
Preface

Altogether, the biochemical, technical and economic limitations on existing prokaryotic and eukaryotic expression systems and the growing clinical demand for complex therapeutic proteins have created substantial interest in developing new expression systems for the production of therapeutic proteins. To that end, plants have emerged in the past decade as a suitable alternative to the current production systems, and today their potential for production of high quality, much safer and biologically active complex recombinant pharmaceutical proteins is largely documented.

The chapters in this volume, contributed by leaders in the field, sum up the state-of-the-art methods for using a variety of different plants as expression hosts for pharmaceutical proteins. Several production platforms are presented, ranging from seed- and leaf-based production in stable transgenic plant lines, to plant cell bioreactors, to viral or *Agrobacterium*-mediated transient expression systems. Currently, antibodies and their derived fragments represent the largest and most important group of biotechnological products in clinical trials. This explains why the potential of most production platforms is illustrated here principally for antibodies or antibody fragments with acknowledged potential for immunotherapy in humans. In addition, a comparison of different plant expression systems is presented using aprotinin, a commercial pharmaceutical protein, as a test system.

Although multiple books and monographs have been recently published on molecular pharming, there is a noticeable dearth of bench step-by-step protocols that can be used quickly and easily by beginners entering this new field. This volume aims to fill the void by presenting detailed protocols for using the main plant expression systems, for rapidly detecting and quantifying recombinant proteins in a crude plant protein extract. Several chapters feature methods to improve the yield and stability of recombinant proteins using targeting to different subcellular organelles, expression of protease inhibitors or fusion to carrier sequences.

Most biopharmaceutical products have the potential to be immunogenic in at least a small population of human subjects. In this respect, the immunogenicity of plant N-glycans in mammals is a major concern. Protocols, extra notes and problem-solving tips are presented to define whether, how and where a pharmaceutical protein expressed in plants is glycosylated. However, until a number of plant-derived therapeutic glycoproteins have completed their clinical development and registration process, the risk related to parenteral administration of these products in humans remains purely theoretical. Principles and methods of biosafety and risk assessment of plant-derived therapeutic proteins for humans and for the environment are detailed in the last two chapters, which are dedicated to the safe development of plant-made pharmaceuticals.

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