing systems and infrastructures. In this innovative landscape, performance data is meticulously analyzed by sophisticated algorithms, enabling critical real-time business and operational decisions that directly enhance production outputs [7]. The progression from basic data collection to digital maturity is a complex transformation in which raw data obtained from manufacturing processes evolves into valuable information through thorough analysis. This information, when enriched with contextual meaning potentially through the application of artificial intelligence matures into knowledge. Ultimately, this knowledge culminates in actionable wisdom that guides decision-making by providing insightful perspectives This wisdom is fundamental to the functionality of autonomous systems and cyber-physical machines, which are equipped with mechanisms governed by computer algorithms. These systems are capable of self-optimization, informed judgment, decision-making, remote operation, and adaptive control[8]. The emergence of Industry 4.0 compels us to envision a fully digitized and autonomous manufacturing landscape, particularly in the pharmaceutical sector, and to understand its profound potential impact on operations and regulations. As digitization, automation, and real-time data integration redefine traditional practices, we are on the brink of achieving exceptional quality standards surpassing even Six Sigma in pharmaceutical manufacturing, applicable to both small and large-molecule drug products.

Ways to emplaced revolution 4 technologies in pharmaceutical manufacturing industries.

Integrated autonomous and robotic systems seamlessly combine real-time and online data with industrial production processes and artificial intelligence, driving optimization in manufacturing and enhancing enterprise-wide management [9]. The integration of multiple data sources allows for the seamless connection of both external and internal information. In the context of pharmaceutical manufacturing, this includes the amalgamation of external variables such as patient experiences, market demand, supplier inventories, and public health emergencies with internal data pertaining to energy and resource management, modeling and simulation outcomes, and laboratory results. The outcome is a highly controlled, interconnected, and digitized ecosystem within the pharmaceutical value chain. Additionally, the journey of data transformation toward achieving Industry 4.0 involves several critical stages. Initially, raw signals are captured from manufacturing processes. These signals are subsequently organized through data digitization and analyzed as Big Data, transforming them into actionable information [10].

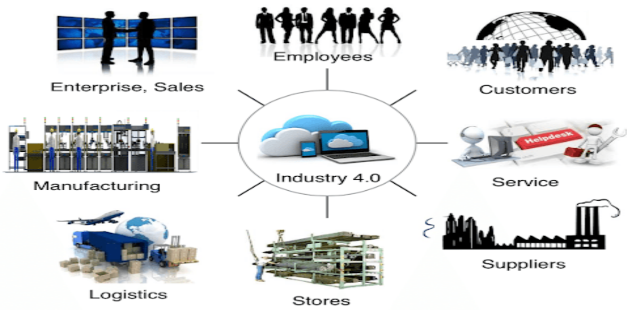

Figure: 2 Ways to emplaced industry 4.0 revolution in Pharma sector.

A cyber-physical system (CPS) for pharmaceutical manufacturing in Industry 4.0 is a transformative framework that integrates key components, including the public cloud, private cloud, and manufacturing floor. The public cloud is dedicated to application services aimed at external customers, while the private cloud manages information for advanced functionalities such as remote monitoring systems, production oversight, energy management, laboratory information, control services, and sophisticated modeling and simulation.

Artificial intelligence

AI involves the integration of digital data and computational analysis for the purpose of making decisions normally made by humans [11]. Tasks that rely on computer-based intelligence may involve reasoning, problem solving, learning, and decision-making among others. The application of AI in pharmaceutical manufacturing has already begun with examples including the use of machine vision technology [12]. AI includes a spectrum of sub-disciplines which take varied ap proaches to designing computer intelligence depending on the desired features and tasks to be performed. Such approaches involve handling large and disparate datasets with specific algorithms. Within the field of AI, and due to the advancements in available technology and software programming, machine learning (ML) and artificial neural networks (ANN) have emerged as two of the more advanced methods for pre diction and risk management. In the hierarchical relationships of AI, ML is a sub-discipline of AI, and ANNs are a sub-discipline of ML. ML primarily involves the ability of computers to learn a task by monitoring data and using statistical tools in order to derive some general knowledge from these data (via the development of mathe matical relationships) without external input or prompt [13] ANN was created by making use of data driven algorithms to find out mathematical relationship between input and output variables. It can be used independently or in connection with other modeling techniques. ANN has been used in pharmaceutical development for:

a- Predication and control.
b- Risk based analysis of biosynthesis.
c- Fault detection for complex dynamic process.
d- Pharmacokinetic and pharmacodynamic outcome prediction [14].

