

# 19 Products of Biotechnology



## OBJECTIVES

After reading this chapter, the student will be able to:

1. Differentiate between the various techniques using living organisms in the production or modification of biotechnology drugs
2. Describe the classification of products of biotechnology used in clinical practice
3. Provide examples of biotechnology drugs for each classification of biotechnology drug type
4. Summarize important concepts associated with biotechnology product handling, storage, and administration
5. Describe the mission of the Food and Drug Administration (FDA) Office of Biotechnology Products and its structure
6. Discuss the general composition of biotechnology products

The term *biotechnology* encompasses any technique that uses living organisms (e.g., microorganisms) in the production or modification of products. The classic example of biotechnologic drugs was proteins obtained from recombinant DNA (rDNA) technology. However, biotechnology now encompasses the use of tissue culture, living cells, or cell enzymes to make a defined product. rDNA and monoclonal antibody (MAb) technologies have provided exciting opportunities for the development of more pharmaceuticals and approaches to the diagnosis, treatment, and prevention of disease.

The biotechnology pharmaceutical market in the United States for 2009–2013 forecasts the biotechnology pharmaceutical market to grow at a compound annual growth rate of 7.7% with blood modifiers accounting for the largest share of the market at 36.3%. The major growth factors include

1. Increased demand for biotechnology drugs with enhanced efficiency, safety, and popularity

2. Revised regulations and standards in encouraging more companies to invest in the field
3. Increased aging population and chronic and age-related illnesses (1)

Biotechnologic products will continue to have a marked impact upon the practice of pharmacy. Research will continue to generate potent new medications that require custom dosing for the individual patient and concomitant pharmacists' expertise in the use of and familiarity with sophisticated drug delivery systems.

*Pharmacogenomics* is the application of genomic technology to genetic variation in response to pharmaceutical compounds. It is an emerging discipline and an outgrowth of pharmacogenetics that seeks to describe the genetic basis for interindividual differences in drug effectiveness and toxicity, using genome-wide approaches to identify genes that govern an individual's response to specific medications. The initial draft of the human genome has demonstrated that the human genome