Original Research Article

Empowering production and operation process optimization through digital technologies

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Abstract: In the context of the rapid development of biotechnology, digital technologies are becoming the core driving force for transforming the production and operational processes of the biotech industry. Based on a biological professional background and production management practices, this paper systematically explores the application paths of digital technologies in the transformation of production processes, optimization of operational processes, and innovative development within the biotech industry. Combining experience in technology transfer from research and development (R&D) to production, it analyzes the significant value of digital collaboration in enhancing production efficiency, reducing operational costs, and promoting sustainable development. This provides a reference framework with both theoretical depth and practical guidance for professionals in the biotech industry regarding career development in the field of business administration.

Keywords: Digital technology; Biotech industry; Production and operation; Process optimization; Technology transfer; Business administration

1. Introduction

As a practitioner with an undergraduate background in biology and ten years of experience in production management and technology transfer from R&D to production in the biotech industry, I have deeply experienced the impact and reshaping of the digital wave on traditional biotech industries[1]. In the entire chain from laboratory bench-scale trials to pilot-scale amplification and then to large-scale production, the complexity of production processes, the precision of operational management, and the urgency of innovation and iteration all urge the industry to embrace digital transformation[2].

2. Application of digital technologies in production processes of the biotech industry

2.1. Digital transformation of production links

In the production practice of the biotech industry, the digital transformation of production links serves as the foundation for improving efficiency and stability. Taking fermentation production as an example, in traditional processes, the control of key parameters such as temperature, pH value, and dissolved oxygen often relies on manual experience and periodic monitoring, making it difficult to achieve precise regulation and real-time optimization. By leveraging digital sensors and Internet of Things (IoT) technologies, various parameters within bioreactors can be collected in real time and transmitted to a central control system[3]. Through establishing a multi-variable dynamic model, full automation control of the fermentation process is realized. For instance, in recombinant protein production, using a digital control system can automatically adjust the feeding strategy according to the cell growth curve, increasing the target product expression level by more than 30%. Meanwhile, digital transformation is also reflected in the interconnection of production equipment. Through an industrial Internet platform, data from key equipment such as centrifuges and purification columns are integrated to form digital twins of production equipment, which can not only predict equipment failures in advance but also optimize equipment operation parameters through virtual simulation, increasing the Overall Equipment Effectiveness (OEE) by 25%.

2.2. Digital means for quality control

Quality control of biological products is highly professional and complex. The full-life-cycle quality management from raw materials to finished products puts forward urgent requirements for the application of digital technologies. In the raw material inspection link, near-infrared spectroscopy (NIRS) combined with machine learning algorithms can complete the rapid detection of medium components within minutes, replacing the traditional physical and chemical analysis that takes hours, with a detection accuracy of over 98%[4]. In the production process, the online quality monitoring system collects real-time data of key process parameters (CPP) and key quality attributes (CQA), and uses multivariate statistical process control (MSPC) technology to establish a dynamic quality early-warning model. When the process deviation exceeds the threshold, it automatically triggers correction measures, reducing the incidence of quality anomalies by 40%[5]. In the finished product inspection stage, the combination of digital image processing technology and AI algorithms enables automatic analysis of complex quality indicators such as the microscopic morphology and purity peak pattern of biological products. For example, in the detection of monoclonal antibodies, the AI system can analyze HPLC (High-Performance Liquid Chromatography) chromatograms 20 times faster than manual analysis, with an error rate of less than 1%[6].

3. Digital technologies facilitating operational process optimization in the biotechnology industry

3.1. Digital integration from R&D to production

As a practitioner with long-term experience in technology transfer from R&D to production, I am acutely aware that the “gap” between R&D and production is a key bottleneck restricting the industrialization of biological products. Digital technologies provide effective means to bridge this gap. By constructing an integrated R&D-to-Production digital platform, full-process data connectivity is achieved from laboratory bench-scale trials, pilot-scale amplification to large-scale production. In the R&D phase, computer-aided process design (CAPD) software is used to virtually screen and optimize biological process parameters. For example, in antibody drug development, Design of Experiments (DoE) software designs hundreds of process parameter combinations, and cloud computing rapidly simulates product expression and quality under different conditions, shortening the process development cycle by 40%[7]. In the pilot scale phase, a digital model for process scaling is established. Based on bench-scale data, it predicts the process performance at pilot scale and identifies potential risks in the scaling-up process in advance. For instance, when scaling up cell culture processes, hydrodynamic simulation is used to predict the shear force distribution in the bioreactor, optimizing agitation speed and aeration strategies to ensure consistency between pilot and bench-scale results. In the production phase, optimized process parameters are automatically imported into the Manufacturing Execution System (MES) to achieve precise transmission and execution of process parameters[8]. Meanwhile, the MES system collects production data in real time and feeds it back to the R&D system, forming a closed-loop optimization of “R&D - Production - R&D”.

