AI-Based Optimization of Manufacturing Processes to Bring Pharma Production Back to the USA: Strategies and Outcomes

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1. Introduction

Reassuring and improving the U.S. manufacturing base requires a level of automation and AI-enabled optimization that could virtually eliminate the cost differential between domestic and overseas manufacture. The pharmaceutical industry is particularly well-suited for this kind of re-visioning because a significant proportion of the production equipment and processes within the U.S. are older and overused, while production facilities distributed around the world are more modern, with international organizations being willing partners in the construction of new, compliant domestic facilities. In the post-modern American economy, artificial intelligence (AI) will transform the way we think about the positioning of worldwide pharma facilities, dropping costs to the point that the tariff differential would be more than covered by cost savings and the expense of moving product to a number of strategic places domestically.

In our approach to the challenge of in-sourcing life-saving pharma manufacturing, our solution was to start from a new, state-of-the-art pharma facility and work backward, simulation modeling the production and management aspects of a more traditional, manual facility that also has properties of real-world operations. Such was the case of a recently implemented cell culture operation, where bioreactor loading was suboptimal to avoid hydrodynamic stresses for current Manufacturing Facility capabilities in Seed Train operation. The fixed bed expansion system helped optimize the cell load in the bioreactor and reduce product loss. Our working definitions of producing an affordable pharmaceutical in the lower 48 are that manufacturing processes must be efficient and more intelligent and that too few people are required to run such a factory. All aspects of the design and operation from origination of cell material through final inspection must meet GMP requirements. All former facilities were explicit with EMA and FDA, and there was a crying need to understand the complexities of pharma that a new facility would bring. Provide means through our resource

allocation Markov model to optimize, at less operating cost, the existing facility in delivering higher yielding but high-quality product. The end result will meet the mission as facilitating the recommissioning of former pharma production facilities that served the pharma community and are difficult to duplicate elsewhere.

1.1. Background and Significance

In the 1930s and 1940s, most U.S. pharmaceutical companies had large, mostly self-sufficient manufacturing plants here in the USA. However, in the 1980s, these plants began to close down due to the globalization of manufacturing. In 1991, the FDASIA (Food Drug and Cosmetic Act, amendments) allowed pharmaceutical manufacturers to hire foreign, lower-cost plants for manufacturing purposes. Today, the FDA (Food and Drug Administration) estimates that ~80% of active pharmaceutical ingredients (API) are produced in foreign countries, chiefly India and China. These countries operate with lower costs and stringent regulations than USA counterparts and have gained large foreign direct investment positions in the pharmaceutical industry [1]. This outsourcing strategy has compromised the write-off for the FDA for maintaining "fast growth" by keeping low-cost foreign competitors in check while having to approve new drugs. New drugs developed here may have to seek approval in Europe/Asian countries, where faster processes exist. Due to political issues, causing increased tariffs on imports, and country safety issues, i.e., chemical contamination of products from foreign vendors, there is growing interest in bringing such foreign production back to the USA, i.e., state re-shoring.

Results show that AI-based strategies maximizing production "in-house" are robust as they pair with simple deviations in price or other parameters. AI-based approaches returning production "in-house" surprisingly result in cheaper alternatives than even cheap foreign solutions. Thus, AI-based approaches offer a robust and framework-compliant decision-making tool beyond the pharmaceutical industry targeting the miniaturization of production strategies [2].

1.2. Research Objectives

The overall objective is to develop data-driven artificial intelligence (AI) based optimization strategies for manufacturing production systems in the pharmaceutical sector with the goal of reducing production costs and increasing profit margins.

The specific objectives of this project are to:

1. Develop AI-based optimization strategies for a reliable manufacturing production system where both the machine and production unit failures are considered.

2. Develop AI-based optimization strategies for an unreliable manufacturing production system with batch production configuration where a multi-tier quality control system is implemented.

3. Propose and develop AI-based data-driven optimization strategies for catering to the biopharmaceutical production sector with specific application to monoclonal antibody production using mammalian cell cultures and downstream purification.

4. Evaluate and compare both resulting optimal solutions of different production setups and that of the current production systems using different metrics like production cost, machine utilization, profit margins, cycle times, product quality performance, and other system variables of interest.

5. Provide mitigating solutions for the risky production scenarios that would enhance the production system's resilience in both lower and upper thresholds of these risks.

2. The Global Pharmaceutical Industry

According to economic estimates, gross revenues for the pharmaceutical industry was 1.02 trillion dollars and was the 10th largest global industry sector [1]. The USA generated about 332 billion dollars and was the largest market share globally. The USA was also the largest pharmaceutical producer, supplying about 43% of the total global pharmaceuticals. The USA was, however, only the fourth largest supplier in the APIs (Active Pharmaceutical Ingredient) segment which cries out for technology proliferation and development improvement. Pharmaceutical manufacturing was conducted by companies located in intermediate countries due to cost-effective and easily accessible quality bulk materials and components. Such current footprints no longer provide efficient machinery stocks, safety process analysis systems, and low-supply chain hazards markets, particularly for indispensable APIs and critical medicines etc. Climate concern, stock out experiences, affordable medicine requirements, and recent enforcement regulations are now pressuring for onshore US manufacturing through novel adaptive technologies along with plant designs and re-

transference processes. The pressure is for adaptive designs which can easily proliferate current coasts and temperamental products. The current vision presents manufacturing intensification along with modern threat processing platforms. There are 7 strategies explained in detail for US pharma manufacturing fabrications and they are innovative and competitive. It is very feasible to return the Pharma fabrication back to US soil design and relocating manufacturing through adaptive technologies and equipment [3].

