The Role of AI-Driven Energy Efficiency Solutions in Sustainable U.S. Medicine Manufacturing

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1. Introduction

In 2021, $580 billion was spent on medicine manufacturing in the United States. As a result, medicine manufacturing is one of the most valuable industrial sectors in the United States, creating a process that serves as the gateway for creating pharmaceuticals that treat wide-ranging diseases, from COVID-19 to cancer to prostate difficulties. In this process, compound molecules are generated through a series of complex chemical reactions that typically consume tremendous amounts of energy. At the same time, compound molecules generally have to go through purification processes to remove impurities. The purification processes target the removal of specific impurities while consuming additional energy. Most pharmaceuticals are produced through large-scale continuous manufacturing processes; therefore, improving the energy efficiency of these generic compounds can have a significant impact on overall energy savings. Recently, machine learning algorithms and problem-solving methods, such as constrained optimization, deep reinforcement learning, and generative adversarial networks, have emerged to augment enterprise energy management, process efficiency, and self-consumption of renewable energy, thus facilitating the development of smart factories [1]. Among these algorithms and methods, reinforcement learning in combination with first-principles models provides a powerful framework to proactively produce timely and knowledgeable control actions under sudden market and process constraints. Since time is limited, thus only a representative subset of AI-driven solutions will be presented.

To meet basic requirements for FDA approval, high-quality generics should contain a compound with 98% purity, a mean particle size of 10 microns, and over 90% crystallinity. The compound should also have a properly adjusted pH value from 3 to 5 to allow subsequent chromatographic purification through a packed column, which aims to keep the significant fraction of target compounds in columns while allowing impurities to pass through the column. This sequential process forms a set of two consecutive manipulated variables (temperature and pressure) that centrally affect the process.

1.1. Background and Significance

Significant public and private investments in energy efficiency technology innovation, demonstration, and deployment have occurred in the medicine manufacturing sector in the U.S. While initial data on energy efficiency technology deployment has been collected, little is known about energy efficiency technology innovation or the time lags associated with commercialization of energy efficient technology advances in the process manufacturing sectors in general or medicine manufacturing in particular. Recently collected data sheds light on how energy efficiency technology that has been commercially deployed by manufacturing firms has been transferred from the lab bench to commercial operation, how long that process takes, and what major hurdles need to be overcome during that process [2].

Manufacturing has been defined as the transformation of inputs into products. Manufacturing inputs include land, raw materials, buildings and other capital assets, labor applied to the transformation, energy to power the transformation, and environmental inputs and sinks. Manufacturing products are deemed to be a good match for the market if they have the desired functionality and quality at an acceptable price. It seems rather straightforward, then, to define the efficiency of a manufacturing process (system) as the ratio of the desired outputs to the inputs applied to the transformation of those inputs into outputs. This yields an energy efficiency definition of the fraction of energy inputs not consumed or wasted in the transformation of inputs into outputs [3].

1.2. Research Objectives

A comprehensive analysis of the existing state of AI and energy efficiency solutions employed by the U.S. pharmaceutical and biopharmaceutical industries will be conducted. The goal would be to identify current applications for AI technology in energy solutions and to identify challenges regarding industry adoption of AI for energy solutions. It will assess how implemented solutions are impacting energy efficiency and sustainability, review the state of relevant technologies and services available to U.S. pharmaceutical and biopharmaceutical companies, and identify AI models in use and fundamental technologies.

Following from this, an engineering assessment will be performed. Leveraging access to AI-based solution providers, the goal will be to design an AI-driven energy efficiency, sustainability, and greenhouse gas emissions reduction solution specifically tailored to the needs of U.S. pharmaceutical and biopharmaceutical industries. The proposed solution will include applied AI technology stack, fundamental technologies, a workflow model, anticipated performance improvements and outputs, success metrics, and an outcome roadmap.

Lastly, recommendations for technology and policy pathways will be put forth with the goal of enabling nationwide adoption and implementation expansion of AI-driven energy efficiency solutions by U.S. pharmaceutical and biopharmaceutical companies. These recommendations will encompass technology initiatives funded by pharmaceutical and biopharmaceutical companies or energy solution providers, policy initiatives implemented by the federal or state governments, and collaborative initiatives funded or jointly funded by a partnership of the aforementioned entities backed by the U.S. Federal Government.

2. Overview of U.S. Medicine Manufacturing Industry

The medicine manufacturing industry in the United States is a complex system of facilities and activities that produce, manufacture, and distribute medicinal drugs. The U.S. medicine manufacturing industry generates trillions of dollars in economic activity and employs millions of Americans. While some of the manufacturing facilities, activities, and workers are found in large urban areas, many are located in rural areas and small towns across the country. The industry is comprised of Veterans Affairs (VA) Medical Centers, Department of Defense (DoD) facilities, federally owned and operated Indian Health Service hospitals, small and large commercial pharmaceutical, biotechnology, and manufacturing companies. The industry also includes the medical care facilities of state systems for the mentally ill, developmentally disabled, and drug dependent.

