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Artificial Intelligence in Bioprocessing: Enabling Autonomous and Predictive Biomanufacturing Systems

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Abstract: Artificial intelligence has become a transformative tool in bioprocessing through predictive modeling and adaptive control. Traditionally, bioprocessing relied on experimentation and static control mechanisms, limiting flexibility and reproducibility, thereby motivating the adoption of artificial intelligence for data-driven interpretation of complex bioprocess interactions. This enables identification of underlying relationships, improves prediction of process behavior, and supports timely intervention. The integration of machine learning, real-time analytics, and digital twin technologies enables simulation-driven optimization of process performance while minimizing experimental risk. Despite these advantages, practical implementation requires careful attention to regulatory compliance, data integrity, and model transparency to ensure reliability and industrial adoption. Artificial intelligence integration in bioprocessing involves its introduction into both the upstream and downstream aspects. This includes the parameter optimization process at the upstream level and the quality management at the downstream aspect. Fundamental algorithms such as supervised learning, unsupervised learning, and reinforcement learning improve prediction capabilities and dynamic adjustment of parameters in these processes. Digital twin technology enables improved process simulation and analysis of different scenarios of operation. Hybrid integration with mechanistic models further supports interpretability and model reliability. However, compliance with regulatory requirements necessitates interpretability and consistency.

Keywords: *Artificial Intelligence, Bioprocessing, Digital Twins, Process Control, Regulatory Considerations*

1. Introduction

Complexity is an intrinsic part of the operation of bioprocessing systems due to the nature of their environment, which is living systems. Biological systems display nonlinear behavior, stochasticity of metabolic processes, and sensitivity to changes in the environment, all leading to the variation from run to run. Such variation introduces substantial difficulties for process reproducibility, scale-up, and quality control in industrial biotechnology. For many years now, strategies used for bioprocess control have been based solely on empirical experience and expertise of operators. These techniques delivered useful heuristics for process development; however, they limited the process consistency and made scaling of operations difficult [3]. Artificial intelligence (AI) is a powerful paradigm that can be utilized in order to aid understanding of processes via discovery of underlying patterns within extensive experimental data sets. Far from being an alternative to expertise in a particular scientific field, AI becomes a tool that adds to existing knowledge and allows for development of predictive models and adaptive controls [4]. Building on this capability, data-driven optimization frameworks enable continuous refinement of process parameters through real-time feedback [4]. For instance, artificial intelligence may uncover relationships between the culture conditions in the upstream process and certain quality features of the resulting product, which might be difficult to obtain using regression or design of experiments techniques. It was shown that such intelligent systems can predict biomass yield in microalgae cultivation more accurately [2].

Incorporating AI into bioprocessing processes must involve careful consideration regarding how it is used by the scientists and engineers that create, observe, and regulate these processes. Integration of AI should be smooth and should work in harmony with current experimental approaches in spite of the inconsistencies that are present in biological data sets [5]. These inconsistencies are due to biological data being characterized by noise, incompleteness, and heterogeneity. Solving the problem of dealing with inconsistent data entails integrating AI into a specific discipline framework so as to keep predictive models both understandable and practical for use by the scientists and engineers [8]. The

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evolution of agentic AI and robotic technologies in recent years has made it even more apparent that there is room for self-reliant bioprocessing technologies. There have been applications of agentic AI technologies in smart manufacturing where they have been utilized for predictive maintenance and decision ecosystems centered around humans. This experience could be replicated in the biomanufacturing industry, which requires robustness and agility [4]. Likewise, artificial intelligence-driven micro and nanorobotics have emerged in the biomedical field, providing insight on how intelligent automation can be incorporated into mechanical devices for targeted actions [5].

The aspect of sustainability is especially pertinent with respect to the growing linkages between bioprocessing and the circular bioeconomy. There have been attempts to design an AI system to determine and improve efficiencies, minimize waste, and enhance life cycle management in applications associated with the bioeconomy [7]. These efforts can be tied into the global agenda for sustainable innovation. Regulations for technologies involving AI are currently being formulated. In this context, the requirement for explainability in AI-driven decisions has led to the concept of causability, ensuring that model outputs remain interpretable and aligned with scientific reasoning [9].

