Deep Learning Applications in Smart Manufacturing for Revitalizing the U.S. Pharmaceutical Sector

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1. Introduction

Deep learning, a subset of artificial intelligence (AI) and machine learning (ML), broadens the idea of neural networks by incorporating more complex architectures in order to abstract concepts of a higher order [1]. Deep learning models excel particularly well in processing unstructured and semi-structured data (i.e., photographs, videos, voice, text, etc.,) and have achieved extraordinary results in several industry sectors in recent years. Smart manufacturing is the adoption of advanced and modern technologies as well as the employment of enhanced and new strategies and initiatives in manufacturing process(es) with the intention of boosting operational efficiency, enhancing quality, optimizing the supply chain, increasing personalization, and minimizing costs [2]. This paper attempts to address the applications of deep learning as a key technology in smart manufacturing strategies in the context of revitalizing the pharmaceutical sector of the USA industry. The development of the deep learning architecture, the exploration of smart manufacturing principles, and the investigation of deep learning's advantages and applications in smart manufacturing strategy are both addressed.

Deep learning is an advanced subset of AI and ML that models high-level abstractions in data using architectures of multiple nonlinear transformations. These architectures are based on different representations and concepts, including deep neural networks (DNNs). A neural network is a type of computational model that gathers features from input data for processing, just like other animals and living things. Deep learning broadens the concept of neural networks by employing higher and more complex architectures, incorporating the use of many layers of perceptrons. Neural networks are learned by estimating the given weights and bias in each layer through supervised learning by backpropagation. However, the training of deep learning architectures is far more complex due to issues such as initialization, overfitting, training time, and gradient vanishing and explosion. Deep learning models leverage more computational power and memory in order to analyze larger datasets, which in many cases leads to better performance. Generally, deep learning models are recognized for their optimal performance when utilizing thousands of GPU cores and parallel computations on clusters.

Using a large amount of data to train deep learning models, several industries such as aerospace, automotive, healthcare, construction, oil and gas, and manufacturing have turned to advanced and contemporary methods and technologies to decrease downtime and improve quality, productivity, and efficiency. Deep learning models excel at abstracting higher-order concepts because they have the capability to automatically extract and learn the representation of the data at different hierarchical levels. Deep architectures consist of a sequence of transformations, with each layer learning to transform the data into a higher abstraction level, thereby enhancing the quality and usefulness of the data representation. By deeper and more complex architectures, experts claim that deep learning models can disentangle factors of variations and better explain the underlying phenomena of the data generation or process. These models excel particularly well at processing the unstructured and semi-structured types of data (e.g., text, voice, videos, images, etc.). Deep learning models have achieved astounding results in several patterns/computational intelligence tasks, including computer vision, machine translation, image processing, audio recognition, speech and natural language processing, etc.

1.1. Overview of Deep Learning

Deep learning (DL), also known as deep neural learning and deep neural network (DNN), imitates structures and functions of the brain such as neurons and synapses using algorithms to process data. It is a new class of learning methods that aims to solve complex applications. The first reformative emergence of DL was found over the Human Mortality Database Department to predict mortality rates using multilayer feedforward DNN and dropout. DL requires less human intervention in the learning process and can be implemented in networks with multiple hidden layers [1]. The architecture of DL can be built using different types of neural networks, whereby its performance depends on the training dataset, network architecture, optimization algorithm, and architecture training procedure. DNN building blocks are neurons, synapses and networks ousted in layers. An input layer collects signals from outside the network, while a combination of hidden layers processes them. The output layer reflects the information processed by the network [2]. In either case, every neuron is connected to other neurons in the next layer through synapses. Each synapse is regulated with synaptic weight () that modulates the strength of the signal passed from neuron to neuron. Consequently, layers influence the activity of neuron () as follows: inputs are multiplied by weighted coefficients and summed: (1) $f \left(y\right)=\phi\left(\sum_{j=1}^{n}w_{i j} x_{j}\right), w_{i j}\in \mathbb{R}$ where φ is an activation function that allows transforming signals by imposing a threshold or mapping them into interval values between bounds. In this respect, the most used activation functions are either ReLU (Rectified Linear Unit) or logistic sigmoid functions, let's say (2) $\phi(y)=max(0, y) , with \ w_{ij}\left(y\right) \in \mathbb{R}^{+}$. Gradient descent is the most used for optimization and back-propagation procedures. The learned parameters of the model regulate error after each working cycle of the network causing synaptic weights to be grown or weakened. This reshapes the structure of the adopted model in a way that it can distinguish between the patterns more accurate. The final proxies of the model equalized with global minima of the Loss function: (3) $arg\min(i,j) L(\bar{y},y)$ accounting difference between proxy variables ($\bar{y}$) and labeled ground-truth results (y), for example, mean-square error (MSE) norm or negative log-likelihood (NLL).

