Perspective

Pharmaceutical BIOPROCESSING

Cell Expression Systems for Biopharmaceutical Production

Umat Kaya*

Department of Pharmacy, Bent University, Berlin, Germany

*Author for correspondence: umat.kay@ugent.be

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Introduction

Biopharmaceuticals, including monoclonal antibodies, vaccines and therapeutic proteins, have revolutionized modern medicine. The production of these biologics relies heavily on cell expression systems, which serve as biological factories to synthesize these complex molecules. These systems are carefully chosen and engineered to ensure optimal yield, quality and functionality of the biopharmaceutical products. This article explores the major cell expression systems used in biopharmaceutical production, their advantages, challenges and recent innovations in the field.

Description

Overview of cell expression systems

Cell expression systems refer to living cells that are engineered to produce specific biopharmaceuticals. These systems are broadly categorized into:

Prokaryotic systems (e.g., *Escherichia coli*)

Eukaryotic systems (e.g., yeast, insect cells, mammalian cells and plant cells)

Each system has distinct characteristics that make it suitable for specific applications, depending on the complexity and requirements of the biopharmaceutical being produced.

Prokaryotic systems

Escherichia coli (*E. coli*): *E. coli* is one of the most widely used prokaryotic expression systems due to its rapid growth, simple genetics and cost-effectiveness. It is particularly suitable for producing small, simple proteins without Post-Translational Modifications (PTMs).

Advantages: High yield and rapid production. Simple and scalable fermentation processes. Cost-effective media and growth conditions.

Challenges: Limited ability to perform PTMs, which are critical for many therapeutic proteins. Potential formation of inclusion bodies, requiring additional refolding steps.

Endotoxin contamination risks, necessitating stringent purification protocols. Despite these challenges, *E. coli* remains indispensable for producing recombinant proteins like insulin and growth hormones.

Yeast expression systems

Saccharomyces cerevisiae and *Pichia pastoris*

Yeast systems bridge the gap between prokaryotic and mammalian systems by offering some PTM capabilities while retaining the simplicity of microbial growth.

Advantages: Capability to perform glycosylation and other PTMs (though simpler than mammalian systems). Robust and scalable fermentation processes. High secretion efficiency for extracellular protein production.

Challenges: Glycosylation patterns differ from human systems, which can affect protein functionality and immunogenicity. Proteolytic degradation of expressed proteins. Yeast systems are widely used for producing vaccines (e.g., hepatitis B surface antigen) and enzymes.

Insect cell systems

Baculovirus Expression Vector System (BEVS). Insect cells, such as Spodoptera Frugiperda (Sf9) and Trichoplusia ni (High Five), are used in conjunction with baculoviruses to produce complex proteins.

Advantages: Efficient expression of high-molecular-weight and complex proteins. Superior protein folding and PTMs compared to prokaryotic and yeast systems. Low risk of contamination with human pathogens.

Challenges: Longer development timelines and higher production costs compared to prokaryotic systems. Limited scalability for industrial-scale production. Insect cell systems have been instrumental in producing viral vaccines, such as the influenza vaccine.

Key considerations in system selection

Choosing the right cell expression system depends on several factors:

Protein complexity: For simple proteins, *E. coli* or yeast may suffice, while mammalian systems are essential for monoclonal antibodies and glycoproteins.

Regulatory requirements: Compliance with stringent regulatory standards for clinical applications often favors well-established systems like CHO cells.

Conclusion

Cell expression systems are the backbone of biopharmaceutical production, enabling the synthesis of life-saving therapeutics. As technology advances, the field continues to evolve, offering new opportunities to enhance efficiency, reduce costs and expand access to biologics. By understanding and leveraging the strengths of each system, the biopharmaceutical industry is poised to address the growing global demand for innovative and affordable healthcare solutions.