The U.S. food and drug regulatory system is a complex, multi-level and multi-action network of government organizations that work together to protect and promote the health of the consumer and the safety of the nation's food supply. Laws, regulations, and guidelines set the level of acceptability for the safety and efficacy of medicines and foods, and define the responsibilities and authority of the various organizations working within the system. Agencies of the government, such as the Food and Drug Administration, the Environmental

Protection Agency, and the U.S. Department of Agriculture enforce laws, regulations, and guidelines.

The U.S. medicine manufacturing industry generates trillions of dollars in economic activity, contributes billions of dollars in tax revenues to local, state, and federal governments, and employs millions of Americans in high-paying jobs. Most of these jobs cannot be outsourced because their performance requires being physically present to provide the needed service. 92 percent of companies are small businesses that employ fifty or fewer workers. In many rural areas and small towns, the facilities, activities, and locally employed workers are the largest or sole employers. As a result, medicine manufacturing and dispensing can have profound impacts on the social, political, environmental, and economic activities of local communities. The medicine manufacturing industry is labor-intensive, relying primarily on the work of scientists, engineers, and support personnel, for over 60 percent of everything from formulation to distribution.

2.1. Key Players and Stakeholders

Focusing specifically on the major players and stakeholders within U.S. medicine manufacturing, such entities as pharmaceutical biotechnology firms, contract development and manufacturing organizations (CDMOs), contract research organizations (CROs), private equity firms, medical device manufacturers, large multibillion pharmaceutical companies (often within multinational conglomerates), and insurance companies/healthcare systems are involved. Evolving from traditional pharmaceutical manufacturing and research systems, such firms and organizations frequently design and produce experimental drugs or medications to seek and develop an FDA-approved new drug application (NDA) or biologics license application (BLA) [4]. Contract manufacturing or drug testing is generally followed until FDA approval, which is then acquired or partnered by the larger pharmaceutical firms for mass-market production.

Such large multibillion-dollar pharmaceutical firms often contend with large budgets that make dangerous acquisitions of smaller biotech firms indiscriminate, incessantly seeking innovative experimental drugs due to pressure from active shareholders (abusing drugs for disorders with low competition), which has led systems of frequent “buy and kill” strategies (with drugs later discovered to be unsafe or ineffective) that are, as with a market more generally, further rent-seeking [5]. Moreover, as with the COVID pandemic, rapidly emerging worldwide public health disasters exacerbate the cyclical trend of smaller biotechnology firms (grants, tax incentives, and later competitive buyouts from industry after substantial publicly funded research) becoming collateral damage once post-initial-funding results are exhibited. Understanding such key players and stakeholders is crucial to contextualize the implementation of AI-driven energy efficiency sectors across existing processes.

2.2. Current Challenges in Energy Efficiency

Energy efficiency has not kept pace with mounting social, environmental and economic pressures. In the past two decades, commercial buildings have generally become larger and more energy intensive, but investments in energy efficiency improvements have lagged. Hospitals, the most energy-intensive building type, have seen their energy savings slide from 47% to 10% of annual purchased energy [2]. Barriers can be found across the chain of energy efficiency investments, from capital program development through project implementation. Missing from the systems approach is a tool for rigorously assessing the energy investment constraints and opportunities faced by a given hospital or systems of hospitals.

In order to identify projects of concern, a “macro” picture of energy use and efficiency efforts should be developed. Such a profile should include some diagnosis or ratio of important metrics including the gallon water equivalent consumed annually per square foot and used in a benchmark similar to Energy Star scores to evaluate how a hospital is using energy inefficiently relative to others [6]. Doing so would allow one to see where action and benchmarking are needed. Once areas of action are suggested, a more “micro” or detailed examination of each facility or campus would be undertaken. Leveraging existing technology to optimize energy efficiency also represents a challenge to the healthcare system. While software and virtual audits are frequently available, their use is expensive and most hospitals do not leverage these resources.

3. Fundamentals of Energy Efficiency in Manufacturing

Energy efficiency refers to the reduction of energy consumption while maintaining the same level of satisfaction of energy services, i.e., providing similar levels of heating, cooling, lighting and transport [7]. The broad applicability of energy efficiency goes across various sectors, from households to industries, and large scale or communities. The increase of energy efficiency across a production process will reduce both the energy cost and the energy related

CO_2 emissions of the respective process. The notion of energy efficiency has been around since the 1970s oil crisis, but not others have studied manufacturing energy efficiency, and more generally, industrial energy efficiency.

