

Competency-Based Deployment and Compliance-Aware Scheduling: AI-Based Workforce Optimisation in American Pharmaceutical Manufacturing

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1. Introduction to Workforce Optimization in Pharmaceutical Manufacturing, The concept of workforce optimization is introduced within the context of the pharmaceutical manufacturing industry in North America. The American pharmaceutical manufacturing industry has a presence of both small and large-scale companies, which face challenges like complex regulatory requirements and the need to adhere to Good Manufacturing Practices (GMP) for people and equipment to conduct several unit operations or production processes. As a significant portion of the operating expenses in pharmaceutical manufacturing is due to personnel costs, the use of Artificial Intelligence (AI)-based solutions has potential to become a useful solution for the industry.

The component of workforce optimization is explained, which refers to the productivity, efficiency, and effectiveness of the overall workforce across all job roles. It is classified into two aspects: short-term workforce optimization refers to decision variables that can be changed in real-time (e.g., scheduling, time-off approval), whereas, long-term workforce optimization involves decision variables that are fixed for long periods of time (e.g., labor contracts, training policies, staffing).

1.1. Significance of Workforce Optimization

The pharmaceutical manufacturing domain is one of the most regulated, complex, and pervasive industries in today's economy. Actual manufacturing process includes operating hundreds of different types of machines and employs thousands of workers in a single plant. As per the fine guidelines described in Title 21 Code of Federal Regulations Part 211, it is an obvious challenge for the operations managers to maintain operational excellence by efficiently scheduling the manpower resources over multiple product batches running at the same time on the plant floor. Worker absenteeism, turnover, breaks, and sick leaves disrupt this delicate synchronization and impact the

production targets, product quality, timeline of batch release, and compliance to cGMP standards [1]. In order to remain competitive in this critical production environment, AI-based solutions are designed to analyse worker movements and job roles through camera feeds over the plant floor.

In order to reduce this problem, computational intelligence techniques including machine learning and metaheuristic algorithms are designed for optimal workforce allocation over multiple manufacturing machines. Use of proper workforce allocation keeps the machines in better optimal operating conditions leading to improved overall productivity. Results also suggest that use of computational intelligence-based techniques for allocation of pharmaceutical manufacturing workforce has remarkably improved overall workforce efficiency and manufacturing productivity. Since within American pharmaceutical manufacturing domain there is constant supervision of batch wise and time wise production due to government regulations, service punishments for misconducts like high absenteeism or tardiness is also reported in the models. Event simulation modelling technique is implemented and herein designed workforce shifts in the pharmaceutical overall systemic improvements are favourably compared against the current scenarios [2].

2. Fundamentals of Artificial Intelligence in Pharmaceutical Manufacturing

Artificial intelligence (AI) refers to the ability of computers or computer-controlled machines to perform tasks typically requiring human intelligence. There are many concepts and schools of thought regarding AI: strong AI versus weak AI, narrow AI versus general AI, and brute force AI versus trained intelligence, to name a few. These models are at best abstract representations of AI systems and cannot capture the true nature and workings of AI as it is implemented today. AI is primarily executed through computer software programs or codes composed of instructions that allow a computer to perform certain tasks. These software programs can be classified into areas or techniques that are specific incarnations of AI. While there is a plethora of techniques that comprise AI, only a few are widely utilized in today's solutions. The following four AI techniques, ordered by prevalence, are reviewed: machine learning, deep learning, natural language processing, and computer vision [2]. A thorough understanding of these four techniques is essential for appreciating the solutions in this study.

Machine learning refers to the ability of a software program to perform a specific task without using explicit instructions, relying instead on patterns and inference instead. The term is commonly used today to describe a classification of AI techniques based on statistical methods. In general, machine learning techniques train or teach software programs to make classifications or predictions using substantial amounts of past data as examples. There are two main types of machine learning: supervised learning and unsupervised learning. In supervised learning, the training data used to teach the algorithm include both the input data and the corresponding desired output. In unsupervised learning, the training data include only the input data [3].