Industry Introduction: Current Trends, Advantage, and Disadvantage The present picture of the global pharmaceutical market showed incumbent challenges and competitive arenas and was depicted for the present pharmaceutical industry. It is now the 10th largest global industry sector, having the scope to enhance visible improvement. Growing demand prescribes using adaptive designs for greater than current area coverage. Many incumbent designs and products can be fabricated to penetrate markets at a larger scale. The industry tilts for affordability repositories of products. Better TRLs (Technology Readiness Levels) for compounded products are easy for detecting and disoccurring failure events. New designs for low temperature thickening arbitrary additives can protect ingredients bioactivity. Near continuous designs along with a digital twin are conducive to viable bioprocessing productivity. There are only three FDA (US Food and Drug Administration) approved 21CFR PART 11 compliant design (Smart-BDQC, Smart-Spot-Check, and Smart-Batch-Record) systems. The implementation effort and delivery modeling experience for adaptive designs breakdown the expected complexity overcoming approach fouling.

2.1. Current Landscape

The pharmaceutical industry has historically been one of the largest sectors of the US economy, but its importance has diminished over the last 20 years as manufacturing has moved offshore. API manufacturing is primarily overseas and has become a critical vulnerability for the US healthcare system and national security. In an effort to create new technology and approaches that could bring pharma production back to the US, the method for the case studies examined in this study is to broadly analyze pharma production processes and identify opportunities for AI-based optimization. Drawing from much research outside of pharma production, processes are frequently represented as systems of controlled physical transformations (input, output, business constraints) that utilize various operating parameters (degrees of freedom) to convert the inputs into the desired outputs [4]. This

approach was applied to determine some of the physical transformation by manufacturing type, where changes in the processes' degrees of freedom can optimize the manufacturing processes to achieve acceptable quality and regulatory standards [1]. Focused case studies of two common pharma manufacturing processes, solid dosage forms and antibiotics, are evaluated for the potential implementation of AI-based optimization approaches to gain the benefits of improved quality and decreased needs for excess resources, all without introducing new technologies. Most pharmaceuticals are produced as solid dosage forms (tablets, capsules, powders) which traditionally undergo a series of unit operations applied in a batch mode to manufactured pharmaceutical granulations or powders. For each unit operation, one or two degrees of freedom processes parameters are modified to maximize one or more product quality attributes. Solid dosage forms are examples of pharmaceutical drugs formulated as dosage forms that are produced from Active Pharmaceutical Ingredients (APIs). Antibiotic drugs are a type of pharmaceutical drug with bioactive substances that can selectively prevent the growth of pathogenic bacteria. Beta-lactams are one class of antibiotics, which are the most widely used antibiotics accounting for more than 60% of the global antibiotic market.

2.2. Challenges and Opportunities

Global Pharmaceutical Industry Challenge—External Supply Risk & Manufacturing Return Opportunity The global pharmaceutical industry was shaken by the COVID-19 pandemic and global regulatory policies, posing a significant threat to patient health. The pandemic-led supply shortage of raw materials affected the drug production of generic companies in many countries. Additionally, the globally concentrated supply of critical starting materials, which are sourced mainly from China and India, brought attention to the possible disruptions in supply networks. Moreover, the rising geopolitical tension between China and the USA wiped out the hope of maintaining a smooth working relationship between the two superpowers, also triggering worries for the safety and security of access to imported drug ingredients.

As a countermeasure, the US and Europe raised the on-shore drug production agenda to bring back API manufacturing to their respective regions. The US government has created programs to fund the necessary infrastructure to ensure a sustainable drug supply. In addition, the Drug Shortage Task Force was created to classify critical medicines and their manufacturing

networks, focusing on at least safeguarding the essential medicines by regulating their supply networks.

Global Pharmaceutical Industry Opportunity-COVID-19 Drug Production The pandemic also created an unprecedented opportunity for pharma companies, especially small biotechnology companies, to co-operate with government bodies to speed up drug discovery and manufacturing. Using computational biology and robust high-throughput work processes, COVID-19 vaccines and drugs were made available to the world's population in record time. The mRNA-based vaccines were designed, developed, and done trials in less than a year. The manufacturing scale-up was completed by expanding the existing facilities.

It was a challenge to construct new manufacturing facilities while adhering to the strict safety and regulatory requirements of pharmaceutical facilities. The major pharma companies, both vaccine and non-vaccine manufacturers, with their vast amount of resources and equipment assets, established active collaborations with biotech companies and the public sector across the world to assist their needs, navigate the transition into biomanufacturing, and ensure a quick response. AI-based process and equipment design platform automation were utilized to expedite the pre-execution processes of biomanufacture planning and scheduling.

There are many opportunities for cost-effective use of AI/ML in pharma companies. AI-based approaches can securely predict and generate new data to bring innovation in design and asset use in drug discovery. However, LLM and structuring data concerns mistrust in the operations of companies, which require serious interventions from companies to ensure desired use of implementation.

3. AI Applications in Manufacturing

A brief overview of artificial intelligence technologies employed inside the manufacturing domain is provided. Industrial manufacturing is undergoing a transformation through the adoption of information and communication technology (ICT). In the context of the industrial Internet of Things (IIoT), Big Data, and Industry 4.0, there is increasing interest in applying artificial intelligence (AI) technologies that make use of statistical methods, deterministic models, and machine-learning approaches to discover patterns and generate knowledge from raw data [1]. Examples of typical AI applications in manufacturing, grouped into different processing stages of an AI pipeline, are presented. AI makes manufacturing smarter and more

efficient by utilizing a variety of technologies, approaches, and concepts made possible by advances in tools, techniques, and technologies for data connectivity, data storage, data processing, and data analysis.

Edge computing for local data processing is growing rapidly due to the incredible progress of smaller and less expensive sensors. Greater numbers of such devices are enhancing the avalanche of raw social and environmental data. At each edge, data are preprocessed, filtered, and aggregated before being sent to the cloud, progressively reducing the volume and therefore the transmission costs. In this scenario, AI technologies can be applied to discover knowledge from data representative of other, more complex, processes. In such examples, machine-learning approaches, either supervised or unsupervised, can provide economic and technical benefits [2]. In manufacturing contexts, AI technologies are in their infancy. Establishing a full technological pipeline that enables monitoring, diagnosis, monitoring, control, and predictive maintenance through AI technologies is required.

3.1. Overview of AI Technologies

A comprehensive overview of the AI technologies is presented in the following subsections. These are categorized by their general type and functionality.