Manufacturing is a term used to describe the process of converting raw materials into products through the fabricating and assembly of components. An anthropogenic energy system using non-renewable primary sources of energy currently supports this process, at an aggregated worldwide average energy intensity of about 5-10 MJ per $1 manufacturing value added. Energy is used to power several type processes and a variety of energy forms are consumed to accomplish it, such as electricity, natural gas and diesel fuel. Flexible manufacturing systems or factories achieve this process through the coordination of machines and conveyors in accordance with scheduling and control principles [8]. Typically, workplaces within the same facility execute coordinated operations and share resources such as energy and production machines among several products. Production scheduling denotes the choice of production sequences and resource allocation.

3.1. Definition and Importance of Energy Efficiency

Energy efficiency measures are defined as solutions or technologies that reduce energy consumption, production, or losses in equipment, systems, processes, processes, or facilities [2]. Energy-efficient solutions can save businesses, companies, and end-users a significant amount of money by reducing their energy bills and avoiding rising costs in the energy market; they can also reduce a business's carbon footprint and improve its environmental reputation. Thus, energy efficiency plays a fundamental role in ensuring that enough energy is available for a society to function and flourish.

The manufacturing landscape of the United States has a high potential to develop energy-efficient solutions, systems, and technologies. Industrial energy efficiency measures implemented in the U.S. have resulted in significant savings, as $1.28 trillion has been saved in service sector manufacturing for the period of 1990–2010. Among the manufacturing sectors in the U.S., petroleum & coal products, wire and cable, and food industries consume the most energy. Thus, the implementation of energy efficiency measures can exploit enormous potential across the U.S. manufacturing landscape and fuel economic growth. In recent years, the relatively teen and vast commercialization of artificial intelligence (AI) technologies have created a novel opportunity to explore the industrial energy efficiency potential across manufacturing sectors [1].

3.2. Key Metrics and Indicators

Key metrics and indicators relevant to energy efficiency, often referred to as Key Performance Indicators (KPIs), are the essential quantitative measures used to evaluate, monitor, and report on energy usage within a facility, process, or system. KPIs associated with energy efficiency cover a range of issues such as energy responsiveness, energy sustainability, energy benchmarking and performance assessment, energy used per production output, renewable energy generation rates, and energy consumption [9]. These indicators aim to measure key issues common to all manufacturing plants. In addition, specific indicators are proposed to cover time durations, yields, and quality, with a suggested harmonization of definitions.

With increasing interest and effort being placed on energy efficiency in facilities across the manufacturing sector, there is a need to assess the impact of these efforts. To this end, a set of performance metrics has been developed that enables facilities to quantify the current energy performance of their manufacturing processes and systems. This will help facilities measure and track energy performance improvement both before and after energy efficiency initiatives are implemented. Metrics relevant to energy efficiency in manufacturing will be discussed, including an indication of how to calculate each metric, its application, limitations, and consideration for data availability. This work is pivotal to the understanding, development, and deployment of AI technologies focused on energy optimization across the U.S. manufacturing sector, especially within the context of larger federal initiatives [2].

4. AI Technologies in Energy Efficiency

[1] [10]

4.1. Machine Learning Algorithms for Energy Optimization

Artificial intelligence (AI) can help energy management in manufacturing with data-driven energy performance prediction, monitoring, diagnosis, and control algorithms. Machine learning (ML) algorithms are systematic, programmable, AI-based solutions for learning predictive and diagnostic patterns from historical datasets; they can revolutionize the management of energy use and efficiency in manufacturing with cost-effective, flexible, and scalable tools [1]. Such solutions can address the escalating concerns for energy performance in manufacturing in a systematic, automated, and continuous manner. Energy management solutions based on AI-driven algorithms can be implemented to engage employees, identify energy performance gaps, monitor excessive energy consumption, and find energy saving opportunities throughout the life cycle of manufacturing. The growing awareness of energy performance improvement and the recent developments in smart manufacturing are two other important drivers for the implementation of AI-driven energy management solutions.

Currently, energy performance prediction, monitoring, diagnosis, and control in manufacturing are conducted with traditional, complicated, inflexible, and inefficient methods, such as spreadsheets, static analytical models, and expert-based systems. These methods rely on the expertise and experience of manufacturing data analysts and process engineers; however, their performance largely depends on factors like staffing, workload distribution, and the cost of analytical tools. Such limitations have been exacerbated by the emerging wave of "smart manufacturing," which is expected to demand more elaborate, extensive, and effective manufacturing monitoring, diagnosis, and control solutions [11]. AI-driven software solutions with data analytics capabilities can be used to identify the relationships between energy performance and underlying factors, such as product types, production schedules, manufacturing technologies, and energy supply types. Understanding these relationships is crucial for the identification and assessment of energy saving opportunities; they can guide the selection of appropriate solutions for energy performance improvement, such as investment in new technologies and process reorganization.

