

Chapter Eight: **Biotechnology Medicines**



The biotechnology industry uses advanced technologies to apply cellular and molecular biology to create new, beneficial products. Medical biotechnology products are used to treat or prevent diseases. These products include therapeutic proteins, monoclonal antibodies, vaccines, allergy **immunotherapy** products, blood components and tissues and cells for transplantation.

Monoclonal Antibodies

Though **monoclonal antibody** technology was invented in the mid-1970s, it took 20 years before the technology showed its true potential. The first experimental monoclonal antibodies developed in mouse models were ineffective because the human immune system rejected mouse antibodies as foreign. The subsequent development of first humanized, then fully human, antibodies has enabled the successful use of this breakthrough technology in fighting cancer and other serious illnesses.

Therapeutic Proteins

Scientists use recombinant DNA technology to make therapeutic proteins, often referred to as biologics. Biologics are used in such fields as oncology, rheumatology, immunology, endocrinology and virology. Approximately 50 recombinant therapeutic proteins are approved for clinical use and are currently marketed, and hundreds more are undergoing clinical trials. Some biologics have been in use for more than 20 years and are considered standard therapy.

Doctors have long used therapeutic proteins to replace or supplement patients' natural body proteins—especially when natural protein levels are decreased or lost due to disease.

Some recombinant proteins are versions of natural body proteins, and other versions are not exact versions but produce similar effects in the body.

Vaccines

Vaccines stimulate the immune system and provide protection against particular diseases. The first vaccines were made with inactivated (killed) or weakened virus unable to reproduce in the body but sufficient to provide immunity upon future exposure to the live virus.

Vaccines are also created with recombinant proteins. Scientists use genetic engineering to create recombinant vaccines by inserting genes for desired antigens into a vector. A vaccine vector, or carrier, is a weakened virus or bacterium into which harmless genetic material from another disease-causing organism can be inserted. Typically, the body recognizes antigens as foreign, and white blood cells will attack them. Recombinant vaccines, however, do not cause disease but do have the antigen, thus tricking the body into thinking it is being

attacked by a pathogenic virus. Recombinant vaccines are safe and easily grown and stored.

Antibodies

A major area of biologics is the production of humanized or fully human antibodies. Antibodies can attach to antigens found on a pathogen and flag the pathogen for destruction by the immune system. Antibodies also can attach to proteins on immune cells that are involved in autoimmune responses in diseases like rheumatoid arthritis and multiple sclerosis.

Humanized antibodies are engineered to be mostly human to avoid problems with rejection. Fully human antibodies are derived from human cells or human antibody genes.

Peptibodies

Peptibodies are engineered therapeutic **fusion proteins** with attributes of both peptides and antibodies but are distinct from each, and bind to human targets.

Diagnostics

In addition to recombinant proteins being used as biologic drugs, scientists use recombinant DNA technology to produce a number of diagnostic tests for diseases, including tests for hepatitis and AIDS. In fact, scientists commonly use recombinant protein antigens as diagnostic reagents in **enzyme-linked immunosorbent assays (ELISAs)** for the detection of infectious agents such as Severe Acute Respiratory Syndrome (SARS).