Indeed, there has been a demand for regulation that would allow the introduction of new technologies while maintaining compliance and ethics [9]. The convergence of digital transformation and advanced analytics is another crucial consideration in the integration of AI. The use of digital twins, robotic process automation, and biological control systems is bringing about significant changes in industrial robots and bioprocess applications [10][11]. This means that the concept of real-time optimization and predictive control can now be implemented, which is characteristic of Industry 5.0. In fact, the AI biofoundries that were proposed as platforms for protein engineering and metabolic engineering [1] can be cited as an example here. AI enables transformation across design, optimization, and control stages in the entire bioprocessing process through designing, building, testing, and learning.

2. Background and Evolution of AI in Bioprocessing

The emergence of AI applications in bioprocesses involves a transition that may not be instantaneous; however, it represents an important paradigm shift towards AI-driven intelligence as opposed to empirically driven heuristics. Early computational techniques were largely based on regressions and design of experiments (DoE). They offered valuable structured insight concerning the effects of various parameters and variable relationships. Machine learning enhanced the ability to conduct analyses, as it could recognize patterns in complex and multivariate data sets. These advancements collectively support continuous optimization strategies, where process variables are dynamically updated using real-time data rather than static experimental designs [4].

Methods like support vector machines, clustering methods, and decision trees made it possible to classify states of processes, predict their results, and determine where variability comes from. These techniques are an advance over traditional models in terms of adaptability and continuous learning from new data inputs. Machine learning has been used in predicting biomass production in microalgal cultures with better accuracy than traditional methods [2]. Biofoundries powered by artificial intelligence are now being used to engineer proteins and metabolism in synthetic biology, thanks to machine learning [1].

Recent developments have made even greater progress towards making use of artificial intelligence in bioprocessing. Neural networks, especially deep learning models, were used to model the non-linear behavior of interactions between process parameters and quality features of products. They perform well in dealing with data in high-dimensional space and can provide predictions in situations when classical approaches fail to do that. Additionally, reinforcement learning became popular due to its capability of optimizing dynamic processes such as feeding, aeration, and temperature control by iteratively acting in a bioprocessing environment and improving the corresponding control policy [6]. The combination of reinforcement learning with digital twins is even more promising in this situation since reinforcement learning allows safe algorithm training in simulation before implementing it into actual processes [10]. Extending this capability, multi-scale digital twin models further enhance predictive performance by integrating biological and process-level interactions within a unified simulation framework [12].

The general trend of AI applications in bioprocessing is intimately connected with the progress made in industrial robotics and intelligent manufacturing. Applications of agent-based AI models in manufacturing predictive maintenance emphasize human-oriented decision-making and reliability [4]. Bio-inspired control systems for robots demonstrate how intelligent adaptive capabilities are applied in hardware and offer sustainable approaches that align with Industry 5.0 visions [11]. It reflects the combination of AI, robotics, and bioprocessing technologies in which autonomous systems are capable of dealing with variability in real-time situations.

Through the use of predictive analytics with lifecycle management, AI ensures that the bioprocessing technologies developed are sustainable in nature. Reconfigurable manufacturing systems that are driven by AI and make use of large language models to facilitate sustainable decision-making provide examples in which AI technologies are used for sustainable purposes [6]. The issue of regulatory compliance has also developed along with the growth in use of AI technologies. The integration of AI technology within bioprocessing requires regulators to focus on transparency, interpretability, and accountability [8][9]. In biotechnology/pharmaceutical frameworks, there has been increasing consideration of how to strike a balance between innovation and compliance such that predictive algorithms will not only work well but will also be trusted within the industry and by regulators.

It is possible to chart the development of AI in bioprocessing from the first use of regression and DoE approaches to the more modern application of machine learning, deep learning, and reinforcement learning models. This area of expertise has been expanded further to create processes that are more sustainable and, at the same time, more predictable and adaptive. The integration of the latest technological trends in artificial intelligence and robotics into digital twin processes, among other things, suggests that in the future, bioprocessing will move toward complete autonomy according to the Industry 5.0 model.