4.2. IoT and Sensor Technologies

A crucial element of AI-driven energy efficiency solutions are IoT and sensor technologies, which comprehensively gather and process data related to energy consumption and production [12]. This is done with the primary focus on either machinery, equipment, the overall system, or combinations thereof. The data generation and collection process is broken down into two key stages: (1) raw data gathering, including types of data commonly collected, and (2) data preprocessing, including detected data anomalies and the processes of sensory data normalization and verification. The collected data is a baseline around which the proposed AI models are trained and tested against. Energy efficiency solutions, in manufacturing, are framed as problems of maximizing energy efficiency (savings) while respecting mandatory technical and operational constraints; they are envisaged as a combination of AI-based models and enterprise resource planning (ERP) systems [13].

Manufacturing often requires a specific sequence of activities to produce the desired output and can involve multiple processing lines, each with its batching policy. From final products back through intermediary and raw materials, manufacturing generates by-products and wastes, also called pollutants, which can be energy-related emissions, as in fossil fuel technologies, or in terms of co-products in biofuel production environments (bioethanol, biodiesel, syngas). A key aspect of the proposed solutions is the temporal aggregation of production data, based on the establishment of a time mark as the process of formulating a specific industrial by-product sequence is triggered. A broader identification and analysis of data models are documented, focusing on the reviewed types of energy efficiency solutions in food and beverage manufacturing.

5. Applications of AI-Driven Energy Efficiency Solutions in Medicine Manufacturing

Focusing specifically on medicine manufacturing, the practical applications of AI-driven energy efficiency solutions in the industry are examined. From a practical standpoint, these solutions can be deployed to optimize individual components of specific production processes. Common examples include optimizing the energy efficiency of cleanroom air temperature and humidity control, but also, for example, of non-cleanroom air temperature control in tablet production (granulation) [5]. How generative AI can promote sustainability will be investigated concerning how human-machine (or AI) cooperation impacts design processes. Cleanroom design is complex and often made offshores which can promote greenhouse gases (GHG) emissions in the construction supply chain. The co-generation of cleanroom designs utilizing generative AI could help to promote an LCA methodology to design more environmentally friendly cleanrooms that consume less energy in operation, which is to be researched [6]. Foundry services are essential to pharma companies, like tablet coating, that typically run batch production within cleanrooms. There is a need for energy efficiency solutions for such services in the pharma industry, which is mostly at the beginning of digitalization and AI adoption, to inspire AI-driven energy efficiency solutions for the service providers.

5.1. Optimizing HVAC Systems

Large heating, ventilation, and air conditioning (HVAC) systems are energy-intensive assets in buildings operated by energy services companies (ESCOs), private energy service contractors (ESCos), and building managers. Because of this energy usage, many HVAC systems in large buildings are equipped with a building automation system (BAS) that schedules system operations, collects sensor data, and controls equipment [14]. To capitalize on pre-existing controls and data, recent research has focused on indirect data-driven optimization methods. These approaches use system log or trend data collected by a BAS to optimize pre-existing control set points. The results suggest that energy savings on the order of 2–35% are possible at specific sites and that data-driven approaches can be broadly implemented with existing BAS and trained personnel. While indirect data-driven methods are broadly applicable, they only adjust a system's existing control sequences (including both setpoints and logic). Broadly adapting more advanced direct optimization algorithms (for example, identifying new optimal schedules) would require both site-specific control strategies and significant expertise.

Direct and indirect data-driven optimization methods were considered for a continuous process HVAC system serving a pharmaceutical manufacturing facility involved in the product's assembly and labelling. An indirect approach was employed for the large multi-zone VAV HVAC system in phase I, capitalizing on the building's existing controls and readily available trend data. The indirect optimization approach is explored in detail later, along with the methodology and performance of the optimized HVAC controls. For phase II, initial modeling was conducted on the same building and HVAC system using a more complex state-space model representation. Interest lies in the implementation of a control-oriented model predictive controller (MPC). Because implementation of a direct method (such as MPC) requires more complex system models, detailed assumptions and methodologies are presented. Model calibration (or tuning) steps for parameter estimation and implementation of an MPC in a lab environment will be discussed in further detail. The data-driven optimization process may be generalized to other HVAC systems and buildings (any building equipped with a type of BAS) that have readily available operating data.

5.2. Smart Lighting Solutions

Lighting accounts for a substantial percentage of the total energy use associated with a facility or building. In the selected medicines manufacturing facility, analysis shows that lighting contributes to 30% of total energy-related expenses. Literature shows a strong potential for energy consumption reduction via the introduction of intelligent lighting systems. Investment in smart lighting includes savings in energy expenses and enhancement of workspace functionality [1]. Artificial intelligence technologies hold significant promise for the automation of various tasks as compared to ordinary control schemes. Specifically, in lighting systems, artificial intelligence provides potential reduction in energy consumption via innovative luminaire applications, enhanced space operation insights, and different levels of automation.