AI also enables other advancements that have a role in smart factories concepts such as digital twins, predicative maintenance, and collaborative robots. A digital twin is a digital replica of a physical process such as an operation, machine or activity used to better understand, evaluate, predict, and optimize its performance. Digital twins can be based on empirical data or integrate both empirical and mechanistic simulations to provide high resolution models together with real-time or near real-time data from which to assess process performance. Such models outperform traditional process models both in terms of resolution and real-time feedback. For example, some com panis outside pharma have employed digital twins in smart factories and inside pharma in smart processes Digital twins enable humans to better understand how de viations or disruptions may impact performance, and how related risks can be mitigated [15].

The development of data digatization’s

Implementing Industry 4.0 hinges on the effective digitization of various intricate components within the pharmaceutical value chain, all while embedding robust cyber-security measures. This approach is essential for the successful development of “smart factories’’ [16].

To successfully develop smart factories in the pharmaceutical sector, digitalizing all available data is essential. This includes transforming previously collected manual documentation into a cohesive digital format. This foundational step is crucial for realizing the full potential of smart manufacturing.[17] We will divide the value chain of the pharmaceutical manufacturing processes into distinct segments, each equipped with its own robust digital architecture, including hardware, software, and infrastructure to effectively support data storage and analysis. Additionally, we will integrate strong cyber security measures to ensure the integrity and security of our systems. Additionally, connection speed is of paramount importance, and with the advancements brought by 5G technology, we are poised to make significant improvements in this area.[18] The tools developed to optimize key value drivers in pharmaceutical firms may differ based on their core competencies and business models, but one thing is certain: the evolution of more integrated systems is inevitable. Digital integration into the Internet of Things (IoT) is set to create groundbreaking pharmaceutical applications, including real-time, on-demand production systems, genuinely personalized dosage forms, and transformative biosensor diagnostics [19].

Complete computization

Full automation of all processes is the ultimate goal of smart factories. This is achieved by gathering process performance data and integrating it with PAT technology (PTA stands for process analytical technology, which is a mechanism to design, control, and analyze pharmaceutical processes through the measurement of critical process parameters (CPP) that will affect critical quality attributes (CQA)). AI is then used to turn this data into information, knowledge, and decisions that eventually improve processes and enhance control

Innovative technologie in 4.0 industry

Today's business strives for localized, adaptable production near its clients. Produce "on demand" and steer clear of big stockpiles. Pharmaceutical firms may create a more robust and flexible production process with fewer errors, fewer interruptions, and better quality control with the use of innovative and adaptive technologies. Pharmaceutical manufacturing facilities will be transformed into "reconfigurable factories" through vertical integration of Industry 4.0, enabling intelligent, adaptable, and agile production lines that permit mass customization of customized medications to satisfy various demands.

Life cycle of a new drug development

Drug research, preclinical and clinical trials, approval procedures, and post-marketing surveillance are all phases in the methodical process of drug development. Each of these processes is explained in brief in the next subsections.

Drug discovery

The initial stage of the drug development process, drug discovery, yields thousands of possible candidate molecules for use as medical treatments. However, following preliminary testing, only a small number of compounds have advanced to the following stages. Typically, the following procedures are used to carry out drug design and discovery: concentrating on a disease's etiology and progression in order to find and pinpoint the right target Identifying or creating a substance that interacts with the designated target to alter illness conditions Identifying potential positive effects for lead identification through a variety of molecular compound tests; looking through the unintended consequences of current treatment regimens in an effort to identify a potential new effect on the target; and creating a novel compound from preexisting materials that will effectively manipulate the target

Eco-system in pharma 4.0

Ecosystem pharma 4.0, which uses the medical cyber-physical system (MCPS) at any point in the drug development life cycle, is an example of Industry 4.0 in the pharmaceutical sector. The term "MCPS" describes networked, context-aware, life-critical systems of medical equipment and technologies that operate together to support a patient's treatment regimen. The primary goals of applying this paradigm to the medication development process are to decrease cycle time and developing expenses while simultaneously enhancing the quality of the drug products by

a. increasing the contributors' intelligence.
b. establishing connections and integrating the intelligent contributors, and
c. giving the regulatory bodies and stakeholders up-to-date status and awareness information. Cyber-physical systems (CPS) technology is used by MCPSs to offer patients in difficult medical situations, such clinical trials, high-quality ongoing care. CPSs combine networking, computing, and physical operations. Networks and embedded computers use feedback loops to monitor and manage physical processes, which influence calculations and vice versa.

