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Molecular pharming: The new frontier for biopharmaceutical production

Dinesh K Yadav

Amity University, India

Abstract

Most biopharmaceuticals are made at great expense in mammalian cells or compromise in fermentation vats containing bacteria. Limitations involved with traditional fermentation vats and recent advancements in the area of plant biotechnology represents an unprecedented opportunity to manufacture affordable modern pharmaceuticals at large-scale and make them available at a global scale. Molecular farming provides an alternative approach for the production of safer and more economical biopharmaceutical proteins than the established systems. Over the last decade, several efficient plant-based expression systems have emerged, and >100 recombinant biopharmaceutical proteins have now been produced. Plants have many advantages over other production systems, particularly in terms of practicality, economy and safety. Plants are now successfully used to produce immunogens as well as adjuvants, microbicides, monoclonal antibodies as effective and preventive immunotherapeutics. Expression level and post-translational modification pose certain limitation to the current technology. The plant-made biopharmaceuticals have shown minor deviation in the structure of *N*-glycans as compared to traditional biopharmaceuticals. These plant-specific *N*-glycans can be immunogenic and pre-existing antibodies against plant-glycans in human serum may lead to adverse effects. Non-human glycans structure can be customized by the development of glycoengineered plants having tailored glycoforms to produce humanized biopharmaceuticals. This customization of glycoform is not achievable in traditional systems.

The original vision of molecular pharming to produce inexpensive, authentic and readily available biopharmaceuticals will only realize and materialize its huge potential if these constraints are successfully customized through rigorous and detailed studies.