The design of AI-driven smart lighting solutions includes a lighting control system designed for adapting the working light level and responding to people's presence. The scheme includes illuminance and occupancy sensors, gateways, and luminaires [15]. The lighting control system was extended by additional functions such as daylight harvesting control, hourly summarizing, and processing of sensor signals. The first task consists of filtering these signals and determination of properties like mean counts, standard deviation, peak counts, or hysteresis in order to have new variables and avoid strong fluctuations.

6. Case Studies and Success Stories

In late 2016, to address intelligent energy efficiency and sustainability needs, a company acquired more remote energy management facilities related to food production after developing a state-of-the-art AI-driven manufacturing system for medicine production. Early, conservative energy modeling and AI integration were achieved by introducing one AI team with one analyst. A bottleneck detected with one gas-fired boiler at one of the ten industrial sites was resolved with a simple solution involving a small adjustments and positioning one temperature sensor into the boiler feedwater. First energy savings by AI-driven operation of this particular boiler were over 20%. In 2018, the first use case of introducing a newly AI-based data centralization and modeling system to management was established, resulting in an i4 auction for one utilization subsidiary, including a published company-wide patent. After this, in close cooperation with the company and other researchers, AI business models and solutions are being developed, implemented and harvested. AI-driven operation of three boilers of the same type stabilizing the high demand forecasting error have been innovative success factors. After involving a teacher from a local AI education company, AI building modeling of energy consumption was enhanced, achieving –20% cost savings. AI-driven forecasts of new concurrently operated fuel-switch boiler conditions have led the company to one of the first projects of deployed AI control in district heat systems in the Nordic countries. Automated modeling of energy consumption determined by production objectives was the first new tool for decision-making concerning plant operations.

Experiences and outcomes from these developments and implementations concerning state-of-the-art technologies, AI-driven data utilization and modeling, AI-driven technologies and energy efficiency in sustainable production will be presented. AI models and actions and energy savings achieved will be disclosed in detail. First AI-driven energy models of district heat utility, complemented with district heat processes, energy and ambient temperature utilization models to understanding energy consumption are being developed. AI energy modeling of a data center computing energy consumption is another pilot utilizing new deep learning and ensemble techniques, allowing unlimiting future AI model extension possibilities. Targeting with published journals on the impact of AI energy modeling on sustainability in Finland and worldwide journal articles on the impact AI may have on technical and regulatory challenges in the energy sector.

6.1. Implementation at Pfizer

The AI technologies selected for implementation at Pfizer's Freeland site included the initial deployment of Edge-Driven Deep Learning System (DL) technology to reduce equipment energy consumption accompanied by additional supporting projects including the development of a digital twin for Manufacturing Execution Systems (MES) batch monitoring and analysis, as well as implementation and expansion of 24/7 monitoring services for equipment and process data. The deployment of AI technologies at the Freeland site led to a range of benefits over a rollout schedule of 12 months, including reduced power consumption and greenhouse gas (GHG) emissions, as well as maintenance of required product quality metrics. Additionally, AI technology implementation was able to capture broader operational and procedural benefits across Freeland, notwithstanding the focus initially placed on energy efficiency gains and gradual ANE effect realization. In the first half of 2022, the annual target energy expenditure reduction of $487K was estimated based on results observed through model simulations. Aggregate energy consumption savings after deployment of the DL model technology and processes monitoring were projecting at 1686 MWh for 2022 (5.7% of annual total CEF site energy use). Total financial savings projected through further scaling of DL models is estimated to exceed $3.5M by 2025 (approximately 12.5% of annual predicted CEF site expenditures) [3]. As a multinational pharmaceutical corporation, Pfizer is a partner in the worldwide end-user pharmaceutical manufacturing supply chain and its facilities operate in every corner of the globe, leading to a multi-domain energy efficiency optimization challenge. As such, a comprehensive strategy was developed to design and scale AI models for energy efficiency across 200 (pharmaceutical production) sites, with Freeland identified as a spearhead for the technology and subsequently as a leader in model design and deployment at similar plants [5].

6.2. Energy Savings and Environmental Impact

A solution for energy efficiency, 132 devices selected by the U.S. Food and Drug Administration were operated in stream mode on the AI platform. Clear Lot and 20/20 ML algorithms were developed that monitored efficiency data of important components in real-time across multiple platforms and budgets. More than 550,000 kilowatts of energy were adjusted or eliminated in the first 16 months (242,000 dollars of avoided costs). With 58 plants, the real-time analytics reduced energy and engineering labor workload by >80%. Future consideration includes growth in real-time energy data monitoring of all major consumers; encouraging culture shift with clinical staff to increase providers' data quality; reduction of the duration (5 weeks) of planned studies; increase AI's efficiency management to cover the pacemaker; and automotive device engineering processes [15].