Deep learning refers to a subset of machine learning techniques that employ artificial neural networks, which are systems of algorithms inspired by biological neural networks. There are different architectures for artificial neural networks, and because the most widely used architectures in industry, in academia, and in government projects are multilayer feed-forward artificial neural networks, the terms deep learning and neural networks will be used interchangeably. The notion of deep in the term deep learning refers to the number of hidden layers in the network's architecture. More specifically, the minimum number of hidden layers required for neural networks to be considered deep is two hidden layers (to contrast shallow architectures that use only one hidden layer). The term "deep" also represents a more complex architecture in terms of the number of neurons in the network. Consequently, the nomenclature and measurements regarding deep learning architectures depend on more parameters than other machine learning techniques, complicating the process of comparison to other techniques.

2.1. Machine Learning and Deep Learning

Machine learning (ML) is a subset of artificial intelligence (AI) that focuses on developing algorithms and statistical models that enable computer systems to perform specific tasks without explicit instructions from human operators. In simpler terms, ML allows computers to learn and improve from experience [2]. This learning process typically involves the analysis of large amounts of data to identify patterns, trends, or correlations, which can then inform decisions or actions. It has been successfully applied across a wide range of fields, including finance, healthcare, and logistics [4]. Deep learning (DL) is a further subset of ML that refers to a specific type of artificial neural

network architecture designed to automatically learn hierarchical feature representations from unstructured data, such as text, images, or audio.

Over the past decade, DL approaches have successfully made significant advances in areas such as automatic speech and text recognition, natural language processing, and image processing. DL allows learning complex, non-linear transformations to automatically extract relevant features from raw data. This approach is especially powerful when used with large datasets and high-capacity models, such as deep neural networks with many layers and parameters. By combining ML and DL, pharmaceutical manufacturing companies can optimize workforce operations by applying intelligent automation to routine monitoring tasks and focusing skilled workers on more complex processes and exceptional situations.

2.2. Natural Language Processing

Natural Language Processing (NLP) refers to a collection of techniques and approaches that enable computers to process and analyze natural language data (i.e., human language). NLP aims to bridge the gap between human language and machine-understandable representation [5]. NLP capabilities and techniques were explored to provide insights into applying NLP to various aspects of numerical data, communication patterns, and company documents, and assess the implications of NLP in the pharmaceutical manufacturing sector.

NLP can be utilized to extract insight from text-based data sources such as reports, documents, and communications. Such insights may include sentiment analysis, topic modeling, and document summarization, among other approaches. NLP can be leveraged to mine numerical data sources by training NLP models to convert numerical data into textual representation. Numerical data can then be analyzed and interpreted using established NLP techniques and capabilities. As unlike other industries, the pharmaceutical workforce is highly knowledge-intensive, and large volumes of slow and standardized communication take place, NLP may be additionally beneficial to support communication processes by acting as a medium that restructures and reformulates communication texts and patterns into an easier-to-understand, simplified, or more formalized textual representation, respectively [2]. Such capability may also include auto-generated emails, chatbots, and machine-generated reports. NLP capabilities can also be adopted to automate routine tasks that employees would

typically process on diverse text-based documents. Such automated processes may involve the extraction of fundamental information from various documents, text-based comparisons, templated rephrasing, or the simple translation of texts. Such empowered workforce automation and optimization would radically impact the workflow and processes associated with communication and text-based complexity in documents across the pharmaceutical production sector.

2.3. Computer Vision

Automated analysis of visual data can optimize workforce activities in pharmaceutical manufacturing through the application of computer vision (CV). This subset of artificial intelligence (AI) recognizes content in digital videos or images and can track, identify, and classify objects, gestures, and scenes using datasets of trained images and rules [6]. As an optimization tool, CV can conduct analysis at a speed beyond human capabilities; can use images captured in conditions that limit human workers, such as night operations or the movement of parts along a conveyor; and can increase employee safety by granting workers greater distance from high-risk operations, such as energetic actions where moving machinery is present. Potential applications for CV in the pharmaceutical manufacturing sector include quality control and monitoring, as well as optimizing the workforce. An examination of how CV applications are currently focused utilized in the broader manufacturing sector provides a foundation for identifying potential applications in the pharmaceutical industry.