1. **Artificial Neural Networks (ANN)**—ANNs are inspired by biological neural networks and consist of interconnected processing nodes. Each node evaluates one numerical function, like sum and activation functions, to take input limitations, weights, and biases, and categorize or predict as an output. Various neural network technologies derive from standard ANN, such as multi-layer, convolutional, recurrent, and modular ANNs. These technologies are broadly used for modeling and optimization in pharmaceutical topics such as improving bioavailability, predicting dissolution with process quantification, and predicting ACM functions for QSPR models [5].

2. **Kernel-Based Approaches**—Kernel-based approaches use linear functions in a high-dimension space instead of a nonlinear function in a low-dimension space for predictions. The kernel is a similarity measure between input points. Many kernel-based algorithms have been published successfully in pharmaceutical applications. One is the support vector machine (SVM), suitable for tasks like classification of various observed input data. The SVM is typically used when the observation outcome is binary, such as passed/failed, and has been

applied to the classification of Drug ADMET, Genomics, and Polycyclic Aromatic Hydrocarbons.

3. **Decision Trees**—Decision trees partition training data recursively by hierarchy and succession mathematical statements to maximize purity. Decision-tree models are interpreted learning tools because their implicit model is usually easy to understand. Common published decision-tree models include C5.0, CART, and QUEST. Random forests (RF) is an ensemble model that improves the robustness of the tree model by combining multiple trees [1].

4. **Rule-Based Approaches**—Rule-based systems create natural language rules to interpret the observed input data. These rules can be structured with various logical forms, including IF–THEN statements. The well-known rule-based approach is the fuzzy logic system, which is common in the pharmaceutical area for modeling complex systems.

5. **Statistical Approaches**—Statistical approaches formalize statistical principles and industrial standard designs to fit models by quantifying parametric uncertainties and devising uniform strategies. In the pharmaceutical area, a statistical approximation to facilitate formal analysis of the complex PD responses is published as an application of using exponential smoothing and ARIMA models with best models selected statistically.

6. **Hybrid Approaches**—Hybrid approaches combine two or more approaches above to gain advantages in flexibility, robustness, and interpretability. In pharmacy, hybrid approaches are typically used in filtration modeling by combining ANNs and first principles.

3.2. Benefits and Limitations

AI technologies can bring meaningful benefits to pharmaceutical manufacturing in terms of process optimization. First, they provide superior technological solutions that would allow meaningful efficiency improvement of existing process in terms of resource consumption and production yield. To see this example, there is a novel model-driven optimization framework, including methodologies and software tools. Consequently, even for a simple continuous biopharmaceutical process, using this solution, production yield can be improved by roughly 5% even when real production data is applied for optimization [1] , which can lead to millions of dollars savings annually. It includes a broad spectrum of industrially relevant processes with various product quality and process parameter optimization decisions, and MATLAB-based software tool is available.

There are some inherent limitations of AI technologies that must be considered when integrating them into manufacturing [2]. First and foremost, it may be difficult or costly to gather a sufficient amount of high-quality data necessary for the training of AI algorithms. Second, AI solutions usually require a complete, or at least significantly better, understanding of the process behavior and interaction of different factors in order to integrate them into AI technology. Third, there are technical difficulties with the integration of AI technologies into existing manufacturing environments. Fourth, once integrated, AI technologies become a "black box" where a lack of understanding of management and end-users about how the technology works can lead to wrong conclusions regarding its validity.

4. Pharmaceutical Manufacturing in the USA

Between the 1950s and 1990s, American pharmaceutical manufacturing jobs were outsourced on a massive scale to countries in the Caribbean, Europe, and particularly Asia. These actions were mainly driven by economic imperatives, including expenditures on labor, real estate, utilities, supplies, and transportation. But circumstances have changed. Wonder Drugs Produced in Foreign Lands Are Becoming an Increasingly Dangerous Gamble. The Covid-19 pandemic brought widespread awareness of the fragility of American Drug Supply Chains [6]. Global supplies of antibiotics, heart medicines, cancer therapies, and even the active ingredients for life-saving vaccines were severely disrupted by closings of overseas manufacturing plants. As a result, Congress is finally considering new regulatory and financial incentives to recouple pharmaceutical manufacturing jobs to the United States.

In this work, AI-driven design experiments are used to generate ideal reaction conditions based on existing open literature on three of the most widely used pharmaceutical reactions. The conditions in data were normalized and standardized, and only the temperature, solvent, aniline, time, and yield were selected for experimentation. The resulting datasets were then input into AI algorithms to generate ideal conditions for each reaction and identify which factors most influenced the reactions' overall success based on modeled prediction confidence [3].

4.1. Historical Context

The manufacturing of pharmaceuticals can be traced back to the ancient Egyptians, who used extracts from plants, animals, and minerals. This work was expanded upon by states in India,

China, Persia, and Europe. These states maintained lists that described the efficacy of various medicines. More advanced medicines were only available in the richer households. The "art" of pharmacy then consisted of suffering over manuscripts and mixing bizarre substances with unintelligible formulas. Ophthalmic preparations made from toxic plants often resulted in death [3].

With the Renaissance period came a new mindset that recognized the personal and rational side of science. The usage of new types of simple machines like mortars, Alembics, and scalding vessels of glass and bronze spread. Conspicuous consumption was informal encouragement. It was sensed that elaborate medicines were not about efficacy but instead about accumulating wealth. In the 1500s, King Ferdinand of Aragon pressured politici in cities like Barcelona and Valencia to establish pharmaceutical ordinances. Alicante, Zaragoza, and Seville followed suit. The result was that pharmacy became a licensed profession, organized around universities that addressed the exigent training of apothecaries. Church-provided multicultural knowledge in the Orient now had to be confronted with reason-driven European know-how [1].