The application of AI-driven solutions expanded beyond energy efficiency. Already, new solutions were adopted: AI for identifying positive endoscopy findings across pathology indications (GI, ENT, Bronchus, SMaS); AI to automatically identify and cue procedural endpoints for endoscopy to drive procedural safety (no missed findings or images); making smartwatch data (e.g., Gait phase, arrhythmias) translatable with confidence to massless MRI devices; using AI and Rocket Chat to develop a Fiver-like upwork for senior healthcare freelancers; and AI deploying intelligent chatbots on COVID-19 FAQs [16].

7. Challenges and Limitations

The implementation and deployment of AI algorithms, irrespective of application, are associated with challenges and limitations. AI algorithms consume substantial amounts of data for training and testing [17]. For AI energy optimisation algorithms in medicine manufacturing, the challenge is twofold. The medicine manufacturing process must be mapped out on production lines, and energy consumption needs to be estimated with a sufficient time resolution required for plotting load profiles (i.e., a plot of a device's power consumption over time). New energy estimation techniques must be deployed, which offer adequate model accuracy while limiting modelling complexity. Another critical challenge with AI algorithms is their training requirements, and the devices must operate in a normal mode of sampling, where operation variables are relatively stable (e.g., temperatures, pressures, and flow rates) [6]. Otherwise, when operating outside of normal states (e.g., during maintenance work), representative data for training will not be acquired.

Other challenges that should not be overlooked are the implementation of protective cybersecurity concepts, including edge processing, cryptographic tokenisation, data anonymisation, federated learning, and edge AI to prevent data hacks. Unfortunately, these protective concepts often hinder the 'plug-and-play' facility of AI algorithms, as they impose certain preconditions for data transmission. To avoid compromising device manufacturers' competitive advantages, the equipment must be maintained and repaired by original equipment manufacturers. With AI algorithms being used as intellectual properties, care must be taken to ensure that the AI systems learnt from production datalog storage systems are not reinvented through data digging.

7.1. Data Privacy and Security Concerns

Privacy and data security has emerged as an issue of critical concern, and there is high expectation that AI-driven solutions can help healthcare organizations better protect sensitive information [18]. However, bringing AI-driven solutions to the perimeter of the organization where data interoperability has largely been left to 3rd party systems inevitably raises questions about who has access to the data, how it is protecting against corruption, and what the data states in the first place. There is a need to rightly ask these questions prior to implementation, not retroactively after a problem occurs. Fortunately, Dixon and others have already developed a positive checklist of the carefully considered questions and criteria that organizations should expect answers to regarding the integrity, protection, and custodianship of their data prior to deploying outsourcing solutions, including AI. Just to recapture their points quickly: 1. Understandable ********** – Does the company explain its service in an understandable way without overly-inflated techno-speak or obscure jargon? 2. Practical control – Does the organization have practical control over its own data and how it is used? 3. Accountability – Can the organization run audit checks to hold the company accountable or to identify possible weak points in the system? 4. External partners – Who does the company itself share or sell the data to? 5. Transparency – Does the organization have a legal right to know, scrutinize and assess how its data is shared, held, and used? 6. Data protection – How does the company guarantee the security of the organization's data? 7. Accessible service – Would the organization be able to easily exit the service and take its data with it? [19].

7.2. Integration with Existing Infrastructure

Integrating AI-driven energy efficiency solutions into an organization's existing infrastructure is a complex task. These solutions employ various advanced technologies that help organize energy usage in the best possible way, such as predictive energy management software, advanced measurement, and control systems, advanced HVAC adjustment control, among others. An important thing to notice is how to integrate these technologies no matter how complex they are [20]. Integration with existing infrastructure can be approached in three steps:

1. **Testing Before Implementing**: To ensure that the energy solution will be a good fit for the medicine manufacturing facility, it can be tested on a similar site before relevant investments are made. Use matters to improve an AI-driven energy efficiency solution; facilities that do not match what was planned may ruin an energy efficiency solution. If it is not possible to test the AI solution, it is recommended not to invest in it.

2. **Analyze Compatibility**: There can be potential incompatibilities in between the energy efficiency solutions and the existing infrastructure. Objective judgment is needed as some incompatibilities are so big that it affects the decision to invest a lot in the energy efficiency solutions. Incompatibilities that usually come up are specific IT systems, building types and/or appliances, installed control or measurement systems, metering techniques, etc. Nonetheless, it is worth revaluating the compatibility situation whenever a facility is remodeled or when new appliances are installed, as that can open possibilities for a fit with energy efficiency solutions.

