16 Biologics

OBJECTIVES

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

1. Define, compare, and contrast the different types of immunity
2. List the standards and control requirements needed for the production of biologics
3. List various sources of valuable information for the proper use, storage, and administration of biologics
4. Compare and contrast the types of biologics for active immunity and their mechanism of action
5. List the sources of biologics for passive immunity
6. Describe the possible adverse drug reactions for biologics based on their mechanism of action, administration, and/or excipients
7. Describe the childhood and adult immunization schedules

The Food and Drug Administration (FDA) refers to immunizing agents as biologics. In an encompassing manner, a biologic is a substance produced by a living source; biologics include antibiotics, hormones, and vitamins, among others. The Advisory Committee on Immunization Practices (ACIP) refers to immunizing agents as *immunobiologics*.

According to the *Code of Federal Regulations*, a biologic product is any virus, therapeutic serum, toxin, antitoxin, or analogous product employed for prevention, treatment, or cure of diseases in humans. The purpose of these products is to help develop immunity in the person receiving them. Immunity is defined as natural or acquired resistance to disease.

Provision of immunity through the use of a biologic is immunization. *Vaccination* is the term more commonly used; it refers to the use of a biologic product (a vaccine) to develop active immunity in the patient.

The benefits of these products is apparent when one considers, for example, that the incidence of poliomyelitis fell dramatically after licensure of the inactivated polio vaccine in 1955 and the oral polio vaccine (OPV) in the 1960s. In the early 1950s, there were more than 20,000 cases of polio each year. By 1960, the number of polio cases had dropped to about 3,000, and by 1979, the last cases (about 10) of indigenously acquired polio in the United States were reported. Similarly, the largest annual number of cases of rubella, or German measles, an acute viral disease affecting people of all ages, occurred in the United States in 1969 (57,686 cases reported). Following rubella vaccine licensure in 1969, the incidence of this disease fell rapidly, and since 1992, the number of reported cases in the United States has been fewer than 500 per year.

TYPES OF IMMUNITY

Before discussing specific biologics, it is important to understand the different types of immunity. There are two main categories of immunity: natural and acquired.