MAMMALIAN CELL PROTEIN EXPRESSION FOR BIOPHARMACEUTICAL PRODUCTION

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Mammalian cell expression has become the dominant production system of therapeutic recombinant proteins for clinical applications mainly due to its ability to synthesize proteins that are similar to those naturally occurring in humans with respect to molecular structures and biochemical properties. Cell line development, optimization of culture medium, and feeding strategies are the key factors that contributed to increase production from below 100 mg/L to over 10 g/L. Chinese hamster ovary cells have been used to produce majority of products both on the market and in clinical development, since the expression system and production process are well-developed. Nevertheless, significant progresses in developing and engineering new cell lines, introducing novel genetic mechanisms in expression, gene silencing, and gene targeting, have been reported in the last several years. Various methods have been reported to increase production yield through engineering host cells, designing vectors with new selection, improving culture media with additives and feeding strategies, and optimizing process control such as temperature, pH, and osmolality. With the latest analytical methods development, much attention is being devoted towards product quality including post-translational modification, which leads to production of therapeutic biopharmaceuticals with better quality. For early development of therapeutic proteins, the transient gene expression has been remarkably improved and has become an attractive approach for supplying material for preclinical and potentially for clinical applications.

Conclusion This presentation is focused on the latest advancements in the field, especially in active areas such as newly developed cell lines, expression systems, glycosylation impact factors, and transient gene expression.

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