

## Chapter One: Introduction



In 1919, Karl Ereky, a Hungarian engineer, coined the term **biotechnology**\* to describe the interaction of biology and human technology. He envisioned a new era of technology based on using biology to turn raw materials into socially useful products. Nearly a century later, Ereky's vision is being realized by thousands of companies and research institutions.

Modern biotechnology began in the 1970s in Northern California and has since grown into a worldwide industry. Amgen, founded in 1980, was one of the first companies to realize the new field's promise by bringing biotechnology medicines to patients.

Today, biotechnology industry sectors include healthcare (**biologics**, devices, diagnostics), agriculture (genetically modified organisms, food safety), industry and environment (biofuels, biomaterials, pollution) and biodefense (**vaccines, biosensors**). This booklet focuses on healthcare.

### Drugs

A drug is a therapeutic substance used to prevent, manage or cure disease. In the United States, the U.S. Food and Drug Administration (FDA) must approve all drugs before they are sold to the public. Most countries follow global harmonized guidelines and have a regulatory agency similar to the FDA that evaluates drug research and approves drugs for marketing. The most familiar type of drug is the synthesized drug, such as aspirin. The pharmaceutical industry traditionally manufactures synthesized drugs. The biotechnology revolution brought about a new class of drug: the biologic.

Biologics are therapies derived from living organisms and include therapeutic proteins, DNA vaccines, monoclonal antibodies and peptibodies [a modality that combines the active portion of a protein (peptide) with a portion of the core structure of an antibody], as well as new experimental modalities such as gene therapy, stem cell therapy, antisense nucleotides and RNA viruses.

Many biotechnology drugs are **proteins**. Proteins, which are made from amino acids, are the workhorses of the cell and perform all functions within a cell. Because cells produce proteins naturally, the biotechnology industry utilizes cells, not chemicals, to manufacture biologics.

#### BIOFACT



To bring a new drug to market (from discovery through clinical trials and FDA approval) costs an estimated \$1 billion and can take 10 to 15 years or longer.\* Only one in 10 new drugs that makes it into human testing actually makes it to market. Given this high failure rate and the tremendous cost of bringing a new therapy to market, companies depend on successful drugs to produce enough revenue to compensate for both the R&D costs of the successful therapies and the expense of failed ones.

\*Innovation.org. (February 2007). Drug discovery and development: Understanding the R&D process [Brochure]. Washington, DC: Pharmaceutical Research and Manufacturers of America.