Stage	Techniques Used	Key Capabilities	Limitations
Early Phase	Regression, DoE	Parameter sensitivity analysis, structured experimentation	Limited adaptability, poor handling of nonlinear systems
Intermediate Phase	Machine Learning (SVM, Decision Trees, Clustering)	Pattern recognition, variability analysis, predictive modeling	Requires large datasets, moderate interpretability
Advanced Phase	Deep Learning, Neural Networks	Modeling nonlinear biological interactions, high-dimensional data handling	High computational demand, low transparency
Modern Phase	Reinforcement Learning, Digital Twins	Real-time optimization, adaptive control, simulation-based learning	Regulatory challenges, validation complexity

Table 1: Evolution of AI Techniques in Bioprocessing [1, 2, 4]

3. Core AI Techniques in Bioprocessing

With the emergence of artificial intelligence technology, various approaches have been created in relation to the computational aspect, which can be applied to the field of bioprocessing, each approach having its own strength in handling the aspect of complexity, variability, and prediction. The three approaches that have proven to be the most popular ones are supervised learning, unsupervised learning, and reinforcement learning.

Nowadays, supervised learning is widely utilized in the field of bioprocessing as a predictive model. Using labeled data, supervised learning techniques can be used to estimate cell growth curves, concentrations of metabolites, and various quality attributes of products obtained in the process. Machine learning models, specifically neural networks and regression, have been proven effective for the establishment of nonlinear dependencies between variables in the process; they provide better prediction than the conventional statistical approaches [3]. For example, in bioprocesses involving microalgae, supervised learning was used to predict biomass productivity depending on different culture parameters, showing the potential of this approach to improve yield prediction [2]. Also, AI-driven biofoundries rely on supervised learning for speeding up processes of protein and metabolic engineering [1].

The unsupervised learning approach serves as an excellent complement to the traditional supervised learning approaches by discovering underlying structures in datasets lacking labels. Methods such as clustering, PCA, and anomaly detection prove especially effective in the field of bioprocessing because they account for noise that is characteristic of biological processes. By detecting anomalies in the state of the process, classifying different operating states, and detecting changes in process operation that could be precursors to deviations in the product quality [5], unsupervised learning contributes to achieving process stability. The use of unsupervised machine learning algorithms to detect anomalies and make decisions in a dynamically changing environment is also relevant in biomedical applications, including AI-powered micro-nanorobotics [5]. Furthermore, the concept of agentic intelligence and AI has been successfully applied in manufacturing to predict maintenance needs using unsupervised learning algorithms [4].

Unlike the traditional method, reinforcement learning is more flexible and better suited for controlling a time-varying process such as feeding, aeration, and temperature. The underlying concept of reinforcement learning involves employing an algorithm that keeps on interacting with the environment associated with the process to optimize the performance of the process with respect to some criteria. Recently, reinforcement learning has been employed for controlling microbial bioprocesses, specifically to optimize feeding strategies [6]. The advantages of using reinforcement learning become even greater in conjunction with digital twins, which allow simulating the operation of the bioreactor before implementing the algorithms in real environments [10]. The integration of domain-specific biological knowledge improves model interpretability and reduces overfitting, ensuring that data-driven predictions remain biologically meaningful and experimentally valid [8]. The use of AI without a sufficiently high level of biological background may lead to overfitting of the system or even misrepresentation of its dynamics. Thus, the incorporation of biological knowledge within the framework of artificial intelligence approaches guarantees that the computational outcomes will be realistic, which in turn increases the confidence of biologists in their usage [8]. For example, AI-powered biofoundries make use of biological expertise coupled with computational methods to design novel and experimentally testable metabolic pathways [1].

A combination of supervised learning and unsupervised learning leads to a type of learning known as semi-supervised learning, in which labeled as well as unlabeled data are used for improving predictive accuracy. In a similar way, when reinforcement learning is coupled with supervised learning, it gives rise to adaptive control algorithms that rely on both experience and environment. As highlighted in the context of industrial robots, bio-inspired control systems represent a form of sustainable innovation in line with the Industry 5.0 ideology [11].

In regard to the sustainability aspect, AI techniques become even more critical for implementation. Different AI-based methods have been introduced for optimizing the resource use, decreasing wastage, and creating a circular bioeconomy [7]. In particular, unsupervised learning may be used for recognizing any inefficiencies in the flow of resources; supervised learning will help predict sustainability initiatives' success; and reinforcement learning can help optimize strategies related to the allocation of resources.

Regulation is another crucial aspect when it comes to the application of AI strategies. Since AI has been incorporated increasingly in the bioprocess, it is essential to note that transparency, interpretability, and accountability are considered vital by the regulators [8][9]. This means that it is crucial for supervised AI approaches to explain the rationale behind the predictions made; unsupervised AI approaches should have the capacity to identify any anomalies, while the reinforcement approach should comply with safety regulations.