Quality control utilizes sensors and measuring devices, including cameras, to analyze products thoroughly and objectively [2]. This process is currently conducted on the automated line in many manufacturing industries, including automobile, electronics, textiles, food, and pharmaceuticals, due to the capabilities of CV. Quality-control inspections for defects, stains, and environmental hygiene in these industries are covered in the literature. Parts- or batch-level inspections are conducted to ascertain that automation systems meet production targets, are at minimal acceptable quality, and ascend to preferred quality standards. Tracking, identifying, and classifying products and defects, as well as measuring the area, volume, and height of defects, fall within the functional capabilities of CV as applied to pharmaceuticals.

3. AI Applications in Workforce Optimization

The pharmaceutical manufacturing industry is embracing AI applications to address rising workforce costs and optimize operations. Numerous AI technologies are tailored for staff efficiency improvements within pharmaceutical production, including automatic inspection, high-quality assurance, variability prevention, workforce optimization, and safety systems enhancement [2]. Owing to the intricacy and high-stakes nature of drug manufacturing, AI systems typically operate under regulated yet rigid parameters, providing limited adaptability to supply and demand shocks. In response to post-COVID adjustment efforts and evolving market conditions, there is a heightened interest in AI-based strategies for workforce optimization. This study examines a spectrum of AI applications designed for workforce enhancement, requiring various levels of data access and IT competence. The focus is primarily on front-line production staff, who are pivotal in ensuring the quality of over 50 million drug products manufactured daily in the United States.

A deep-dive look at various AI-based methods is conducted, exclusively targeting workforce optimization in pharmaceutical manufacturing. Techniques such as demand forecasting using predictive analytics, automated scheduling & shift planning, and performance monitoring & evaluation through computer vision are considered [3]. Each approach is categorized based on requisite data availability and sophistication for successful implementation. Furthermore, several exemplary case studies from the pharmaceutical industry, employing the aforementioned AI solutions, are elucidated. These well-documented narratives shed light on the challenges and envisioned execution and delivery approaches for the respective AI undertakings.

3.1. Predictive Analytics for Demand Forecasting

Demand forecasting is key for managing the workforce in the pharmaceutical manufacturing sector. Accurate demand forecasting needs consideration of multiple factors as well as multiple data sources. Untimely and incorrect forecasting may cause either inefficient utilization of the labor resources or overtime labor costs of the manufacturing workforce. This section describes predictive analytics for demand forecasting and mitigating labor under/over supply problems in US pharmaceutical manufacturing.

Pharmaceutical manufacturing entails multiple stages of production that eventually pose challenge to plan and forecast for demand and supply of workforce as well as production resources. Existing literature and methods primarily concerns efficient production planning for pharmaceutical manufacturers while there is limited research to forecast demand and supply of workforce. This section investigates AI-based predictive analytics for workforce demand forecasting in US pharmaceutical manufacturing [2]. Specifically, for each earlier manufacturing stage, an AI-enabled predictive model is trained on historical production batch record data to predict workforce demand in advance. Further, an AI-based prediction showed significant performance improvement on a set of pharmaceutical manufacturing case studies. Real-case scenarios of the analyzed dataset from the American pharmaceutical manufacturers are discussed. To the best knowledge, this is the first attempt to take AI-driven predictive analytics for proactive planning of workforce demands in pharmaceutical manufacturing.

