Understanding the Biomanufacturing Process and the Role Played by Biofoundries

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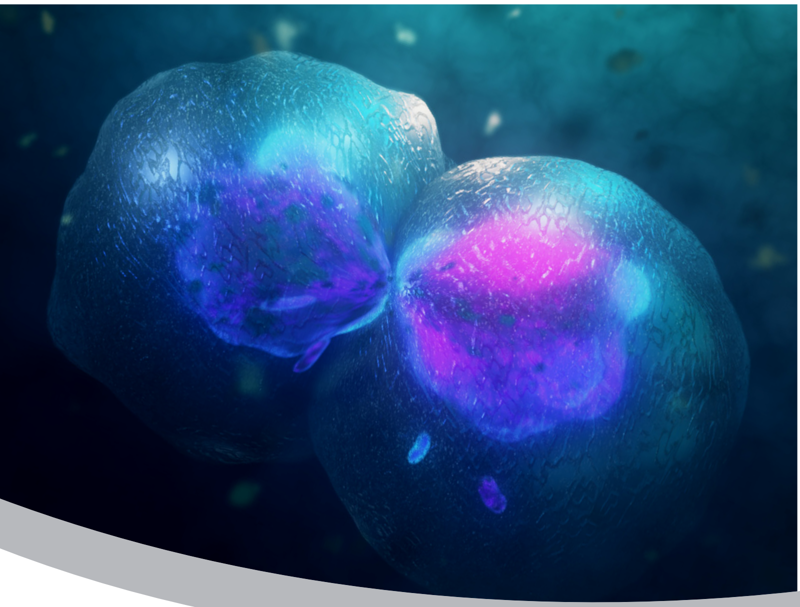

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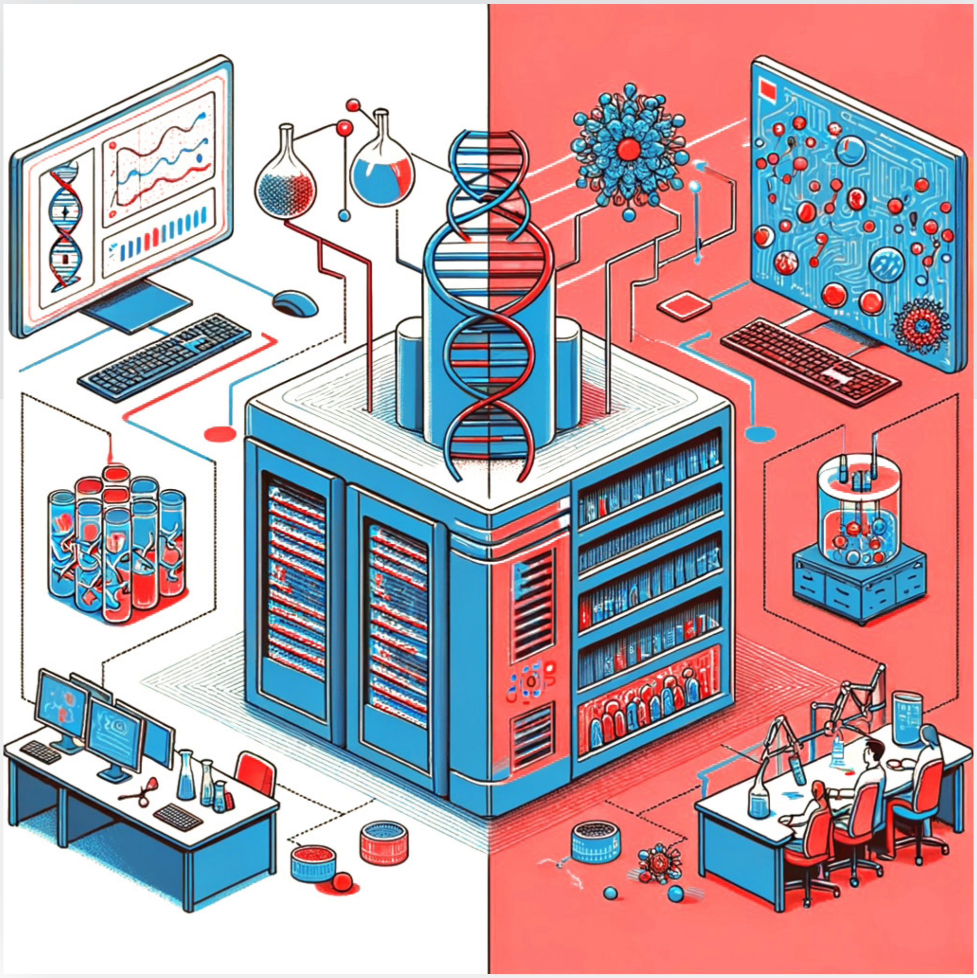
BIOMANUFACTURING is the application of biological systems and processes to produce commercially valuable products. It involves leveraging biological systems—such as microorganisms, cells or enzymes—in a controlled manufacturing environment to produce a range of products. These products span from pharmaceuticals and vaccines to biofuels, industrial materials, food, beverages, and beauty ingredients.



