Editorial

Pharmaceutical BIOPROCESSING

Developing an Free Bioprocess to Produce Pharmaceutical Quality Grade

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Abstract

In 2005, the American Chemical Society (ACS) Green Chemistry Institute (GCI) and global pharmaceutical companies established the ACS GCI Pharmaceutical Roundtable to encourage the integration of green chemistry and engineering into the pharmaceutical industry. The Roundtable developed a list of key research areas in green chemistry in 2007, which has served as a guide for focusing green chemistry research. Following that publication, the Roundtable companies have identified a list of the key green engineering research areas that is intended to be the required companion of the first list. Intense efforts in bioprocessing development have been made to improve the production of Chinese hamster ovary-based biopharmaceuticals. However, lacking an efficient host cell has hampered therapeutic protein production. This article reviews means by which biopharmaceutical production can be improved via cell engineering. Finally, rational cell engineering facilitated with 'omics technologies is presented.

Introduction

The pharmaceutical industry is devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives and is committed to bringing key medicines to the patient with minimal environmental impact. The concept of Green Engineering is not new in pharmaceutical manufacturing.

In 2007 the Roundtable developed a list of key Green Chemistry research areas1 that was published as a perspective article to provide an assessment of the current state of the art in those areas, and to highlight opportunities for future improvement. As a natural follow up to the 2007 work, the Roundtable has decided to develop and publish key green engineering research areas from the perspective of pharmaceutical and fine chemical manufacturers. In this paper, the process for defining these key areas and research needs is reported, and their research challenges and opportunities for improvements from the pharmaceutical industry perspective are defined.

For drug product production, additional research and development is required for understanding the fundamental engineering of operations such as blending, granulation, and drying. Although it is assumed that the benefits of continuous operation may be more fully realized with the design of new production facilities, there is a need to develop process intensification approaches that can be applied to convert batch multipurpose facilities into continuous. The increasing patient population needs high-level production of biopharmaceuticals. For instance, the dosage requirement of non-antibody proteins, such as tissue plasminogen activator and erythropoietin, is relatively low (25–125 IU/kg). However, several hundred milligrams of monoclonal antibody (mAb) each week is needed to maintain antibody level over 10 g/ml in human serum. Therefore, it is desirable to achieve high production capacity of mAb, for example 10,000 kg/year for a single branded biopharmaceutical.

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Conclusion

With the continuing growth of CHO cell-based biopharmaceutical market, it is of great interest to rationally design and develop an effective host cell to achieve the desired features of therapeutic proteins, in other words, high productivity, quality and stability., all the achievements in traditional and next-generation cell engineering will accelerate the efficient production of biopharmaceuticals and the development of innovative therapeutic protein, which will finally benefit the disease treatment for humans and extend the lives of millions of patients.