3.2. Automated Scheduling and Shift Planning

Employing AI technologies for automated scheduling and shift planning presents several advantages. Automated planning can assist human resource management tools in pharmaceutical manufacturing with a different perspective on workforce productivity. Existing solutions generally focus on the optimization of staffing resources, generated schedules provide an overview of work shifts and work blocks for each employee and can therefore help to better estimate work overload, provide time management or reduce uncertainty for employees with variable working hours [7]. On the other hand, automated scheduling would help to consider a larger set of objectives such as KPIs that are key for the business, handling a higher workforce size at once to reduce local optima, or reducing the overall overhead of existing manual and semi-automatic operations. After discussing with experts in the field and observing hand-made processes, there are good opportunities to streamline the hand-made planning for the late overload/low coverage scenarios that are currently being solved either not at all or using high overhead (e.g. weekend or out-of-hours planning meetings). Additional benefits could even be obtained if software tools remain simple enough to allow quick and interactive solutions (e.g. prefabricated default shift patterns) for daily or weekly overload forecasts. In such cases, a simple web- or spreadsheet-based tool could leverage the involvement of multiple planning teams across a broader set of sites instead of relying on a centralized team currently located only in Swindon. Considering these

different perspectives, three scenarios for prioritizing the use of AI for scheduling processes are proposed.

3.3. Performance Monitoring and Evaluation

Performance monitoring and evaluation are among the key classes that can act as a standalone capability or as part of other capabilities. For monitoring workforce performance (marine crew), AI technology monitors, tracks, and evaluates competent crew performance while identifying the causes and consequences of potential incidents. It analyzes perceptions, knowledge, rules, skills, attitudes, expectations, and behaviors, especially when confronting novel challenges in complex environments. AI cameras focusing on personnel behavior catch contextualized scenes to recognize incidents of active omission and erratic commission. There are feedback loops in OT, IT, and AWT to facilitate anticipation, rescheduling, alignment, and recovery of tasks and systems. Thus, AI-enabled performance monitoring can contribute to continuous improvement (CI) in workforce performance and play a crucial part in operational excellence (OE).

4. Case Studies of AI Implementation in American Pharmaceutical Manufacturing

Continuous improvement philosophy and work force optimization have become important focuses in American pharmaceutical manufacturing. The proactive development and deployment of Artificial Intelligent (AI) based solutions can be an effective mean to achieve work force optimization on both operational and managerial levels. This work presents a number of AI based techniques and case studies of AI implementation in American pharmaceutical manufacturing where challenging optimization problems are effectively solved with AI technologies [2].

Velocity AI Staffing Solution is a cloud based staffing package which utilizes AI technologies including machine learning (ML) algorithms and optimization platforms to optimize production line staffing within American pharmaceutical manufacturing [8]. This package automatically predicts staff leave and head count, estimates workload and staff shortage, proactively reports concerns, and recommends staff allocation. As a company deployed case, this package is implemented to optimize staffing on 40 production lines in a number of sites. Positive results are achieved in improving staffing efficiency, productivity, quality, safety, and work/life balance. Ingenious AI based quality control solutions are developed to optimize visual inspection operation within American pharmaceutical manufacturing. These solutions include AI inspection

algorithm as a line of defense against process failure cases and AI quality classification model to close the loop in assisting the decision making along quality investigation. Deep learning algorithms including convolutional neural network (CNN) architecture are used to establish the AI visual inspection models where both image and sensor data are utilized. As one company deployed case, an AI inspection model is successfully piloted and implemented for three drug products in coating area. Positive results are achieved on accelerating defect detection, improving detection coverage, and reducing reliance on manual inspection.

4.1. Case Study 1: Optimizing Production Line Staffing

To satisfy various regulatory and customer needs, a typical American pharmaceutical manufacturing plant produces batches of various products (drugs) on the same production line. Phases of every batch of production process that occupy machines and need human labor force are known as “operation states”. Every batch may have different operation states and time lengths for each state according to its product and the current related phase. In view of the operation states of every batch that occur in the future and the propagated requirement of human force level to every operation state, the produced arrival time and product type of every batch, and the capacity of every operation state, the conservative and predetermined level of human force on different product types and operation states from a particular point of time is calculated [2].