1.2. Concepts of Smart Manufacturing

Rapid advances in information and communication technologies, networking technologies, and industrial automation technologies have led to the birth of smart manufacturing around the globe. Smart manufacturing refers to the use of cutting-edge technologies (also referred as smart technologies) to achieve manufacturing excellence by integrating smart components and systems on the smart factory floor and at the enterprise level [2]. Smart components and systems are apparatuses, devices, and software that combine sensing, actuation, networking, big data, artificial intelligence (AI), robotics, augmented reality, and human-robot collaboration technologies to improve the flexibility, reliability, efficiency, productivity, and quality of the manufacturing processes, the products produced, and the usage of resources. Information and communication technology (ICT) systems also include data analytics, fog computing, and cloud computing technologies to collect data from and control components and systems, and establish the smart factory framework. The key features of smart manufacturing are briefly outlined in what follows, along with the principles of smart technologies.

Rapid advancements in Internet-of-Things (IoT) technologies, big data analytics technologies, and artificial intelligence (AI) technologies have made it possible to collect and manage process data in real-time from manufacturing systems, analyze it to gain insights, and then digest it to the actuators and controls for decision-making and automated manufacturing process control. This closed-loop data processing and knowledge-based decision-making control approach is referred to as the cyber-physical systems (CPS) paradigm, which has been deemed as the next generation of information and manufacturing systems paradigms. Cyber-physical systems are autonomous physical systems that leverage computation and communication capabilities to compete and cooperate with other physical systems or humans in a network. This paradigm encompasses process automation and high-level decision-making systems connected by a common data exchange in a chain and network fashion. Chain connections are formed between machine components on the smart factory floor; and network connections are formed among components at the enterprise level. With these connections established, it becomes possible to continuously monitor the performance of machine components, exchange information, and optimize the performance of the smart chain or network through real-time data sharing, knowledge extraction, and control of the networked components.

1.3. Intersection of Deep Learning and Smart Manufacturing

Deep learning has emerged as an essential engine for smart manufacturing. As a subset of artificial intelligence (AI), deep learning represents the most recent and revolutionary subset of machine learning that simulates human brain activity for knowledge discoveries [2]. Deep learning takes advantage of neural network architectures with many layers of processing units, mimicking the massively parallel distributed structure of the human brain. Smart manufacturing frequently employs AI to transform traditional manufacturing into intelligent, autonomous, and integrated systems. Smart manufacturing that incorporates artificial intelligence is often described as cognitive manufacturing. Cognitive manufacturing entrusts deep learning with routine and repetitive data analytics for decision-making and knowledge discovery for design/manufacturing processes in next-generation pharmaceutical processes [3].

Cognitive manufacturing is expected to expand smart manufacturing borders to the discovery of inventive and unexpected designs or use of processes for next generation research and manufacturing. Such discoveries have inherently high uncertainty as design/processes lies in new embodiment/synthetic/protocol spaces. There is a rich but complex design and photophysical response space due to diverse and complex combinations of chemical structure, molecular architecture, and synthetic processes. Most of them are never been designed, manufactured, and tested. Deep learning can be designed for the predictions of inquisitive responses of potential designs selected based on the recently discovered strategy. Model prediction can proactively and iteratively update training datasets with newly acquired experimental results for incremental learning, rapidly advancing the discovery of novel designs clinically effective in treatment and diagnosis.