The following AI techniques can be mentioned as significant AI techniques applied in bioprocessing innovation: supervised learning, unsupervised learning, and reinforcement learning. Each of the three methods mentioned above has its own advantages, which might contribute to the improvement of process knowledge and process control. The integration of AI and experimental skills, along with sustainable models, emphasizes the significance of the technology.

AI Technique	Data Requirement	Primary Function	Application in Bioprocessing	Strength
Supervised Learning	Labeled data	Prediction	Biomass estimation, product quality prediction	High predictive accuracy
Unsupervised Learning	Unlabeled data	Pattern discovery	Anomaly detection, process state classification	Handles noisy biological data
Reinforcement Learning	Interactive data	Optimization	Feeding strategies, aeration control	Dynamic adaptability
Hybrid Models	Mixed data	Combined prediction & control	Integrated process optimization	Balanced performance

Table 2: Comparison of Core AI Techniques in Bioprocessing for Predictive Modeling and Process Monitoring [2, 4, 14]

4. AI-Driven Process Control and Optimization

Traditionally, bioprocesses have been controlled using mechanistic models, as well as experience of the operator. However, with increasing complexity in biology, these methods have proved to be inadequate, making artificial intelligence a promising technology for process control, which is based on predictive adjustment according to real-time data streams. Such control systems are able to constantly monitor process parameters, including culture growth, metabolite concentration, and the quality of product attributes, and use predictive models to anticipate any issues and prevent their negative consequences [5]. Predictive models created with the help of supervised learning have proven useful in forecasting the yield and the product quality of processes in biopharmaceutical plants [2][3]. In particular, neural network models, which can predict nonlinear relations between conditions of the cultures and characteristics of the product, prove to be more efficient than regression models. This approach may be especially beneficial for upstream processing due to the significant effect of feedstock quality and other environmental factors on performance in downstream stages.

The benefit that unsupervised learning offers in process control is its ability to detect deviations and identify underlying patterns in the process data. The application of clustering techniques and principal component analysis enables the detection of any deviation or change in the state of the processes, which helps avoid failure [5]. Biomedical robots have also utilized unsupervised machine learning to detect abnormalities in the dynamic environment and adapt their behavior accordingly [5]. Applying similar principles in bioprocesses will help ensure that any deviation is detected and batch variation is avoided. Reinforcement learning allows for the optimization of process conditions through interaction with the process environment and improvement of control policies over time. Control actions such as feeding regimes, aeration, and temperatures can be optimized based on learned experience, resulting in higher process output and better energy efficiency [6]. By combining reinforcement learning with digital twins of biological production processes, an AI system can safely train control policies and then apply them to actual processes [10].

Hybrid methodologies that combine the strengths of mechanistic models and data-driven knowledge prove to be highly successful. On the one hand, the mechanistic models have been found to be important for the interpretation of biological processes. On the other hand, AI models have adaptive capabilities. Therefore, a combination strategy has been designed that takes advantage of the strengths of both the modeling approaches in such a way that their weaknesses are overcome by each other. For instance, the reconfigurable manufacturing systems based on AI use large language models in order to achieve sustainability through mechanisms [6].

The requirement for AI-based control processes also emerges from the need for ensuring sustainability. In fact, it has been argued that AI technology could play a significant role in increasing efficiency, reducing wastage, and creating a circular bioeconomy [7]. It implies that apart from efficiency, the bioprocess control approach needs to address the environmental sustainability concerns. In addition to technical performance, regulatory compliance remains a critical requirement for AI-based control systems. In this context, AI-driven process control improves operational stability, predictive capability, and scalability in complex bioprocess environments. Utilizing different types of machine learning, including supervised learning, unsupervised learning, and reinforcement learning along with mechanistic models, such technologies enable foresight and preparation for uncertainties. Considering that bioprocessing is heading toward Industry 5.0, AI-based process control plays a vital role in shaping the future of bioprocessing ecosystems.