3.2. Digital production planning and scheduling

The high complexity of biological production processes and the characteristics of multi-variety and small-batch production make production planning and scheduling a challenge in operational management. Digital technologies achieve full-process optimization from demand forecasting, capacity balancing to process scheduling by constructing an intelligent production planning system. In demand management, machine learning algorithms analyze multi-dimensional data such as historical sales data, market trends, and policy changes to establish an accurate demand forecasting model. For example, in vaccine production, combining epidemic monitoring data with vaccination plans to predict demand fluctuations for different vaccines in different regions increases the prediction accuracy to over 90%. In capacity planning, based on the digital factory model, the production feasibility of different product portfolios on existing equipment is simulated. The Theory of Constraints (TOC) is used to identify capacity bottlenecks, optimize equipment configuration and capacity allocation, increasing equipment utilization by 20%[9]. At the production scheduling level, an Advanced Planning and Scheduling (APS) system is adopted, considering multiple constraints such as material availability, equipment status, and process routes to generate the optimal production schedule. For example, in multi-product collinear production, the APS system automatically calculates the minimum time cost of product changeovers, optimizes batch sequences, and reduces changeover losses by 35%. In addition, through real-time data collection and visual dashboards, production managers can dynamically monitor production progress. When abnormalities such as equipment failures or material shortages occur, the system automatically reschedules and adjusts production plans to achieve dynamic optimization of the production process.

4. Digital technologies promoting innovation and sustainable development in the biotechnology industry

4.1. Integration of product innovation and digital technologies

In the innovative development of the biotechnology industry, digital technologies are emerging as accelerators for product innovation. By deeply integrating digital tools with biotechnologies, new paths for product innovation have been opened. In the field of drug R&D, Computer-Aided Drug Design (CADD) technologies leverage methods such as molecular docking and molecular dynamics simulation to screen potential drug candidate molecules in a virtual environment. For example, in small-molecule drug development, CADD technology can reduce the number of candidate compounds from hundreds of thousands to hundreds, significantly lowering experimental screening costs. Emerging AI-powered protein structure prediction technologies like AlphaFold have further shortened protein structure prediction time from months to hours, providing robust support for the development of biological products such as antibody drugs and enzyme preparations. In the medical device sector, the combination of digital modeling and 3D printing technologies enables personalized customization of biocompatible implants. For instance, a bone model constructed from a patient's CT data can be used to manufacture a titanium alloy implant that perfectly matches the patient's anatomical structure via 3D printing, improving surgical success rates and patient comfort.

4.2. Application of digital technologies in green production

Against the backdrop of global sustainable development, the green production transformation of the biotechnology industry is imperative. Digital technologies offer effective means to achieve low-carbon, energy-saving, and eco-friendly production models. In energy management, intelligent energy management systems are constructed to monitor real-time consumption of electricity, steam, natural gas, and other energy sources during production. Big data analysis technologies identify energy-wasting links—for example, analyzing fermenter operation data to optimize agitation and aeration strategies, reducing energy consumption by 15%–20% while maintaining production efficiency. In waste treatment, digital technologies optimize waste classification, disposal, and recycling processes. For instance, in biopharmaceutical enterprises, digital waste management platforms track medium waste liquid, purification column residues, and other wastes generated during production in real time, automatically matching the optimal treatment plan based on waste properties. Blockchain technology is used to record the entire waste treatment process, ensuring environmental compliance. Water resource management is another key aspect of green production: digital water system management technologies optimize the recycling of production water. For example, in purified water preparation, the combination of membrane separation technology and digital monitoring systems increases water reuse rates to over 70%.

4.3. Role of digital technologies in the biotechnology industry's innovation ecosystem

The innovative development of the biotechnology industry relies on a robust innovation ecosystem. Digital technologies reshape this ecosystem by connecting all industrial chain links and promoting knowledge sharing and collaborative innovation. In industry-university-research collaboration, digital platforms break down information barriers between universities, research institutes, and enterprises, enabling the sharing and collaboration of R&D data and experimental resources. For example, a digital collaborative R&D platform established by a biological innovation center allows research teams to share data such as gene sequences and protein structures online, while enterprise R&D personnel can participate in project discussions in real time, accelerating the transformation efficiency of scientific research achievements. In industrial clusters, digital technologies foster collaborative innovation among enterprises in biotech parks. By establishing park-level digital service platforms, resources such as shared laboratories, pilot workshops, and testing services are provided, reducing innovation costs for small and medium-sized enterprises. For instance, a biotech industrial park in Shanghai increased the utilization rate of idle analytical testing equipment from 30% to 70% through a digital sharing platform, while saving equipment procurement costs for resident enterprises.

5. Conclusion

In summary, digital technologies represent the key to the transformation of the biotechnology industry. They optimize production and operations while driving innovation and sustainable development. Practitioners should integrate professional, digital, and management capabilities to seize opportunities in industry transformation and achieve career breakthroughs.

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