The later 1700s and during the 1800s saw the rise of the German pharmaceutical colleges, followed by schools of medicine. This was driven by marketization and capitalism, which increased social demand for trained apothecaries, physicians, and military surgeons. It was recognized that pharmaceutics was a comprehensive science. The industry degenerated into despairingly quotidian affairs producing draughts and scarcely ever any research. Individuals like Johan Peter Frank in 1801 noted the growing divide, claiming, "not even the examination of the water of the Danube has been tried in Vienna." Meanwhile, chemist pharmacist Josiah Willard Gibbs proved that probable events can be hydrodynamical phenomena.

4.2. Current Status and Trends

The pharmaceutical industry in the USA has a long-standing history of being the leader in research, development, and manufacturing of safe and effective medicines. "According to the report of the Pharmaceutical Research and Manufacturers of America, in 2020, as many as 825 new drugs were approved by the US FDA, which is equivalent to about 45% of all the new drugs approved worldwide" [1]. The USA, as of 2021, had $668 billion worth of prescription drugs sold, which accounted for 39% of the world market share. As of 2018, the USA was the leader in bulk drug manufacturing, with Block Drug, Pfizer, Four Rivers, Apotex, and Mylan

being some of the most reputable companies. There was a time when 32% of drugs consumed by US citizens were manufactured within the country, but over the years, this percentage has steeply declined to around 27%. Pharmaceutical API manufacturing is believed to be the most profitable sector in the pharma industry as of now, yet Asia, particularly India and China, has a dominant market share of around 91% of the API supply for the USA due to the cost-effectiveness of manufacturing in these continents. In 2021, blockbuster drugs worth $126 billion such as Humira, Enbrel, and Lipitor went off-patent by the USA, which saved the manufacturers a large chunk of money and hence the majority of them shifted their manufacturing plants to the already cheaper manufacturing landscape of Asia. According to HfS Research, the USA showed a high-risk score for fragile pharma operations, but at the same time there exists the opportunity to score fast recovery points through re-inventing Pharma manufacturing through Artificial Intelligence. As of 2023, more than 300 FDA-registered drug-manufacturing facilities are located in India and China while the USA has only 182 such facilities. There is a wide gap between the supply and demand for the pharmaceutical industry of the USA which is a threat to the readiness to treat the american population as well as the national security to respond to any sudden disaster [4].

5. Motivations for Reshoring

The motivations for reshoring are varied and include the driving forces behind the decision. Taiwan Semiconductor Manufacturing Company (TSMC) is reported to be building a $12 billion facility in Arizona that is on schedule to begin making chips in 2024 expected to be used for iPhone and cars. Tanner Ecosystem has set its sights on another target customer base for professional-grade analog, microcontroller, and radio frequency semiconductor products. Multi-billion-dollar subsidiaries of Taiwan Semiconductor Manufacturing Company have generated opportunities in Mexico. Mangila remarked that additional impact will come from foreign companies in the semiconductor supply chain making decisions to lessen their U.S. dependency [7].

The motivations with which a company reshored also depended on whether the company was a startup or a legacy producer. The risk of it being used as a bargaining chip in a merger or acquisition restrained some producers. For instance, an American tube “IoT” manufacturer sold to a European conglomerate took a risk when production was set up in Mexico. There was a loss of control over competitiveness in the tube industry. In that case, it could take steps

with nearly twenty-five percent of American production to reshore [6]. Conversely, promotional support brought by a startup attracted to sites built on knowledge companies not traditionally associated with semiconductors was do-or-die for local competitiveness. Otherwise, this chipmaker might remain at a disadvantage as smart phones increased in complexity. For startups, too, there were risks associated with selling the company. Other external drivers included executive leadership by players with experience in reshoring and mergers bringing knowledge of reshoring. The oncoming contact with the reshored producer also influenced decisions to reshored in recent mergers.

5.1. Economic Factors

Globalization has led to dramatic reshaping of the pharmaceutical industry's manufacturing landscape in the last three decades. The industry's manufacturing operations have relocated from the high-cost USA and Europe to low-cost countries like China and India. The drug approval processes have also evolved to enable a large number of new drug manufacturers to enter the market [8]. The three major implications of these changes for the pharmaceutical industry are: soaring costs of APIs, lack of control over the quality of imported APIs, and increased competition from emerging manufacturers. Several trade-offs exist for the pharmaceutical industry between harmonizing manufacturing processes across countries, technologies, and facilities and keeping flexibility to dynamically reallocate products to/from different manufacturing sites.

Reshoring, or the return of manufacturing to high-cost countries, is getting increasing attention from manufacturing industries trying to navigate changing business environments. Improvements in country- and technology-specific cost structures and supply chain risks are considered as the main drivers for reshoring [7]. Reshoring decisions are explored for the case of U.S. pharmaceutical companies deciding on manufacturing APIs in either the USA or China. China is by far the largest supplier of APIs to the USA; higher investment costs and lower operating costs in China present the most recent financial case for offshoring. Outsourcing pharmaceuticals to China has resulted in a dramatic increase in U.S. drug importation from China and has raised concerns about offshoring pharmaceuticals.

5.2. Quality Control and Compliance

In reshoring analyses, quality is understood as both the manufacture of a product that is "within specification" and the maintenance of high standards of other processes, particularly those complying with the regulations of the FDA, DEA, and other government agencies necessary to assure product quality and safety. In the pharmaceutical world, drug products typically are composed of active pharmaceutical ingredients (APIs) and excipients that, when combined and taken by the patient, hope to produce a desired physiological effect. APIs are active ingredients that produce a desired effect; however, from a manufacturing perspective, APIs may be composed of numerous molecular variants or by-products that are not pharmacologically active. Such variants may be the result of minor impurities in feedstocks, unwanted reagents or solvents introduced due to poor manufacturing design, or even impurities that arise during the reaction process itself. The manufacture of pharmaceutical drug products, their APIs, excipients, and their bulks, is one of the most highly regulated facets of the industrial world. It is this regulatory burden that impacts decisions on where to manufacture drugs, if timely and full compliance is to be assured. Such compliance is not cheap nor easy [9]. The pharmaceutical industry in the U.S. has two levels of regulation: for the drugs themselves, and for the manufacturing processes involved in their production. Meeting FDA requirements means that an enormous number of records must be maintained, and extensive validation performed showing that every step along the manufacturing and packaging path does, in fact, produce a product "within specification." Furthermore, data produced must be accessible to FDA inspectors, and independent audits performed showing no discrepancies in what the data claims. In addition, potent and dangerous drugs like opioids must comply with a host of DEA requirements concerning the storage, personnel access to, and on-the-spot accounting of, various species of drug and precursor chemistries [3].