Feature	Traditional Control	AI-Driven Control
Control Strategy	Fixed, rule-based	Adaptive, data-driven
Response to Variability	Limited	Real-time adjustment
Predictive Capability	Minimal	High (forecasting deviations)
Data Utilization	Low	High (continuous learning)
Scalability	Challenging	Improved scalability
Efficiency	Moderate	Optimized resource utilization

Table 3: AI-Driven Process Control vs Traditional Control [3, 5, 6]

5. Integration with Digital Twins

The concept of digital twins is a breakthrough technology that holds the capability to revolutionize the bioprocessing industry. Digital twins make use of real-time data and predictive modeling for replicating the behavior of processes. As virtual models of actual processes, digital twins are very useful for performing experiments on various scenarios, optimizing a process, and minimizing the associated risks. The application of artificial intelligence increases prediction accuracy, supports adaptive optimization, and provides autonomous decision-making capabilities [6]. Digital twins combine real-time sensors' data with mechanistic models. In this way, a dynamic simulation model is developed that can replicate the process behavior. The application of artificial intelligence to these models enables the identification of underlying patterns and prediction of future behavior. Reinforcement learning techniques can be applied in the digital twin environment to train algorithms, which then can improve the feeding strategy or optimize the aeration profile [10].

In the context of experimentation in laboratories, digital twins make it possible to conduct assessments of scenarios before the experiment takes place. The scientist can test the impact of several parameters such as different levels of nutrients and variations in temperature on the result obtained at the end of the process. With digital twins, there will be no need for tedious processes of testing different scenarios, and thus time and energy are saved. The following examples show the application of biofoundries that use artificial intelligence [1]. In the application of digital twins, sustainability forms an essential component. With the aid of artificial intelligence simulations, aspects such as resource usage, production of waste material, and energy consumption can be analyzed to facilitate the emergence of a circular bioeconomy [7]. Digital twins make it possible to optimize the flow of resources through a simulation of real-life processes. The implementation of digital twins in bio-inspired control of robots is an additional example of their alignment with Industry 5.0 requirements.

Regulatory aspects also impact the uptake of digital twins. With predictive modeling becoming increasingly crucial in bioprocessing operations, regulatory authorities demand transparency and explainability of the process [8][9]. It is imperative that digital twins provide a valid rationale behind each prediction and exhibit reliability and robustness when used for different purposes. Another option to ensure better performance of digital twins includes their hybrid approach implementation. The combination of the two types of modeling—mechanistic modeling and AI-driven analysis—results in the creation of simulations that are both reliable and innovative. On the one hand, mechanistic modeling enables the use of biological concepts, while on the other hand, artificial intelligence introduces adaptability. In this context, digital twins integrate real-time data, mechanistic modeling, and machine learning to enable predictive simulation and process optimization. Through the provision of scenario analysis, risk reduction, and sustainability, digital twins are set to change the landscape of bioprocessing processes and their control. Artificial intelligence contributes to the effectiveness of digital twins through enhanced accuracy, flexibility, and adherence to regulations to create trust in practitioners and regulatory agencies. As biomanufacturing heads towards an autonomous and predictive environment, digital twins will be key.

6. Regulatory Considerations and Practical Implementation Challenges

There is no doubt that artificial intelligence offers great potential for enhancing the performance of bioprocessing, but its application needs to take into account the scientific and technical aspects involved. The regulatory regime in the field of biotechnology and pharmaceuticals requires reproducibility, traceability, and the ability to provide a mechanistic explanation for each step in order to ensure the quality of the final product [1]. Despite the benefits associated with the use of AI algorithms, they do not usually provide an easily understandable rationale for their decisions. Instead, the system acts like a "black box," giving predictions without any explanation [3].

That reproducibility and traceability are key to bioprocess development. According to the regulator, every decision made regarding process development and control should be justified and explained. It has always been done using mechanistic models, as they provide an interpretable explanation of how a certain change affects the result. However, modern AI models have shown their ability to produce equally accurate predictions as traditional models but without such clarity in their logic.

There are further challenges associated with bioprocess data. Biological data tend to be scarce, messy, and contextually dependent, presenting problems for training and validating models [4]. As part of laboratory work, an iterative validation process needs to be incorporated. Ensuring data integrity in laboratory information management systems is essential for AI's success, as inconsistencies may affect not only the model's performance but also the legal status of a procedure [2]. Given these constraints, current implementations primarily position AI as a decision-support tool to augment operator judgment rather than replace it. In other words, AI should serve as an auxiliary system that enhances operator performance and skills, enabling them to improve their performance in bioprocess management. Using AI in such an incremental manner will be more consistent with regulatory requirements.

The integration of AI technology into currently existing frameworks such as PAT, QbD, and CPV will be crucial to this development. The use of artificial intelligence should augment and not substitute current regulatory frameworks by adding a layer of predictive analysis within these frameworks [1][6]. Such an approach includes the incorporation of AI into the PAT framework through the improvement of sensor data interpretation, into the QbD framework by discovering the critical process parameters, and into the CPV framework through real-time monitoring and predictive controls.

