



Advances in Recombinant Protein Therapeutics

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DESCRIPTION

Therapeutic protein drugs are an important class of medicines that help patients who are most in need of advanced treatment. Recently approved recombinant protein therapies have been developed to treat a variety of clinical indications, including cancer, autoimmunity or inflammation, exposure to infectious agents, and genetic disorders. Recent advances in protein engineering technology have enabled drug developers and manufacturers to optimize and leverage the desired functional properties of the protein of interest while preserving the safety and or efficacy of the product. Similarly, protein therapies containing monoclonal antibodies and large or fusion proteins can be orders of magnitude larger than small molecule drugs with molecular weights. In addition, protein therapies have complex secondary and tertiary structures that must be maintained.

Protein therapies cannot be completely synthesized by chemical processes and must be made in living cells or organisms. Therefore, the choice of cell line, species origin and culture conditions will affect the properties of the final product. In addition, most biologically active proteins require post-translational modifications, which can be compromised using heterologous expression systems. In addition, the product is synthesized by cells or organisms, requiring complex purification procedures. In addition, viral clearance processes such as removal of viral particles by the use of filters and resins, and inactivation steps by the use of low pH values or detergents are implemented to prevent serious safety issues of viral contamination of protein drugs. The complexity of therapeutic proteins is high in molecular size, while increasing the safety and efficacy of the product achieved by protein engineering, given

the various biological materials involved in post-translational modifications and manufacturing processes. The ability to enhance certain functional attributes. The strategy is achieved, maintained and highly desirable.

The integration of drug modification strategies and approaches for new proteins is not trivial but potential therapeutic benefits are increasing the use of such strategies during drug development. Currently, many protein engineering platform technologies are used to improve the circulating half-life, targeting, and function of new therapeutic protein drugs to improve production and product purity

With factor enzyme hormone replacement therapy frequent dosing regimens can have serious adverse effects on patient health, especially in infants, in terms of ease of administration and compliance. Addition of signal peptide or antibody-formation of drug conjugates there by limiting toxicity and increasing drug efficacy. In addition, the utilization of specific functional properties of protein drugs can be achieved by protein engineering. For example, engineering strategies that affect the glycosylation pattern of a protein can affect the receptor binding properties and overall effector function of the protein incorporated by a recently approved therapeutic protein. The ease and stability of performing genetic engineering is especially important because all expression systems require the use of transgenic organisms or cell lines. Expression systems with many genetic tools, such as well-characterized and optimized expression vectors and strong promoters for use in that particular system, have advantages. Using a well characterized system reduces development time and increases the predictability of the production process. Plant expression systems are relatively easy to manipulate genetically, and transgenes are generally more stable than bacterial systems.

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