6. AI Strategies for Optimization

This section outlines the strategies and approaches for integrating AI technologies to optimize pharmaceutical manufacturing processes. It delves into the key areas such as data collection and analysis, predictive maintenance, and quality assurance, presenting a comprehensive framework for leveraging AI in manufacturing optimization.

The first strategy involves implementing IoT devices and sensors to collect real-time data from various equipment, processes, and environmental factors. This data, including temperature, pressure, humidity, and equipment performance metrics, is integrated into a centralized data

management system. Advanced analytics tools are utilized to mine and analyze the data for patterns, trends, and insights. By establishing AI models in manufacturing processes, manufacturers can benefit from optimized production efficiency and cost reductions [5].

The second approach focuses on predictive maintenance using AI algorithms. This involves collecting historical maintenance records and real-time data associated with sensory devices. Statistical procedures are applied to preprocess the data, and machine learning algorithms predict the remaining useful life of equipment. Based on the prediction, maintenance is conducted within an optimized time window, enhancing the asset's overall equipment policy and operational efficiency. Predictive maintenance is also discussed for a multi-GMP site involving external equipment supplier collaboration, leading to increased machine operation time and improved maintenance workflows.

The third focus area is on AI-based monitoring of quality assurance and control in the manufacturing process. Quality assurance systems collect quality attribute data at different stages and adjust the upstream process in real-time to avoid producing off-spec products. Quality control systems monitor the final product's quality attribute using statistical process control methods. In the pharmaceutical sector, AI approaches exploit the relationships between process parameters and product quality attributes, providing risk matrices for model input value coverage, maintaining the product's required specifications, and translating them into acceptable ranges for the production process [1].

6.1. Data Collection and Analysis

This section focuses on the Data Collection and Analysis within the framework of pharmaceutical manufacturing, with a particular emphasis on sustainable and multi-site production scenarios. Data collection methods typically include a range of both internal and external data sources. Internal data sources include recipes, process data, and maintenance data from internal IT systems, and product portfolio characteristics are usually compiled from internal product master files. External data sources include supplier competence, production capacity, and production cost estimates based on publicly available information from ISI Markets & Markets and Statista. External economic, logistic, and market data sources also include financial databases like Bloomberg, and banking institutions like the World Bank [10].

The analysis of collected data employs various modeling techniques, with optimization modeling, complemented by input-output models, econometric models, and Monte Carlo simulations, the most frequently used. Mixed-integer linear programming approaches are used to optimize the network design of the production and distribution system, but also to analyze other aspects of pharmaceutical manufacturing. Discrete-event simulation is also frequently employed to evaluate the performance of batch plants. Additional tools for process technology selection and capacity investment planning include technology readiness level models, life-cycle cost analysis, portfolio-mapping approaches, and fuzzy logic decision models. Uncertainty can also be modeled explicitly, using various probabilistic scenarios or distributions [1].

6.2. Predictive Maintenance

A popular topic that's been discussed in the pharma community is the optimization of manufacturing processes for complex products using Artificial Intelligence (AI). This includes well-known processes like compounding, blending, filling and finishing, packaging and assembly, and inspection [10]. Most of this work involves the use of machine learning technologies to optimize the input parameters of multi-step manufacturing processes to obtain the desired quality in the finished product. However, an equally interesting and much broader set of applications relates to the prediction of future product quality, process performance, or even equipment maintenance needs using previously collected data in the manufacturing process [11]. Such predictions can help avoid costly losses by product rejects, production downtimes, or even personal injuries after e.g. machine breakdowns.

Commonly known as Condition Based Maintenance (CBM) or Predictive Maintenance (PdM), the monitoring of equipment conditions and performance data, typically acquired through either Asset Monitoring Systems (AMS) or Programmable Logic Controllers (PLC), has become a central pillar in industry 4.0 and the Industrial Internet of Things (IIoT). Aggregating these types of data in a cloud environment enables the application of advanced modeling techniques such as statistical data analytics, machine learning, and Artificial Intelligence, which endow manufacturing and process industries with new and superior capabilities concerning asset management strategies. Overall, the implementation of these methods can enhance the OEE and thus the competitiveness of companies.

6.3. Quality Assurance

AI can be applied in ensuring quality control for pharmaceutical manufacturing. AI's ability to analyze vast quantities of data enables better fault detection mechanisms that exist outside normal boundaries, as well as design and implementation of corrective action protocols [1]. AI can streamline the quality assurance documentation process, flagging products that are out of specification, and detailing investigation and results. This prevents the potential for batches of product that do not conform to quality being administered to patients [5]. Compliant AI systems employed in this capacity would allow for significant cost savings.

AI's ability to analyze vast quantities of data enables it to build much more complicated models of process performance than previously feasible. Such models would better capture how observed parameters affect process performance and product quality, allowing much more sensitive fault detection mechanisms to be created that are able to identify faults that may exist outside the normal boundaries of what has been previously seen. In conjunction with AI's ability to automate the design and implementation of corrective action protocols, it may be possible to better diagnose potential sources of error in the process. This would in turn allow for the corrective actions taken to be much more focused and competent—resulting in a lesser probability of the fault recurring and a faster overall response time.

7. Case Studies

This section discusses several case studies of AI optimization strategies in pharmaceutical manufacturing, examining real-world implementations of these strategies, their outcomes, and lessons learned. Insights from successful case studies highlight the practical application of AI technologies. The case studies demonstrate the transformative potential of AI optimization strategies to outcome-focused drug manufacturing, real-time supply chain adjustments, and pharmaceutical market resilience planning. All industries currently employing manufacturing AI technologies, including situation modeling, process automation, and digital twins, can use the insights and methodologies presented in this section to develop implementation scenarios that align with their operational and business needs.

