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Mitigation of Scale-Up Risks in Technology Transfer of Vaccines and other Bioproducts

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ABSTRACT

This article explores the subject of mitigating the risks associated with technology transfer in the bioproduction sector such as vaccine industries, which is a challenging and multifaceted process. Based on an examination of case study data, industry reports, and insights gained from over 20 years of bioprocessing experience, it is evident that a comprehensive understanding of the variables involved and meticulous attention to detail are necessary for successful scale-up. Key technological factors include strict regulatory compliance, equipment compatibility, and optimization of process parameters. Organizations can minimize the risks associated with scaling up bioproduction processes and effectively manage the complexities of technology transfer by implementing data-driven strategies and advanced modeling tools.

INTRODUCTION

Technology transfer and scale-up are common yet crucial activities in the bioproduction industry. Technology transfer is the process of disseminating technology from the organization or individual that owns or holds it to another entity, with the aim of transforming inventions and scientific outcomes into new products and services that benefit society [1, 2]. This process enables the duplication of procedures, techniques, and technologies in a different setting, ensuring reliability and consistency in output. Technology transfer is closely linked to technology management practices and skills.

When pursuing commercialization, technology transfer is often necessary at some point, whether the manufacture of a drug/vaccine candidate is handled by a contract development and manufacturing organization (CDMO) or a drug/vaccine developer. A technology transfer is required for scale-up projects to achieve better manufacturing efficiency due to the need for a larger batch size (e.g., when transitioning from clinical or laboratory to large-scale manufacturing for product launch). Furthermore, insufficient resources or capacity may exist for supply chain management, secondary packaging, commercial manufacturing, process optimization, and/or commercial production. Biopharmaceutical companies often require technology transfers to ensure patient supply and the availability of a backup manufacturing plan, both of which are essential for risk management. Effective technology transfer can help companies accelerate time-to-market, reduce costs, and improve competitiveness in the market.

Despite its importance, technology transfer poses significant risks during the scale-up process [3]. Scaling up processes introduces several challenges that can impact product consistency and yield, such as variations in operating conditions, equipment performance, and raw material quality. Transitioning from small-scale to large-scale production often necessitates different equipment and infrastructure, leading to compatibility issues and operational challenges. Additionally, meeting regulatory requirements for large-scale production is complex and can have significant implications for product quality and market approval. Technology transfer already comes with numerous complexities inherent to the product and the process, and scaling up introduces a host of new problems. Due to these complexities, every technology transfer carries a high risk and involves strict regulatory requirements and meticulous attention to detail. If critical details are overlooked, a poor technology transfer can result in significant and enduring consequences.

There are several considerations to be made in the scale-up step because as the scale increases, various process parameters typically behave differently. For example, the difference in dimensions when scaling up cell culture from bench-top bioreactors to single-use bags at a 50-500 L scale, to a 1,000-10,000 L stainless steel tank, leads to changes in fluid dynamics

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and physical limitations. This necessitates adjustments in the management of gas transfer, shear, mass, and heat transfer, among other elements, and potentially longer mixing times incorporating additional limiting nutrients. Similarly, for chromatography, bed height adjustments are often needed, columns will feel the effect of increased loads and hold times, while column packing and acceptance criteria become more complicated and relatively unknown. Furthermore, the impurity profile can be affected at larger scale due to sampling around peak cuts during engineering runs, and buffer management must be carefully considered [4].

As such, it is critical to minimize the risks associated with scale-up to ensure a smooth and viable technology transfer. The significance of anticipating process development (PD) is crucial, as it involves recognizing the potential challenges that may arise when scaling up, such as the increased complexity in sourcing high-quality raw materials. Additionally, strategic preplanning and meticulous selection of unit operations at initial stages can yield significant benefits as the scale increases. For example, it is important to avoid using a fermenter that generates heat of 60 kW/m3 in the early phase, as this would be beyond practical use at larger scale.

A firm understanding of the development process is crucial. Comprehensive knowledge of the process simplifies scaling up, conducting experiments and criticality analysis, investigating the design space, and performing robustness studies. To further minimize risk, undertaking specific small-scale experiments early on is encouraged, as these can mimic and prepare the team for the effects of scale-up and scale-down, while also offering a better understanding of hold time validations [5]. To mitigate scale-up risks in technology transfer, scientists and practitioners in the biotech industry can consider the following recommendations:

1. Comprehensive Process Understanding: Conduct a thorough analysis of the process parameters, critical quality attributes, and potential sources of variability to identify the key factors influencing successful scale-up.
2. Robust Process Validation: Implement a systematic approach to validate the scaled-up process through pilot studies, risk assessments, and performance evaluations to ensure consistency and reliability.
3. Collaborative Partnerships: To maximize their knowledge, resources, and best practices for technology transfer and scale-up initiatives, collaborate with experienced suppliers, partners, and regulatory specialists.
4. Continuous Monitoring and Optimization: To analyze process performance, detect deviations, and promptly adopt corrective actions, establish effective monitoring systems, data analytics, and feedback loops.

Technology transfer is a multifaceted and dynamic process that encompasses several key steps: knowledge creation, disclosure, assessment and evaluation, intellectual property protection, fundraising and technology development, marketing, commercialization, product development, and impact assessment [6]. The primary aim of technology transfer is to ensure that scientific and technological developments are accessible to a wider range of users, who can then further develop and exploit the technology into new products, processes, applications, materials, or services [7]. In practice, this dynamic process requires comprehensive consideration of the regulatory and reporting requirements, documentation, available technology tools, risk management, contractual obligations, and communication with contract development and manufacturing organizations (CDMOs). Regarding the fact that scaling up can impact the productivity and quality of biologics, proactive future planning in process development design can help minimize risks.

By understanding the necessity of technology transfer, recognizing common scale-up risks, and implementing proactive strategies to overcome these challenges, scientists and practitioners can enhance the efficiency, quality, and competitiveness of their production processes. Through collaboration, innovation, and continuous improvement, the biopharmaceutical industry can achieve sustainable growth and success in a dynamic and evolving market landscape.

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CONFLICT OF INTEREST

The author declares that he has no conflict of interests.

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