Integration of AI in the current laboratory practices is an inevitable stage required for gaining permission and implementing the technology effectively in biomanufacturing. It is important to test the AI model with actual data and document it as well as comply with the regulation requirements. Definitely, collaboration in this field will demand collaboration from scientists, engineers, and even those engaged in regulatory affairs. While this can be tough, there are numerous ways of overcoming such obstacles.

Challenge	Description	Impact on Bioprocessing	Possible Mitigation
Lack of Interpretability	AI models act as black boxes	Reduced trust and regulatory acceptance	Use explainable AI methods
Data Quality Issues	Noisy, incomplete biological data	Poor model performance	Data preprocessing and validation
Regulatory Compliance	Strict requirements for traceability	Slower adoption	Align with PAT and QbD frameworks
Model Validation	Difficulty in reproducibility	Limits industrial deployment	Hybrid modeling approaches
Integration Complexity	Difficulty fitting into existing systems	Operational inefficiencies	Gradual implementation strategy

Table 4: Key Challenges and Regulatory Considerations in AI Integration [1, 8, 9]

7. Discussion

Artificial intelligence holds vast opportunities for enhancing efficiency, reducing variability, and promoting sustainability within the bioprocessing sector. Through its capability to predict, detect anomalies, and optimize dynamically, artificial intelligence provides a boost to scientific knowledge and autonomous decision-making processes [4]. Nevertheless, the incorporation of artificial intelligence technology into laboratory settings requires careful consideration of the principles guiding the lab operations and regulatory requirements. As mentioned earlier, biological systems' complexity necessitates proper integration of AI technologies, which must work hand-in-hand with traditional approaches [1].

Effective collaboration is vital for the successful application of artificial intelligence technology. Professionals in the field of science, process engineering, and data analytics are important for creating functional computational algorithms. The method allows one to have an effective assessment of these algorithms along with making sure that the created algorithm is practical and useful. As evidenced by agentic artificial intelligence systems implemented in manufacturing companies, human-oriented approaches toward designing predictive tools should be considered as the key element in such projects [4]. One can also mention artificial intelligence biofoundries in biology labs as another example of computational intelligence [1]. AI will continue to find applications in bioprocessing systems of the future by working alongside current process systems. Such examples show how AI technologies could work within regulatory frameworks in an efficient manner. A gradual approach to using AI technologies, starting with relatively risk-free applications like process monitoring, is recommended to facilitate trust in such methods [5].

Sustainability will be another key factor in determining the role that AI would play in bioprocessing. For example, sustainable production models and resource optimization frameworks based on AI tools could be developed to ensure that bioprocesses are in line with current global demands for responsible innovation [7]. Sustainability could be built into AI systems through development of predictive models and bio-inspired robotics processes as part of Industry 5.0 [11]. AI has a lot of potential in bioprocessing applications, but its success depends on integrating it effectively into the laboratory process, regulation, and environment. The cooperation of multidisciplinarity leads to the creation of effective, implementable, and socially responsible AI. Collectively, the convergence of artificial intelligence, digital twins, and advanced sensing technologies is driving the transition toward autonomous and self-optimizing bioprocessing systems.

Conclusion

Artificial intelligence represents a transformative capability in bioprocessing, although proper implementation and sound science are key factors in realizing such potential. It enhances process understanding, repeatability, and scalability across biomanufacturing systems. These advancements do not rely on eliminating human expertise or fully automating biomanufacturing processes. Instead, hybrid integration of mechanistic modeling and AI-based prediction ensures accuracy and interpretability. The automation of biomanufacturing continues to advance by applying methods like digital twin, abnormal behavior detection, and adaptive control. Eventually, biomanufacturing technologies are expected to achieve a balanced integration where human expertise and artificial intelligence operate synergistically. Future development for success in future endeavors includes improving data quality, validation of the models, and their incorporation into existing bioprocessing systems. The success of such an approach depends on the capability to handle biological variability, which can be accomplished using effective data collection methods. Regulatory compliance requires model interpretability, traceability, and proper documentation. Furthermore, the use of real-time process monitoring technology, in combination with sensor technology, enhances adaptability and robustness under dynamic operating conditions. Such integration establishes a foundation for reliable, scalable, and adaptive biomanufacturing systems

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