ADVANCES IN BIOTECHNOLOGICAL PROCESSES

VOLUME 6

Editor
Avshalom Mizrahi

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Preface

This, the sixth volume in the series **Advances in Biotechnological Processes,** covers in depth several important and interesting aspects of the production and manufacture of biologicals.

For the first time, the topic of biosafety in experimental and commercial production of biologicals is covered in detail. This contribution was intended to fill a gap in the literature, particularly with regard to safety applications in R&D relating to infectious agents and genetic engineering hazards. Also included is a risk assessment that considers the agent, the worker, and the process. Another topic covered in detail is the subject of cyclodextrin manufacture by microbial digestion. This chapter deals with the biochemistry of cyclodextrin glycosyltransferases, including their isolation and purification, as well as their degradation, production, and modification. The applications of the cyclodextrin inclusion complexes are described fully, with special reference to their enhancement properties.

Solar energy applications have also found a role in biotechnology. Through the bioconversion of solar energy into microalgae, it is possible to create polysaccharides, lipids, hydrocarbons, pigments, and antibiotics, among other pharmaceuticals.

On-line instrumentation for determining biochemical and physiologic parameters that govern the fermentation of animal cells permits refined applications of biosensors in the determination of various enzymes and their levels of production, a topic that is covered in the third chapter of this volume.

Hybridoma technology in the production of human monoclonal antibodies and lymphokines is also described fully. From preparation of parent cells, through fusion techniques, to large-scale production and long-term storage, this technology has broad applications in the 1980s and beyond.

The last of the seven chapters in this volume of **Advances in Biotechnological Processes** describes in detail the problems associated with the handling of synthetic viral vaccines, particularly those that are genetically engineered.

It is to be hoped that the comprehensive treatment of these aspects of creating and producing biologicals will be of value to laboratory scientists in industry and in the university, as well as to postgraduate students and others interested in this burgeoning field of scientific growth—a field that has widespread applications in the pharmaceutical and health sciences, agriculture, nutrition, pollution control, and energy conservation.

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Biosafety in Biotechnological Processes

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I. INTRODUCTION

The great Chinese philosopher Confucius asked: "What can you do if you have to confront a tiger?" He analyzed the alternatives and suggested three strategies: 1) you can put on heavy armor that the tiger cannot harm; 2) you can use suitable weapons to kill the tiger; 3) you can throw a cage over the tiger and lock him in.

What are the parallel concepts applied to biotechnology safety? Let us say that the various hazardous biological agents are the tiger. As for the armor—we can defend ourselves by safety equipment and regulations; the weapons used are decontamination methods and materials; and the cage is the safety cabinets that keep the hazardous agents away from the worker and the environment.

But let us ask ourselves: are biotechnological processes hazardous at all and do we have to be concerned about our safety? In the tiger case the danger is understood by everybody; it is not so obvious when we deal with routine laboratory experiments and techniques in research and development, and much less so in the vast variety of well-established and upscaled biotechnological processes.

Let us ask another question: do we have to be afraid of the big bad tiger, or shall we say the little bad virus? We all fear the unknown if we know that a danger exists and do not know how to handle it. This fear might lead to wrong decisions and faulty execution, which can result in accidents and infection. Conversely, overconfidence, negligence, or ignorance of the danger cause many accidents. That is why we have to be aware of the hazards and to learn how to minimize them by applying relevant safety rules, procedures, and equipment.

Another point to consider is the attitude toward biological safety. Some scientists tend to mitigate the hazards, bearing in mind only the execution of the experiment, and dismiss all safety demands. This attitude is wrong and inconceivable today. The motto in the biological laboratory should be: "No experiment is so important that it can't be done safely." There is nothing heroic in getting infected in the lab; maybe it was in Pasteur's day, but it is unacceptable today. Additionally, it is one thing to take a chance with your own health, as did Pasteur, but unsafe handling of hazardous biological agents can affect innocent bystanders and can have an unforeseen impact on the environment.

A special emphasis must be applied to safety in biotechnological processes; in addition to the usual hazards in the research and development