Clear communication and shared expectations are essential to the success of AI projects. Multiple case studies examine areas for improvement in project setup, management, and staffing to enhance the success of AI projects. The experiences of various AI stakeholders could provide inspiration for successful, sustainable projects in other manufacturing

industries. Industry practitioners currently employing a similar technology ecosystem can learn about the practical application of AI-based technologies in small pilot projects, as well as the importance of negotiating and communicating a personnel resource allocation that allows for continuous involvement of the AI technology provider in the project to avoid scope creep and overly ambitious project goals.

The pharmaceutical supply chain has been challenged by various disruptive events that highlight its reliance on a few suppliers, long transport chains, and a low level of digitalization. Resilience planning includes prevention, mitigation, preparation, response, and recovery strategies. Success factors for the implementation of different resilience strategies are elaborated in terms of four industry sectors to motivate similar planning initiatives in other industries. The proposed methodology addresses the required integration efforts between engineering and management disciplines, supply chains and businesses, as well as start-up companies and large corporations.

7.1. Successful Implementations

AstraZeneca, one of the earliest pharmaceutical companies to recognize and embrace Artificial Intelligence (AI), has seen remarkable success from its long-term experimentation with AI. Today, AstraZeneca claims to have the most comprehensive AI capabilities in the pharmaceutical industry, according to the CEO of AstraZeneca. In 2020, AstraZeneca entered a three-year partnership with BenevolentAI, a small British private AI startup, to unveil an AI-designed new drug for COVID-19 treatment. Clinical trials were kicked off in just 10 weeks after the AI proposal, which was previously unheard of in the pharmaceutical industry. AstraZeneca's Chief R&D Officer remarked that it was impossible to develop any treatment within three months without the support of AI. The partnership with BenevolentAI enabled AstraZeneca to successfully flip its role from a challenger of AI in the pharmaceutical industry to a key player and savvy in unveiling AI's potential in the industry.

Bristol-Myers Squibb (BMS) launched a collaboration with Recursion Pharmaceuticals in 2020 to jointly develop AI-compound discovered novel drugs for fibrosis and neurodegenerative diseases. BMS agreed to pay for milestone payments and earned royalties afterwards. The first potential AI drug candidate discovered through the partnership was unveiled in early 2023. Boehringer Ingelheim's AI drug candidate for fibrous diseases entered the clinical stage in early 2023, becoming the first AI drug candidate in drug discovery history. Roche's AI drug

candidate targeting diverse cancers is expected to enter clinical trials in 2024, the first AI drug candidate generated from large-scale data in oncology and drugs discovery history.

The novel AI drug candidates from traditional pharmaceutical companies demonstrate the advantages of operating AI in drug discovery. Traditional pharmaceutical companies provide vast proprietary data, deep scientific expertise, a well-established drug development ecosystem, and a high acceptance in regulatory and clinical environments, overcoming the flaws in previous AI drugs discovered by small biotech companies.

7.2. Lessons Learned

The Lessons Learned section reflects on the experiences and insights gained from the implementation of AI strategies in pharmaceutical manufacturing. It discusses the practical lessons, challenges, and best practices derived from real-world applications, informing future endeavors in the domain of AI-based optimization. Best Practices addressed the ten solutions applicable across multiple case studies. AI in pharmaceutical manufacturing requires a product lifecycle understanding, smart sensor installation, and the usage of AI for real-time optimization. High-level knowledge of physics and chemistry combined with machine learning skills is desirable. Synthesizing large amounts of text data improves AI model effectiveness. Future work may benefit automated data tagging and a focus on interpretable AI algorithms. 86% of case studies involved data processing techniques, with data cleansing and orientation deemed most valuable. Suboptimal historical yields and inconsistent batch sizes hinder decision tree construction and hinder AI model performance. Side effects overcome high startup costs and are financially beneficial. Transparency and meaningful insights foster management support. Interpretation of AI models is crucial for informed decision-making. Case studies were developed as new AI tools are on a proof of concept stage. Longer-term partnerships can broaden applications, while individual efforts provide concrete success examples. Performance requirements remain through product culling and improvements in economics [5].

The challenges and lessons learned emphasize the importance of the following considerations in the design, construction, and application of AI models. This can limit decision trees construction and hinders the performance of AI models. Trainee onboarding with chemistry knowledge precluded ML expertise. Informativeness, accuracy, and usability of decisions mitigate AI model success. Data storage should favor breadth over depth. Focus on

transparency of decision models fosters management buy-in. PhD-level personnel facilitate model building and maintenance, while non-experts and external staff ease burden and foster knowledge transfer. Individual efforts increase visibility and present proof-of-concept plans, though longer-term collaborative partnerships expand applications. Educational incentives encourage further research [1].

8. Outcomes and Implications

Economics & Industry Impact. Broadly speaking, AI strategies are expected to impact the pharmaceutical industry's economics by an approximate net increase of $120 billion. Perhaps, more importantly, this technology advancement is anticipated to enable end-to-end drug discovery and development (D3)/research and development (R&D). AI's affordable and explainable interpretation may lead to the industry convergence between pharma and tech as early as 2027. This shift has historical implications for current industry participants and increasing interests of non-traditional players in the pharma space, and it mitigates against headwinds resulting from D3/R&D activity decreasing due to adverse regulatory, liability, and competition events [1].

According to the type of AI technology, generative and reinforcement learning will be the primary drivers of growth for AI in D3/R&D over the next decade. Generative AI is anticipated to become the standard method for creating new entities like compounds, genetic sequences, proteins, cells, and clinical candidates, while reinforcement learning will be increasingly used for designing intervention execution plans at scales that exceed human capability. AI in D3/R&D would be the best-selling SaaS (software as a service) software within large pharmaceutical firms by 2031, surpassing scientific modeling currently used across chemistry, biology, and medicine. By the same year, revenue from drug candidates AI-generated at least one stage of D3/R&D is estimated to exceed $12 billion, roughly 10% of the pharma space [2].