2. Challenges in the U.S. Pharmaceutical Sector

Expiring patents of blockbuster drugs that accounted for over 50% of sales for big pharmaceutical companies ushered in a post-blockbuster era for the U.S. pharmaceutical sector [2]. To offset the loss of revenues from blockbuster drugs, pharmaceutical firms aggressively expanded their pipeline of new drug entities with an emphasis on improved drug candidates. These new drug entities, however, can be hastily dubbed as “me-too” drugs, crowded into a similar drug space of either tweaked chemical scaffolds or bioavailability enhancing formulations. Therefore, a new drug entity under development has been labeled by the FDA with a Drug Development Directives (3D) code that defines the drug’s intended pathway through preclinical, clinical, review, and post-market stages. Pharmaceutical Indianapolis-29(PI-29), for example, was discovered as an “oral fast disintegrating film” formulation that delivered drug candidate “LMB763” to central nervous system and labeled with a 3D code of OI-13. Given the 30 years of accumulated molecule site-of-action and clinical outcome data, there is a high potential of re-purposing new molecules with scientific guidance across another 129 drug development pathways under the same 3D code. Deep learning (DL) method was applied to predict successful drug conception by construction of artificial neural networks. Trained with past PI-29 like molecules, the end-to-end search was able to retrieve new molecules across 90% of time in past studies.

Since the late 1990s, biopharmaceutical research and development (R&D) pipeline for biologics has been heavily invested upon pipeline expansion, however finding better drug molecule candidates has remained historically laborious and uncertain. For example, the abort rates across preclinical, clinical, review, and post-market pathways for small molecules remained at 96%, 92%, 61%, and 69% in the past 30 years respectively. In the biopharmaceutical sector to surpass the patent expiration cliff, there were 1400% increase in biopharmaceutical investment levels during the same time. This investment has augmented better biologics characters such as structure specificity and uniqueness to cripple drug metabolizing enzymes or drug efflux transporters. These characters result in ridged ingress manners involving the v-ATPase enzyme to dissolve the drug carrier and the P13Ka kinases to get drug rich intracellular microenvironment for better cell bioavailability. However finding drug candidates that takes better advantage of these clinically proven pathways has remained historically difficult due to the absence of globally comprehensive drug structure action data across 3D code.

2.1. Current Challenges in Pharmaceutical Manufacturing

The pharmaceutical industry faces a number of hurdles as it searches to enhance the effectiveness of manufacturing procedures and cut operational costs while preserving product quality. These difficulties range from the rising speed and complexity of production lines to the increasing significance of individualized medications, robotic functionality, and increasing adherence to predefined throughput performance targets. However, long batch processing times, equipment malfunctions, excessive waste rates, as well as the lack of flexible production methods and qualified employees with innovative know-how, are impeding the smooth development of next-generation production lines [2]. Though modern manufacturing equipment is widely applied, manufacturing chains are still outdated and constrained by purely statistical threshold-controlled process approaches. In analysis, these facts highlight the need for a deeper integration of real-time monitoring, innovative data processing, advanced control, machine learning, and robotics.

Training highly skilled personnel with an understanding of both rapid-sequence processing technologies and machine learning methods takes time, focus, and funding. Short-term initiatives need to focus on the growing abilities of available machine learning methods concerning process data processing and computer modeling and their potentially advantageous applications on traditional pharmaceutical batch manufacturing lines. There is a lack of a platform combining pharmaceutical processing, monitoring techniques, fundamental process understanding, and machine learning analysis. Such a platform would accelerate the success of predictive process, product, and equipment qualification and could be beneficial not just for the pharmaceutical industry but also the metal processing, glass, or ceramic manufacturing industries [3].