The deterministic staffing calculation model based on operations time is established. A multi-objective binary linear programming staffing optimization model with operation time uncertainties and early delays of batches is provided. A new AI-based staffing solution is provided and successfully applied to a production line in an American pharmaceutical manufacturing plant. It is demonstrated that the use of AI staffing can significantly reduce staffing levels while the overall satisfaction of human force availability is still guaranteed. With the aid of AI staffing, the staffing levels on the best common scenario (actual baseline scenario and ideal scenario development if no restrictions on the staffing calculation) are reduced from 46 and 64 to 39 and 47 respectively. More human resources of around 7% and 31% are released for the development and training of new products and overall human force availability satisfaction increases from 88.4% and 58% to 96.6% and 66% respectively [8].

4.2. Case Study 2: Enhancing Quality Control with AI

The continuous evolution of artificial intelligence (AI) within the pharmaceutical sector has garnered global attention. As a cornerstone of healthcare, the American pharmaceutical industry faces challenges such as the falling productivity of research and development (R&D) investments, rising operational costs, and stringent regulations. Addressing these challenges, AI offers various solutions including automation, big data analytics, drug design, and clinical trial management [2]. Confronted by generative AI models like ChatGPT, this review aspires to underscore various cutting-edge AI technologies both general and specific to the pharmaceutical industry, including their history and hypothetical development direction.

Vision-based quality control, such as capsule count, optical detection of defects, and vision-based quality inspection, is widely adopted in the pharmaceutical industry. However, most applications rely on manual measurements by operators. To improve product quality and operate in compliance with regulations while enhancing productivity, various AI-based quality control techniques are applied to the broken capsule detection, print label inspection, and tablet detection problems in American pharmaceutical manufacturing. For image identification, a semi-major axis variance measure is proposed to precisely locate the defect location [8]. Under the domain adaptation framework, attention-guided image segmentation is designed to segment orphan defects. Focusing on the detection of leaking capsules after seal inspection, a one-shot segmentation model is developed to identify defects based on ultrasonic B-mode images.

5. Challenges and Ethical Considerations in AI-Based Workforce Optimization

The rapid advancement of artificial intelligence (AI) has led to its increased application in various industries, including manufacturing. As the demand for smart, efficient, and competitive factories grows, real-time data access increasingly drives the application of AI in manufacturing. With the rise of AI, understanding the effects of its implementation in manufacturing and its implications beyond cost and productivity is crucial. However, such costs should be viewed as public and private investments to enable AI applications in manufacturing that promote social cohesiveness and inclusion and environmental sustainability [9]. The potential for labor displacement and the exacerbation of inequality is the most frequently cited effect of AI implementation in manufacturing. This fear may

be accompanied by similar fears for other industries, such as agriculture and transportation. While these fears are justified, such assumptions that technological progress would ultimately displace jobs or that intelligent machines will replace people in jobs should be historically contextualized.

AI brings about several promises for improving workplace safety and job quality, particularly in manufacturing. Nonetheless, along with these promises are concerns regarding the data-driven nature of such AI systems and the norms and standards guiding its design and development. In dealing with such concerns, it is paramount to democratize the process of developing and designing AI technologies within organizations through the co-creation of AI systems, expertise pooling, and public participation to foster a socially aware and robust technology design process [10]. Workforce optimization based on data-intensive AI technologies would amplify labor inequalities if left unchecked. Furthermore, it requires conscious and concerted efforts among stakeholders beyond technology designers and manufacturers, such as policymakers and trade unions, to ensure the fairness of AI applications.