Master plan for implementation of industry 4.0 in small plants.

Small manufacturers may find it difficult to use Pharma Industry 4.0 technologies, but there are some techniques that can help them get beyond these obstacles and successfully implement these cutting-edge technologies. Here are some important strategies.

a. Start Small: Small businesses should first identify the areas of their production process where Industry 4.0 technologies could be applied. This could involve installing sensors to monitor the equipment's operation or a simple automation task. Starting small will make it easier to gain confidence and develop a plan for scaling up.
b. Work Together with Experts: Small factories may not have the tools or expertise required to take full advantage of Industry 4.0 technologies
c. Stress Data Security: Data security is crucial while using Industry 4.0 technologies. Data security should be a top priority for small businesses.
d. Employ Cloud Computing: Small factories may make full use of Industry 4.0 technology by utilizing cloud computing to provide the processing speed and storage capacity they require.
e. Support Change Management: Adopting Industry 4.0 technologies successfully necessitates cultural shift and the ability to accept change

Chronology of small factories having effectively used pharma 4th revolution.

Inovapotek is a small contract research firm that specializes in creating dermopharmaceutical and cosmetic products. The company adopted Industry 4.0 technology to increase efficiency and optimize its operations. Using IoT sensors and AI algorithms, Inovapotek was able to monitor and optimize its manufacturing operations, resulting in a 40% reduction in product waste and a 30% reduction in production time. Pharma pack: To enhance its manufacturing procedures, this small pharmaceutical packaging business adopted Industry 4.0 technologies. The company was able to track and monitor its inventory in real-time by utilising RFID technology and machine learning algorithms, which led to a 20% decrease in inventory expenses and a 50% reduction in order lead times.

Challenges affecting industrial revolution 4 in pharmaceutical sector

Utilizing cutting-edge technologies is not always simple. Industry 4.0 has encountered certain difficulties as well. It is difficult to find qualified personnel to manage the sector due to the highly developed technology. As several technologies are connected by Industry 4.0, security is the primary concern [20].

1. Cost:
2. Lack of experience:
3. Data Security and Privacy:

Governance difficulties

Many pharmaceutical companies continue to use traditional processes despite the positive aspects of modern technology, such as improved quality and lessened regulatory load, mostly because there is no worldwide regulatory governing agency. Rather, they are several international jurisdictions with varying standards for regularity or perhaps no explicit laws that are appropriate for the modern period.

Technical complications

Large volumes of stored and real-time data must be captured, processed, and retrieved in order to traverse the realm of "Big Data," which is now being explored by most businesses.One of the main technological challenges in Industry 4.0 will be identifying and explaining the meaning of the data [21].

Logical challenges

A new set of talent is needed to turn the pharmaceutical industry's smart factory concept become a reality. These factories require individuals with advanced expertise in data management, such as data scientists, IT specialists, computational and system engineers, in addition to the conventional biologists, chemists, and engineers. There is now a limited reservoir of such expertise and fierce rivalry among several companies rom other industries, which might lead to higher operating costs. In addition, intellectual property and rights are the foundation of this industry, but they also provide a challenge to its full participation in the fourth industrial period, which necessitates close collaboration and communication across several organizations [22].

Suggestions for the future of pharmaceutical manufacturing foe small firms.

1. Invest in industry 4.0 Technologies

Small firms should spend money on Industry 4.0 technologies like IoT, AI, automation, and machine learning to boost output, reduce expenses, and stay competitive.

2. Adopt a digital Strategy

Small manufacturers should adopt a digital strategy that integrates digital technology into every aspect of their operations, including production, distribution, and research and development.

3. Accept flexibility

Small firms should give their manufacturing processes some leeway in order to adjust to the changing needs of the market [23].

Conclusion

Industry 4.0 offers transformative opportunities for the pharmaceutical sector, promising enhanced efficiency, quality, and patient care through technologies like AI, IoT, and automation, while also presenting challenges like regulatory complexities and high costs The emergence of Industry 4.0 offers a transformative gateway for the pharmaceutical sector, heralding fresh prospects for innovation, operational efficiency, and enhanced patient care.

Author Contributions

All authors are contributed equally

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Declaration of Competing Interest

The Authors have no Conflicts of Interest to Declare.

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