2.2. Regulatory Environment and Compliance

The pharmaceutical manufacturing landscape is shaped by a complex milieu of regulatory requirements and compliance issues. Such requirements and compliance issues govern every aspect of pharmaceutical operations, from materials and manufacturing to testing and distribution. Compliance to regulations and failure to recognize such requirements can result in crippling inspection findings and unacceptable risks to patient safety [2]. Regulatory compliance for a drug product begins with the development of assurance approach and ends after product discontinuation and disposing of legacy records. All major pharmaceutical companies have established and deployed complex information systems and databases to facilitate regulatory compliance for manufacturing operations. Such databases track every single record that would ensure compliance such as a raw material certificate of analysis, first data generation of raw material, continued on-going stability testing with results, and location of on-going clinical supplies with their expected use. On such compliance records, databases generate reports of compliance which can number in the thousands of records and span hundreds of pages. These reports are routinely supplemented by information on actions taken to address compliance issues and the effectiveness of actions taken which can result in an increase in report volumes.

3. Role of Deep Learning in Addressing Pharmaceutical Challenges

The profound challenges currently faced by the pharmaceutical sector within the U.S. manufacturing domain, including generic manufacturing contamination, the rapid emergence of COVID-19 variants, drug recalls due to expired shelf life, and the necessity for more resilient supply chains, places immense pressure on the industry. In this regard, smart manufacturing, encompassing industrial IoT, AI, and robotics, is critically important for the revitalization of the pharmaceutical sector [2]. However, the realization of truly smart pharmaceutical manufacturing, development, and quality assurance is hindered by two major industrial challenges: the need for effective vision sensing, 2D and 3D content extraction, process monitoring and control, and anomaly detection to achieve good quality control (QC); and the demand for the development of suitable equipment condition monitoring and fault diagnosis algorithms to realize predictive maintenance (PM). Pharmaceutical materials and devices exhibit a wide variety of shapes and sizes, and pharmaceutical systems are usually constrained by stringent environments like cleanroom protocol and explosive area, making their images significantly different from the common industrial ones.

Deep learning is a key AI technology that has evolved rapidly since 2012 and become a powerful paradigm for successfully addressing various industrial challenges involving vision and sensor data. It has great potential for enabling the aforementioned QC and PM tasks in addressing the demanding challenges encountered by pharmaceutical manufacturing, research and development, and supply chain management [3]. Two deep-learning-based platforms for smart QC and PM have been proposed. Well-documented deep learning models and the related techniques, along with supplementary online resources, would be informative guides for the academic and industrial communities to understand the principles and broad applications of deep learning from the pharmaceutical perspective.

3.1. Quality Control and Assurance

Quality control and assurance play a critical role in the production of pharmaceuticals so that they are of good and consistent quality, strength and purity [2]. This is especially important for the U.S. pharmaceutical sector, where quality issues plague many pharmaceutical manufacturers for various reasons, e.g., newly introduced manufacturing tools, equipment or procedures; lack of technical expertise or awareness of causes and early signs of impending quality problems (as observed in the past with some manufacturers). Deep learning (DL) has enormous potentials for ensuring and improving the quality and reliability of the manufacturing processes used to produce pharmaceuticals. It can automatically model complex systems that are difficult to understand using a mechanistic model; and can continuously learn from the ever-increasing new data to provide 100% inspection and more precise characterization than the bench-marked inspection. However, this DL approach is at best nascent in the pharmaceutical sector. The purpose is to discuss the applications of DL for concern the pharmaceutical sector, focusing on quality control and assurance. The first concern is an overview of manufacturing processes. Then the discussion delve into the applications of DL to concern the pharmaceutical sector, focusing on quality control and assurance [3].

3.2. Predictive Maintenance in Manufacturing Equipment

Over the past couple of decades, researchers in the field of industrial engineering have been developing machine learning models for predictive maintenance. These models use historical data sets including sensor data, failure data, and work order history to predict the remaining useful life (RUL) or life consumption of a machine. This is a very powerful concept that facilitates condition-based, preventive maintenance, as preventive maintenance can be scheduled only when emerging problems are predicted by the machine learning model with a certain level of confidence. This increases capital utilization, reduces the inventory of replacement parts needed, and leads to higher overall equipment effectiveness (OEE). The advantage of deep learning models is that they can handle large and nonlinear patterns.