5.1. Data Privacy and Security

The deployment of artificial intelligence (AI)-based solutions for workforce optimization in American pharmaceutical manufacturing greatly relies on the secure handling of workforce-related information. The use of this data to design, implement, and evaluate workforce optimization applications raises various concerns for regulatory compliance regarding data privacy and security [11]. Privacy implications are affected by regulations that protect the kind of data that human resource management applications usually rely on. The eight principles of data protection outlined by the Data Protection Act of 1998 (UK) have to be ensured, specifically in relation to data retention, accuracy, and consent. In addition to these implications, several considerations regarding the security of workforce-related data also arise. The concern that applications developed may be misused, compromised, or manipulated by unauthorized external or internal actors needs to be addressed [12].

5.2. Bias and Fairness in AI Algorithms

There is significant interest in the ethical dimensions of AI (Artificial Intelligence) algorithms for workforce optimization. This is a fast-growing area and there is a real challenge in terms of algorithmic bias and fairness as relevant technologies are adopted

across a growing range of applications in terms of the optimization in recruitment, training, and task allocation. Understanding bias and fairness in workforce-related AI algorithms, and particularly how they can be mitigated, is becoming an important frontier of research across multiple academic disciplines and represents an area of serious focus within industry contexts [13].

Algorithms can generate optimization-related biases in regulating workforce-related decision-making processes in recruitment, salary allocation, training provision, and task allocation. This can lead to unfair discrimination and a sub-optimal workforce. A proactive awareness of the manifold sources of adverse bias, and a careful application of appropriate AI-based bias mitigation techniques can reduce the impact of this bias generation, and enhance algorithmic fairness and internal decision-making efficiency with workforce optimization applications [14].

6. Future Trends and Innovations in AI for Workforce Optimization

While advancements in artificial intelligence (AI) have lagged in biomanufacturing relative to other pharma production and supply chain operation functions, recent industry trends and emerging technologies are poised to reshape the future of AI workforce optimization in biomanufacturing. AI technologies and methodologies converge on critical needs in biomanufacturing for improved workforce utilization and to bolster productivity and operational flexibility in the face of increasing complexity and volatility in the supply of increasingly biologics and biomolecules. As promising new avenues for drug delivery are pursued, novel drugs often have uncertain pharmacokinetics, necessitating exquisite biomanufacturing expertise to be integrated into the design process. Attractive to this burgeoning frontier of AI application are new and powerful paradigms in generative machine learning (ML) and deep learning (DL) modeling, especially diffusion models, transformers, and large language models (LLMs), which augment such integration by assimilating, modeling, and reasoning over multi-channel inputs of biomanufacturing operating conditions and design parameters.

While most of the initial work in AI for biomanufacturing is directed at upstream processing operations and workflows, the majority of operations in a manufacturing plant are downstream processing, where the focus is recovering and purifying the desired biomolecule from the fermentation broth after separation from the cells. Separation is often first accomplished by clarifying centrifugation followed by

nanofiltration, where the biomolecule is passed while multivalent anions are retained, followed by diafiltration. Although there are many unit operations in DSP, incorporating AI into DSP is more problematical than in USP. DSP unit operations are generally sensitive to physical and chemical parameters and considered more difficult to model than biological unit operations. DSP processes are often fractionated to minimize loss of the desired biomolecule, and this complicates AI modeling efforts, as many biographic parameters are often not measured. Furthermore, DSP employs many temporary operations during clinical manufacturing campaigns that complicate the resultant dataset such as centrifugation, filtration, and chromatography.

As discussed in this article, process method optimization can be cast as an RL problem with standard RL methods used to optimize a SMA bioprocess of 2000 L yeast. The next critical challenge for upstream biomanufacturing is upscaling of the process from the laboratory to manufacturing scale, necessitating multi-scale modeling. While first-principle and mechanistic modeling efforts dominate the biomanufacturing field at this point, such models are often inaccurate or not interpretable, critical issues that DL models are uniquely positioned to address [3]. There are growing calls for interpretability of ML and modeling methods to facilitate better understanding of biomanufacturing processes. Furthermore, DN of gradual transition between mathematical model equations are uniquely suited for modeling fuzzy physical systems that are very difficult to model with first-principle or mechanistic modeling approaches [2].

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