3. **Integrity of AI-Driven Systems**: AI-driven systems can come with many concerns about fraud and security. It can be damaging if a model gets hacked and used in an organization's interest, as sustainability is hard to measure. Focus is needed to find out if the energy efficiency solution guarantees safeguards for its proprietary models. In addition, it should be made sure that there is a fallback option to keep operations running if the IT or cloud does not work.

Integrating AI-driven energy efficiency can be a challenge for some organizations, but at the same time, it can be adopted in a way that prevents major disruptions. Compatibility with existing infrastructure is one of the major barriers for facilities to adapt [6]. AI-driven energy efficiency solutions will have the biggest impact on facilities that do not already have smart building solutions to monitor and optimize energy usage.

8. Future Directions and Emerging Trends

With the introduction of Artificial Intelligence (AI) technology, it is anticipated that the development and implementation of AI-driven energy efficiency solutions will evolve. More AI technologies such as machine learning routines, neural networks, and other AI models will be developed and refined. It is envisioned that these AI technologies will progress to become commercially viable products. The hope is that such AI-driven energy efficiency solutions would provide the needed technological advances to accelerate the shift toward the sustainable U.S. manufacture of medicines and vaccines [10]. New avenues of AI-powered technology development for energy efficiency will be cultivated. These could involve partnerships with American universities, non-profits, and community colleges to provide training and educational opportunities. As AI-driven energy efficiency solutions become more developed, available, and affordable, the hope is that the adoption of such solutions would become more widespread. It is expected there will be a corresponding surge of interest in AI-driven energy efficiency offerings from different sectors of the U.S. pharma manufacturing industry, growing from the current initial interest to widespread adoption.

In addition to foreseeable technology advancements, many foreseeable changes in laws and regulations to commercial energy efficiency actions, including AI-driven energy efficiency solutions, in the U.S. pharma manufacturing industry could facilitate industry adoption. Interest in the development of regulations on energy efficiency in the pharma manufacturing industry has been growing. While these regulations are not specifically on the developed solutions, there is a natural synergy between the goal of sustainability in pharma manufacturing and the goals of energy efficiency solutions developed in the AI ecosystem [4]. The experience of the commercial introduction of energy efficiency as a new class of compliance technologies (with new processes to comply with regulations that govern consumables such as drugs, chemicals, etc.) shows that regulation and legislation frequently precede commercial adoption, signing a new paradigm for industry.

8.1. Advancements in AI Technologies

Advancements in AI technologies are rapidly transforming the operational landscape of various industries, including the U.S. domestic medicine manufacturing sector. By projecting a technology scale-up, this study describes potential developments and innovations that could lead to the commercialization of AI-driven energy efficiency solutions. In this regard, the study focuses on the deep learning workplace dimension and outlines technological advancements in the energy management systems and machine learning algorithm domains. The energy management systems domain evaluates the potential of controllable technology and cloud-based sensors and energy management systems for energy savings. Integrating AI into existing physical on-site energy efficiency technologies will more likely yield operational excellence dividends, such as stabilized production and improved productivity in mature modes of operation. The expansion of machine learning algorithms will provide enhanced viability for AI-driven energy efficiency solutions. However, there are still hurdles associated with the interpretation of regulatory and liability resolutions regarding industrial AI applications and the successful handling of the technology's dependency and brittleness [5].

In considering the implications of the projected advancements, the focus is on promoting the sustainability imperative in the U.S. medicine manufacturing sector and its operational excellence implications. Enhancing the energy performance of energy-intensive industry sectors is imperative to combat climate change and promote sustainability [21]. The U.S. manufacturing sector is a pivotal part of the economy but heavily relies on non-renewable resources and fossil fuels. Furthermore, the energy-intensive domestic medicine manufacturing sector produces therapeutic drugs for millions of patients annually. In recent years, the biopharma supply segment of the manufacturing industry has grown in domestic medicine volume and global market importance with increased public health attention spurred by the COVID-19 pandemic.

8.2. Potential Regulatory Changes

In light of increasing relevance of reducing energy consumption in industrial sectors, this part details anticipated regulatory and policy changes expected in the United States that will likely affect energy efficiency methods in manufacturing medicines. The data needed to identify changing regulations is difficult to get. Many of the expected regulatory impacts are indirect effects associated with changes to the energy efficiency landscape rather than the result of laws or regulations proposed or enacted at the federal, state, or local level.

There is growing awareness of and concern about greenhouse gas (GHG) emissions associated with energy consumed in the United States, which includes 16 percent of all GHG emissions from industrial facilities [22]. More than 300 regulatory requirements associated with energy efficiency and/or emissions reductions have been proposed or enacted, and they are expected to grow quickly. Some states like California and New York have already proposed additional regulations aimed at increasing industrial efforts to reduce energy consumption. It appears, however, that such states have proposed and enacted regulations that other states will likely subsequently consider. As a result, all states with industrial sectors must be ready for the enactment of potentially far-reaching regulations affecting energy efficiency and use where.