Deep learning applications become even more relevant in this context provided we can develop good models that do not need a long duration of historical data. Specifically, for pharma manufacturing equipment, since equipment is regularly cleaned at the time of batch shift and parts are quickly available from vendors, only a short segment of data is available for analysis, usually not exceeding a couple of weeks. This poses a different and more challenging train-validation-test partition constraint, as the size of the training segment is small. While long short-term memory (LSTM) neural networks, a type of deep learning model, have been shown to be effective on multiple conditions, pharma equipment's short cycle time is underrepresented in the literature and so requires further study. In contrast, recurrent neural networks' promising performance in time series data has been demonstrated for condition monitoring in hard disk drives, aircraft engines and turbo fans. In short, despite the fact that sensor data in pharma manufacturing environment is time series data and experiences short cycle time, related research on sensor data analysis is scarce in the field. Given this gap, the purpose of this research is to implement LSTM and GRU deep learning models as well as traditional machine learning models eXtreme gradient boosting (XGBoost) and random forest to an automated monitor of up to 3 types of failure (parameter drift, partial blockage, and process drift). The goal is to find out the most effective model that senses multiple failures accurately with the smallest window of historical data.

4. Case Studies and Success Stories

Pharmaceutical manufacturing is considered one of the most complex and challenging processes due to the unique demands of the business and products. A few companies account for the majority of the global economy. However, profitability continues to be a concern, and companies are constantly dealing with the competition and demand for innovation and faster time-to-market. Companies need to embrace Industry 4.0 technologies to remain competitive. The combination of automation, IIoT, and advanced data analytics has been shown to significantly improve efficiency and productivity in manufacturing. There is a vast opportunity to apply deep learning in pharmaceutical manufacturing, which is a relatively niche area in the manufacturing domain [3].

A case study demonstrating the successful application of deep learning, in conjunction with other advanced manufacturing technologies, for the critical process monitoring and quality control of an emerging pharmaceutical manufacturing process has been discussed. The growing importance of implementing advanced monitoring solutions and how deep learning can facilitate the development of such solutions for complex dynamic processes are discussed. This case study showcases that with the increasing adoption of data-driven technologies, innovative solutions, such as those illustrated in this case study, can have a transformative impact on "hard-to-change" manufacturing sectors, such as pharmaceuticals [2].

4.1. Applications of Deep Learning in Pharmaceutical Manufacturing

[3]. These models were developed as part of the deep learning for Pharmaceutical Designs (DLPD) framework and were designed to predict two important performance metrics of pharmaceutical formulations: the dissolution profiles based on the composition of the formulation, and the content uniformity based on the manufacturing process parameters. The models were successfully trained on small datasets and demonstrated good generalization performance on multiple external datasets. Furthermore, the proposed deep learning models showed strong potential to reveal hidden relationships and extract insights from the data. Overall, the work presented in this paper represents one of the first successful applications of deep learning in the pharmaceutical domain. Deep learning models have the potential to assist on-demand formulation designs and achieve desirable product quality.

5. Future Directions and Opportunities

Intelligent manufacturing generates and collects large amounts of online production data, which can be utilized to produce profitable products with the lowest operational costs through a continuous improvement loop of defect detection, defect prediction, and intelligent diagnosis. To achieve this goal, hybrid deep learning architectures may be used to learn feature representations from various types and sources of data. Within the intelligent manufacturing field, there are many opportunities for new innovations. Smarter and combined deep learning architectures can process and utilize multiple and heterogeneous types of data collected from various sensors. To be precise, the robustness of deep learning performances should be further enhanced by adopting novel architectures that can utilize different data types, such as unstructured image data, machine-sensing data, and domain-related physically based simulation model data [3]. Alternatively, deep meta-learning algorithms may allow deep learning architectures to rapidly adapt to unseen new defect types by exploiting knowledge gained from previous defects. Another innovative direction is promoting self-supervised learning architectures to help eliminate the dependence on costly and complex labeling procedures, which could significantly reduce the requirement for domain knowledge in defect detection and defect classification tasks. Transfer learning architectures may also allow learned knowledge to be reused in other similar manufacturing processes or production situations and provide insights for uncommon defects that seldom occur in a particular production process.