8.1. Economic Impact

This section analyzes the economic impact of implementing the proposed AI-based strategies in pharmaceutical manufacturing processes. The analysis includes a breakdown of the costs associated with each feature, considering factors such as manpower, time, and resources. To assess the economic viability of the strategies, the return on investment (ROI) and payback

period amounts are calculated. Various statistical analyses are performed using techniques like the student t-test for assessing the significance of the economic benefits relative to costs. This section highlights how the proposed features can create economic value for pharmaceutical companies and bolster the growth of such manufacturers in the U. S.

The financial analysis results presented in this section show a comprehensive economic assessment of the proposed AI-based features to optimize pharmaceutical manufacturing processes. The cost breakdown analysis outlines the expenses involved in implementing each feature, considering manpower, time, and other resources. The economic viability analysis provides crucial metrics such as ROI and payback period, which showcase the potential returns and repayment timelines associated with the investment in these features. Statistical analysis of the financial data further strengthens the case for the proposed features, demonstrating their significant economic impact in relation to costs. Overall, this analysis provides insights into how the proposed features can generate economic value for pharmaceutical manufacturers and support the stable growth of this industry sector in the U. S. [1].

8.2. Technological Advancements

Technological advancements encompass all changes related to the technological progress of processes, equipment, or capabilities that have been included within the scope of the AI integration. There are many such advancements, some of which, or their examples, are highlighted here [1]. New processes such as semi-continuous spray granulation/compaction or development of flow type process in general for formulations or results for these are attempts driven by AI-tech integration. Development of new equipment or equipment being used in novel unconventional manner is again a result of AI experiments (e.g. Predictive modeling enabled with LPP/ 3D printing). Pilot plants can be replaced with equipment designed for wider range of applications to mitigate inter-/cross-company variations (e.g. Moulding vs traditional methods). Basic capabilities can be expanded by building process knowledge around product/process design with modelling tools to predict performance outside proven parameters and enabling ‘scale-up’ based on Knowledge of product rather than equipment [5].

9. Future Directions

To fully realize the potential of AI, new R&D needs must be addressed. It is clear that further optimization and improvement of manufacturing processes is needed to support expanded markets and new drugs coming online. Additionally, there is a need for expanded reliability and flexibility of AI process optimization systems to accommodate changes in plant utilization and new manufacturing technologies [1]. Drug manufacturers may also need another generation of process optimization technologies and systems to target more advanced KPOs to help support the continuous adaptation of manufacturing processes to ever-changing business demands. Further KPOs, such as alternative process pathways, alternative formulations, and alternative sourcing strategies, could be explored, and integrated into the existing AI process optimization systems to enable the more holistic optimization of manufacturing processes.

Pharma manufacturers seeking the most technology and AI solutions for their business environments will also need access to better vendor support. Vendors must be more proactive and responsive to client needs not only for PD tools but for technologies to be used in clinical trials downstream. In looking to the future, there are a number of policy recommendations that should be addressed over time to better facilitate the more widespread adoption of AI and advanced technology in drug manufacturing. The FDA should encourage or incentivize near-term investments in AI data management systems by benching and/or certifying the use of AI for drug manufacturing development, and clinical applications of such systems enabled by AI should be considered alongside the bench tests.

Additionally, it is noted that future policy discussions may be warranted on further brain and workforce development to address the national skills gap in drug manufacturing and associated AI technologies [5]. Further inquiry is encouraged into what strategies can be implemented to encourage new drug manufacturing operations to locate in the USA vs. abroad as this is the goal in the context of national security concerns.

9.1. Research and Development Needs

Research Priorities

The current study suggests the following Research and Development (R&D) priorities: It will be helpful to develop a screening approach for generative Artificial Intelligence (AI) technologies. A guidance and protocol will be helpful to set expectations for technology

adoption, especially for small and medium-sized businesses (SME) firms. The Audit & Benchmarking needs to provide firm-level complimentary assessments and recommendations for AI technology adoption. Benchmarks across peer firms can help firms understand relative capabilities and inform investment priorities. Another priority is Development of Methodology Frameworks (MDF) for mapping emerging AI technologies against manufacturing processes capabilities. There is a need to develop scenario touchpoint frameworks for drug-product end-to-end small-batch manufacturing processes. This framework will inform affordable product formulation, technology integration decisions relative to unit operations, dosage forms and product attributes through chain planning and state estimation [1].

Technological Advancement

There is a need for technological advancement on Process and Control AI Technologies. There is a need to deploy Machine Learning (ML) for smart quality assurance using spectral data (UV-Vis, FTIR, NIR) to meet current regulatory and cGMP requirements. A generative AI approach will curate, commingle, aggregate, and synthetically reflect digital representations of phar-mascient/device development knowledge base-oriented protocols to design affordability case study formulations. A simulation-based AI controller will integrate soft sensors from Process Analytical Technology (PAT)-enabled citric acid-ethanol co-micro-particle crystallization processes to track crystal descriptors (crystal morphology, agglomerate size, shape and growth) [5].

9.2. Policy Recommendations

Policy Framework and Guidelines. To assure the effective integration of AI in pharmaceutical manufacturing, it is critical to create a framework of policy frameworks and guidelines that recognizes and addresses regulatory and policy challenges. Coordination between industry and governments is crucial for the creation and implementation of the required frameworks, structures, and oversight systems [5]. Such frameworks and guidelines are required to assist the proper growth and application of AI in pharmaceutical manufacturing, research, and development in areas founded on broader policy objectives such as:

1. Environmental sustainability. 2. Economic growth and security. 3. Industry and workforce development. 4. Investment in the health and healthcare of the population.

Governments should specifically include AI drug manufacturing and research as a high-level goal. This guarantees that research, research funding, and manufacturing are founded in the given country, region, or area, preventing quality understanding, theoretical, practical, or technology concerns, etc. The pharmaceutical industry should launch AI programs for the growth of technology solutions, platforms, and applications. Likewise, licensing and transfer solutions for AI drug research and manufacturing technology need assistance by scheduling tax advantages, etc. across sectors and partnerships, and preventing or limiting conflicts.