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01 Introduction

Introduction to biomanufacturing

Biomanufacturing is the application of biological systems and processes to produce commercially valuable products. It involves leveraging biological systems—such as microorganisms, cells or enzymes—in a controlled manufacturing environment to produce a range of products. These products span from pharmaceuticals and vaccines to biofuels, industrial materials, food, beverages, and beauty ingredients.

Integrating cell-free systems and in vitro transcription/translation into biomanufacturing can enhance production efficiency and versatility by enabling faster prototyping, easier optimization, and the synthesis of difficult-to-express proteins. For instance, in vitro transcription (IVT) is commonly used in the production of mRNA vaccines, and for protein production in vitro transcription/translation (TX/TL) is applied (Klocke et al., 2018; N. M. Drzeniek et al., 2024).

While for the applied market the biomanufacturing goal is time to market and diminishing cost, for drug development, the main goal is effective therapeutics. Nevertheless, both domains need to apply similar research processes of bioengineering and organism selection. In this article we will focus on the non pharmaceutical processes, that try to develop sustainable processes that minimize environmental impact.

This includes creating eco-friendly biofuels, improving agricultural practices, applying the *"farm to fork strategy,"*[1] and reducing reliance on non-renewable resources.

The biomanufacturing process involves several key stages (Sadiku et al., 2023).

1. The "Farm to Fork" strategy is increasingly being adopted globally to create a more sustainable and resilient food system. It recognizes the interconnectedness of all stages of food production and consumption and strives to improve the overall health and sustainability of the food supply chain.

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Key stages of the biomanufacturing process

Upstream Development

This stage involves selecting or modifying organisms using advanced technologies such as synthetic biology and gene editing. The goal is to optimize these organisms for the production of specific commercial products.

Analytical Validation

Ensures the quality and accuracy of the product through rigorous testing. This stage is crucial for meeting regulatory standards and ensuring product efficacy and safety (Cameron et al., 2014).

Data Treatment and Integrity

AI in synthetic biology helps navigate the vast design space of engineering organisms. Accurate data and meticulous treatment are essential for AI to effectively narrow down possibilities and pinpoint optimal solutions.

Downstream Processing

Focuses on scaling up production while maintaining strict quality control. This stage includes the purification of the product and preparation for commercial distribution.

Industrial companies recognize the imperative to develop sustainable processes, but the major challenge today is time. Achieving Net Zero across Scopes 1, 2, and 3[2] within the agreed timelines requires not only significant investments but also the rapid adaptation and development of new technologies that can accelerate both research and operational efficiency. The pressure to reduce emissions quickly, while maintaining competitiveness, has created an urgent need for solutions that can decrease time-to-market and risk of failure. As a result, industries are now seeking breakthroughs that allow for faster innovation cycles, scalable decarbonization pathways, and leaner, more adaptive supply chains (Rogelj et al., 2021).

In response to these pressing challenges and the need for rapid innovation, industries are increasingly turning toward a **confluence of advances in biological science**, often referred to as the Bio Revolution.

McKinsey defines the Bio Revolution as a transformative period in biological sciences that has the potential to significantly impact various sectors, including human health, agriculture, consumer products, and materials. This revolution is characterized by the increased ability to engineer and reprogram both human and non-human organisms, enhancing control and precision in biological processes (McKinsey Global Institute, 2020).

2. Scope 1: Direct emissions resulting from vehicles, fuel use, and/or chemical leakage; Scope 2: Indirect emissions resulting from bought electricity, cooling, heat and/or steam; Scope 3: Other indirect emissions that occur in the value chain of a company and are not already included within scope 2 (such as emissions resulting from purchased goods and services, transport, or business travel)

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Modern biotechnology advances span pharmaceutical innovations (cell, gene, RNA, and microbiome therapies), reproductive medicine, drug development, and industrial applications including enhanced fermentation processes and biopolymer production (McKinsey Global Institute, 2020). Industries are actively exploring new manufacturing options and selecting the right clones for producing biological alternatives to conventional products.

Figure 1: Examples of Biomanufacturing Systems

Explore in this article the critical stages and innovative technologies in upstream biomanufacturing development, focusing on organism selection, genetic modification, and process optimization, all supported by advanced automation and data management solutions. Examine how laboratory automation solutions can efficiently respond to time constraints and help researchers and industry achieve net zero scope. Walk through the biofoundry world and witness real-time application of functionalities, as demonstrated by Lesaffre Biofoundry at the end.

02 Upstream Development

This is the end of the preview. If you would like to download the entire casebook, please visit becls.co/43YM9Se

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