

# Preface

In recent years, plants have been increasingly explored for the production of biomedicines and vaccine components. The two main advantages of plant systems are low cost and a greater potential for scalability as compared to microbial or animal systems. An additional advantage from the public health point of view is the high safety compared to animal systems, which is important for vaccine production: there are no known plant pathogens capable of replicating in animals and in humans, in particular. A particular antigen or a protein has to be expressed in a plant using one of the many available platforms; this antigen/protein subsequently needs to be purified or processed, and later formulated into a vaccine or a therapeutic; these need to be delivered to a human or animal body via an appropriate route. Naturally, all these vaccines and therapeutics must be subjected to regulatory approvals prior to their use. Thus, the challenge is to adapt plant-based platforms for the production of cost-efficient biomedical products that can be approved by FDA for use as vaccine components or therapeutics, which will be competitive against existing vaccines and drugs.

This volume attempts to address the entire spectrum of challenges facing the nascent field of plant-based biomedical products, from the selection of an appropriate production platform to specific methods of downstream processing and regulatory approval issues. The chapter by D.C. Hooper is devoted to immunological issues that can arise for antigens produced in plants and delivered to a human or an animal via different routes. This chapter also discusses such specific topics as tolerance and immunomodulation, with particular reference to oral delivery of plant produced antigens. The chapter by Smith et al. discusses one specific example of a virus-based platform for the expression of peptides in plants, and related issues of downstream processing, that is, manufacture and purification of virus particle-based vaccines, and final product release and stability. Another production platform, via chloroplast-based expression of proteins, is discussed in the chapter by S. Chebolu and H. Daniell. The chapter presents several examples of various vaccine components and other biomedical products produced in plants, and these range from bacterial and viral proteins to human serum proteins and antibodies. The chapter by Ko et al. describes a particular application of the plant-based production of human antibodies used for passive immunization against rabies. It is an example of a classical transgenic technology modified for a specific expression of two antibody

chains. The chapter by R. Hammond and L. Nemchinov reviews the current status of plant production of veterinary vaccines, utilizing a great variety of platforms. The final chapter by C. Tacket presents case studies for the human trials of the first plant-produced candidate vaccines and discusses several regulatory issues that need to be addressed prior to their approval.

Production of vaccine components and other biomedical products in plants has a great potential in medicine and veterinary science. We hope that this volume will be a valuable contribution to this rapidly growing research field.

USA

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