9. Conclusion and Recommendations

The findings of this research provide substantial evidence that AI-driven energy efficiency solutions can significantly enhance the sustainability of U.S. medicine manufacturing. Firstly, the examination of industry and policy conditions surrounding energy efficiency efforts identified an urgent national need for increased energy efficiency in medicine manufacturing to maintain cost-effective and competitive practices. This pestering issue, spurred by pressures from high energy prices, extreme weather events, and climate change, has significant implications for the quality of life of all citizens. In response, the emerging field of AI-driven energy efficiency solutions was identified as being at the forefront of this complex research area. Several solutions currently existing in various industries were characterized, alongside the identification of gaps in the solutions as applied to the U.S. medicine manufacturing industry. Qualitative research with industry and policy stakeholders further assessed these AI-driven energy efficiency solutions in-depth, revealing both the ambitious promise of the solutions combined with the absence of proactive engagement by the industry and policy stakeholders. These findings have significant implications for both the U.S.

medicine manufacturing industry and the welfare of all U.S. citizens, highlighting the need for proactive engagement in the AI-driven energy efficiency solutions space to ensure a sustainable medicine supply chain and to otherwise alleviate the national need for increased energy efficiency [1]. On a broader scale, the findings have implications for the sustainability posture of industries in general, highlighting both the urgency for medicine manufacturing industries to adopt internally-focused solutions and the urgency for policy stakeholders to adopt nationally-focused solutions.

To foster the proactive engagement of both industry and policy stakeholders in the field of AI-driven energy efficiency solutions within U.S. medicine manufacturing this research proposes three actionable recommendations. Firstly, it is recommended that the U.S. medicine manufacturing industry create energy efficiency task forces, championed by large organizations and inclusive of medium and small organizations, to develop a collaborative roadmap for energy efficiency efforts, prioritizing AI-driven energy efficiency solutions. This process could comprise the three key steps of gaining a joint understanding of current energy efficiency efforts in the industry, exploring opportunities and challenges for implementing AI-driven energy efficiency solutions, and creating a unified course of action as an industry. Secondly, in support of this effort, it is recommended that state and federally focused organizations develop a strategic plan for studying and addressing the implications of the work for U.S. medicine manufacturing and leverage the collaborative processes established in conjunction with the industry to shape national policy. This strategic plan could comprise the four key tasks of assembling a central working group of relevant stakeholders from state and federally-focused organizations, developing a strategic research effort to unify understanding of energy efficiency in U.S. medicine manufacturing, learning from analogous processes undertaken in the Australian and EU industries, and mobilizing resources to enact national AI-driven energy efficiency initiatives within U.S. medicine manufacturing. Thirdly, it is recommended that policy stakeholders such as the FDA and AMIA build greater awareness of the urgent national circumstances increasing the necessity for enhanced energy efficiency in U.S. medicine manufacturing, with a particular focus on AI-driven energy efficiency solutions [10].

9.1. Summary of Key Findings

AI-driven energy efficiency solutions can significantly enhance energy utilization and sustainability performance in the U.S. medicine manufacturing industry. A comprehensive methodology, action plan, and supporting framework have been developed to facilitate effective implementation. Researchers have proposed specific approaches and best practices to support the successful deployment of energy sustainability analytics tools. Moreover, they have evaluated multiple metrics of energy sustainability performance and AI-driven energy efficiency solutions. Data demonstrated that AI-driven operational analysis system tools can substantially improve the energy utilization and sustainability performance of medicine manufacturing facilities in the USA.

Collectively, this research provides a comprehensive understanding of the development, deployment, and evaluation of AI-driven energy efficiency solutions. As energy efficiency and sustainability become increasingly important in production operations, these insights will advance the adoption and utilization of AI-driven sustainability platforms in other high-energy consumption industries, further promoting efficiency and sustainability improvement in the U.S. manufacturing sector.

9.2. Implications for Industry and Policy

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The transformative potential of AI technologies for the manufacturing sector including the medicine manufacturing industry, plant transformation from fitting and fixing to predicting and preventing, enabling 24h-monitored and real-time processes, and paving the way towards fully autonomous manufacturing plants, processes, and machines. Some issues were identified in literature focusing mainly on the pharmaceutical industry (i.e. process intensification), having an indirect focus on the circular economy (i.e. modelling BATs technology, recycling pharmaceutical compounds), or being too vague to be acceptable, while most literature focusing on the energy aspect is oriented on thermal energy consumption (i.e. alternative thermal sources, chillers), fuel use (i.e. sustainable biofuel), electricity (i.e. smart grids) supply, fuel price effects (i.e. natural gas and petrol), or Energy Management Systems (i.e. ISO 50001) [10].

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