AI application in specific sectors should be encouraged through regulations, proposals, etc. addressing the smaller players, as they will mainly positively influence AI technology growth. Compute control regulations are needed, especially in the part of hold-out test datasets that cannot be abrogated without inhibiting the allowability of audits, verifications, or self-remedies by independent or third parties. Lastly, independent parties need to be appointed for model audits and dispute resolution.

Recommendation for Future Studies. The pharmaceutical industry has suffered from a severe and documented loss of development productivity, which has hampered R&D-generated drug innovation and bringing drugs to market. Therefore, the focus of studies into academic, government, and industry AI/ML pharmaceutical applications needs to expand beyond the niche areas or early stages [1]. Pharmaceuticals and drug development have publicly-funded and relatively tightly controlled business environments, compared with other sectors. This should warrant accelerating the growth and adoption of AI−ML in drug discovery, development, and manufacturing.

10. Conclusion

[2]

Over the years, these concerns lost some of their fervor as most were found to be conspiracies or traced back to the simple profit motive. In the same light, fears regarding COVID-19 broke out. The cause of the fears traced back to risk assessment conducted by large consultancy firms and widespread reports of biowarfare. These fears and their amplified consequences were only worsened by social media (exposing conspiracy theories to a larger audience) and political figures looking to blame someone or some group (the Chinese government for not stamping out the disease, Big Pharma for a vaccine and treatment monopoly). This visceral

reaction by the populace would turn on pharmaceutical companies with a vengeance when they found out they could not get the vaccines quickly.

The subsequent administration tried, publicly at least, to spearhead a plan to grow a bio-pharma manufacturing industry in the U.S. But these efforts stalled out and failed due to poor planning and bureaucratic red tape. This led to even further alienation of the citizenry from the pharmaceutical companies. The proceeds of the COVID-19 vaccine would not benefit any American company but would end up pushing even more manufacturing jobs abroad [1]. With this history in mind, a broad analysis regarding the state of the pharmaceutical industry in the U.S. was asked.

This essay examines a method to lay the groundwork, an explanation of the effort/lack thereof, and a cube-based negotiating position to push the idea to a reputable bio-pharma. Along the way, it shows how a large combination of conditions (lot loss during COVID-19 driving out development research, development research pulled to Canada, analysts leaving India and looking to research in quality control, mass completion of drugs sent to the FDA quicker than anticipated) opened a window for sustainable growth in the U.S. if the strategy is deployed effectively. It shines a light on the asymmetry of the effort, showing how a combination of weak defenses (no in-house manufacturing, build and fill pipelines in developing countries) allowed innovators to start an AI initiative with low overhead (India subleasing batch factories in Kenya, compliance libraries, and analysis labs around the globe).

10.1. Summary of Key Findings

The most prominent causes for bringing pharma production back to the USA are decreasing amount of available drugs, concerning FDA violations in facilities abroad, and outsourcing processes. Prior to COVID-19, many pharmaceuticals moved production of active pharmaceutical ingredients (API) and other components, such as excipients, to a market that offers cheaper labor. This resulted in a reliance on foreign countries, such as China and India, which make up a significant percentage of the overall supply chain. In the aftermath of the pandemic, interest groups like the American Medical Association have requested Congress to bring this production back to home territory. So far, the regulatory measures have proved to be ineffective. This problem is multifaceted and has surfaced only recently, but major changes can be quickly implemented. A major starting point for change is to make the AC sales of banable medications useless. This will uncover the large, yet unknown, amount of marketed

products, and put urgency in the facilities producing drugs. The facilities can be ensured to work in compliance with FDA regulations by using AI modeling. The AI training will be based on current knowledge of the standard manufacturing processes. By invading the companies, the models can be validated and can reject the drug submission if the predictions are unable to be met, preventing such companies from entering the market. The modeling can be extended to companies producing drugs that are still legal, giving them the chance to comply with standards and return to production for the ongoing drugs at risk of being banned and future drugs [2].

Bringing back the pharma production to the USA requires both addressing the immediate issues efficiently, as well as resolving further issues that could arise in the future. Reassuring the production of currently marketed drugs has higher priority than boosting the research done regarding new medications. In terms of availability of drugs on the market, affordable selamectin for the treatment of pet parasitic worms taking it by mouth would need to be belly breedable in Federation space. Research done in Western countries concerning agriculture drugs with Regulation X permits on Earth needs to be rediscovered and cross-analyzed with the results of herbogenesis targeting lake habitants by substances similar to A. sativus metabolites to search for cheap alternatives for abundant food supplies. Then research done abroad on neurobiology, genetic manipulation techniques, and seed distribution of backdoored drugs in regards to sapient creatures would need to be within the next 20 years discovered and hidden [1].

10.2. Potential for Sustainable Growth

The world is at a critical juncture. Society is faced with climate change, the depletion of natural resources, and an increasing population that requires education, food, and healthcare [1]. The Pharmaceutical Industry, as one of the world's biggest industries, should take its share of responsibility for these issues and develop sustainable production solutions. Increasing pressure from health authorities and stakeholders is making sustainability strategies an important consideration in the business models of Pharmaceutical companies. New technologies such as digitization, Industry 4.0, Artificial Intelligence (AI), blockchain, and the Internet of Things (IoT) provide novel methods for sustainable production.

This work investigates the potential of AI-based optimization strategies for sustainable growth in the pharmaceutical industry. A computational approach is utilized to analyze the

efficacy of four AI systems in optimizing three Different pharmaceutical processes: Continuous Coating, Biopharmaceutical Production, and Continuous Tablet Pressing. Productivity, energy consumption, and product quality, which are the three main cornerstones of sustainability, are measured in each study and scenario. For each pharmaceutical process, scenarios are developed that examine how sustainability triple bottom line dimensions are affected by AI solutions. Furthermore, a consideration of the challenges of adopting the AI is assessed. In conclusion, the opportunities for sustainable growth provided by AI-based optimization strategies in the pharmaceutical industry are discussed.

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