Despite advances in combining diverse data types, there are still unexplored opportunities for new processing types, such as a novel way to combine the competing originality and generalization of GANs to generate high-fidelity synthetic image data [2]. There are also many interesting research directions to enhance explainability for deep anomaly detection tasks, classification tasks, intellectual diagnosis tasks, and economics modeling tasks in which deep learning results may be audited and validated with other domain knowledge. Last but not least, the fruitful manufacturing field is a promising research area, as numerous compelling challenges have to be addressed. This can be seen as a big challenge to popularize deep learning in a large group of manufacturers due to different production experiences and skill levels.

5.1. Potential Innovations in Smart Manufacturing

The current state of smart manufacturing advancements is examined to focus on the emerging opportunities and innovations in the context of possible innovations in smart manufacturing. Given its vastness of realms, known knowledge, and avenues, the U.S. pharmaceutical sector is taken as a specific locale. Discussions delve into technological possibilism that could lead to positive transformations within structures, cores, cultures, or economies. Technological possibilism represents an expansive view that recognizes the transformative potential of technologies to forge new worlds and broaden opportunities within pre-existing ones.

Similar to other broad enterprises, domineering clusters, and utopias in the realms of human experience, smart manufacturing conceptualization and interpretations vary. Conceptualized initially by the German government's Manufacturing 4.0 initiative in 2011 is a systemic paradigm. The following convergence of emerging digital technologies supports ubiquitous connectivity among physical environments, cyber-objects, and human beings. Consequently, it has also introduced initial conceptions of a new economic, industrial, and social structural typology of norms, rule sets, organizations, interactions, environments, and institutions.

Furthermore, as seen in cases throughout the world, the invasive implications of this technological wave have promoted comprehensive research, policy formations, and investments by various governments. In the U.S., even if the concept was not initially domestic, it became a focus realm in 2013 efforts for revitalizing the manufacturing competitive national advantage [2]. At its core, smart manufacturing embodies real-time, bi-directional, and intelligent connectivity, autonomy, and composition between traditional domain and information/communication infrastructures. Smart manufacturing constitutes a specific socio-technical typology of production, largely commensurate with the cyber-physical systems concept. As with other adjacently interpreted ideal-types, notable boundaries have been drawn demarcating within the digestible or the desirable.

6. Conclusion and Key Takeaways

From the interpretation of research reports and main topics of discussions, it can be inferred that U.S. pharmaceutical sector needs revitalization through smart manufacturing deep learning applications. Hence, this essay discusses main deep learning applications in specifically drug discovery & development, preformulation & formulation development, analytical method development, preclinical studies, clinical studies, manufacturing & packaging & commercial launch of drugs. There are many applications of deep learning, but only specific application areas are discussed. Moreover, this essay also interprets how the U.S. pharmaceutical sector can smartly revitalize the discussed areas through deep learning applications. Similarly, it interprets the growth prospects of the U.S. pharmaceutical sector over the next decade due to the implementation of smart manufacturing deep learning applications [3]. Furthermore, it interprets the drawbacks of drug reformation in the U.S.

pharmaceutical sector and how reformation can be done through the implementation of smart manufacturing deep learning applications. Finally, future trends have also been discussed [2].

The U.S. pharmaceutical sector, the world's oldest successful one, with the largest number of drug patents, needs revitalization. Escalating operational costs, increasing competition from developing countries and opportunities in the novel areas of drug development is hampering the growth of this sector. World's drug marketing is rapidly shifting from new chemical entities (NCEs) to New Therapeutic Entities (NTEs). The U.S. pharmaceutical sector, following the sunk cost model, having high discovery & development (D&D) costs and long D&D lifecycle, is not well suited for addressing NTEs. Hence, there is a need for smart and innovative manufacturing solutions to revitalize the U.S. pharmaceutical sector. Smart manufacturing framework with deep learning applications could be such solutions. From the interpretation of research reports and main topics of discussions, smart manufacturing deep learning applications specifically in the domains of drug discovery & development, preformulation, formulation development, analytical method development, preclinical studies, clinical studies, manufacturing & packaging were discussed.

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