



A PHARMACY CONTINUING EDUCATION PROGRAM

W-F Professional Associates, Inc. 400 Lake Cook Rd., Suite 207 Deerfield, IL 60015 847-945-8050

Nov/Dec 2008 "Biotechnology: Pharmacy Perspective" 707-000-08-011-H01-P



*This Month:
Biotechnology:
Pharmacy Perspective*

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RENEWALS FOR 2009?---IF YOU HAVEN'T RESPONDED YET, DO IT NOW & SAVE! Biotechnology is an area of science, medicine & pharmacy that has come upon the scene over the past several years. It especially encompasses new ways of developing drugs & treatment options. Our goal in this lesson is to review some of the aspects that are significant for us as pharmacists. This lesson provides 2.50 hours (0.25 CEUs) of credit, and is intended for pharmacists in all practice settings. **The program ID # for this lesson is 707-000-08-011-H01-P. Pharmacists completing this lesson by November 30, 2011 may receive full credit.**

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

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The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe history & development of biotechnology techniques.
2. Define "biotechnology" & list its subclasses.
3. List main components of a cell.
4. State principles of recombinant DNA technology.
5. Describe genetic diseases as well as genetic therapy.
6. List examples of recombinant therapeutic agents, their use, & adverse effects.

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BIOTECHNOLOGY AND HISTORY

Biotechnology is a laboratory based technique that utilizes biological systems, living organisms (e.g., bacteria, yeast, stem-cells), or derivatives thereof, to modify the DNA or the genetic material of microorganisms, plants, or animals for the purpose of producing products to improve quality of life.

The rationale for including a lesson on this broad topic is twofold:

1. To review the significance of this new approach in development of disease treatment.
2. To present a few therapeutic options that testify to the value of biotechnology.

This science encompasses genetics, molecular biology, biochemistry, embryology, cell biology, chemical engineering and bioinformatics. It can be subdivided into subclasses called red, green, white, and blue techniques.

Red biotechnology involves medical processes designed to produce new drugs. Stem cells are being used to regenerate damaged human tissue and ultimately to re-grow organs.

Green biotechnology refers to agricultural processes. The result may be production of transgenic plants that flourish under certain environmental conditions, or the development of pest-resistant plants and/or disease-resistant animals. The result may be eliminating the need for external application of pesticides. The area of green technology has stimulated considerable debate in the scientific and social communities.

White biotechnology applies to industrial processes whereby microorganisms or enzymes are used to manufacture useful chemicals such as biofuels, or to breakdown polluting contaminants.

Blue biotechnology is a term rarely used, but refers to processes in the marine and aquatic environment.

In spite of the benefits that might be gained from biotechnology, it has the potential of being misused. Certain aspects, such as human cloning and embryonic stem-cell research, have triggered debate and controversy. It is not our intent to be controversial with this lesson...only to present some of the science.

Prior to the 1970s, the term biotechnology was utilized in food and agricultural industries. One of the earliest applications was the alteration of crop genes by cross breeding or cross pollination. This improved some species of plants and animals.

The overall concept of biotechnology has been known for centuries. Brewing beer was practiced by ancient Egyptians and Mesopotamians. Beer is produced by using melted grains that contain enzymes. The enzymes convert starch to sugar which is broken down to alcohol by adding yeast. The Babylonians described the process by which wine, a fermented product, is produced. Ancient Egyptians used yeast to produce bread. Fermentation processes have been known for centuries. Examples include:

- producing bacteria to manufacture yogurt,
- molds to produce cheese,
- acetic acid-producing bacteria to make vinegar.

In 1850 Louis Pasteur determined that enzymes in yeast are responsible for the conversion of sugar to alcohol. The use of microorganisms in industrial processes began in 1917 when *Clostridium acetobutylicum* was used to convert corn starch to acetone, a substance used in explosives. A quarter of a century ago a bacterium from *Pseudomonas* genus was developed in order to breakdown crude oil encountered in oil spills. The use of corn and soybeans in the production of ethanol as a biofuel will play an important role in reducing the demand for petroleum-derived fuels. It has been estimated that by 2030 consumption of petroleum-derived fuel will be reduced by 30%. Bacteria may be employed to recycle, and treat waste and eliminate industrial contaminants.

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BASIC CELL STRUCTURE

To explain how biotechnology works, it is important to review cell structure.

DNA is common in all organisms. Living organisms are made of cells that constitute the basic units of life. A cell consists of:

1. cell membrane
2. cytoplasm, and
3. cell nucleus.

The cell membrane, whose outer surface is largely made of lipopolysaccharides, matrix protein, and phospholipids, protects the inner core by controlling the passage of substances into and out of the cell. It allows the entry of nutrients and oxygen and the exit of carbon dioxide and waste. This is accomplished mainly by active transport. A semitransparent, thick liquid known as cytoplasm is immediately inside the cell membrane. The cytoplasm is primarily made up of differing proteins. Cell organelles like the endoplasmic reticulum, ribosomes, Golgi complex, mitochondria, and lysosomes are distributed within the cytoplasm. These organelles play an important role in the growth and maintenance of the cell. The nucleus is located in the center of the cell. It is separated from the cytoplasm by a membrane called the nuclear envelope. It permits the entrance and exit of substances into and from the nucleus. The function of the nucleus is to direct protein synthesis, which occurs in the ribosomes, and also storing genetic information in fibers known as chromatin. Immediately prior to cell reproduction, the chromatin becomes organized into bundles known as chromosomes. Each chromosome consists of one DNA strand. The DNA in the chromosomes is the ingredient that carries genetic information in order to

1. preserve hereditary information; and,
2. deliver instructions for protein synthesis.

As the cell undergoes reproduction (or mitosis), the parent cell divides into two identical daughter cells. Duplication of chromosomes occurs with one set going to each daughter cell. Thus, each daughter cell receives an exact copy of genetic information and instructions that were contained in the nucleus of the parent cells. This ensures transmission of the organism's traits and characteristics from one generation to the next. Synthesis of every protein needed by the organism occurs as a result of genetic information stored in the DNA. These proteins are utilized by the cell to provide enzymes and hormones. The DNA in the nucleus of a human cell provides genetic information and instructions to manufacture thousands of different proteins.

Synthesis of protein takes place outside the cell nucleus. Consequently, in order for the DNA, which is located in the cell's nucleus, to transfer the genetic information needed for protein synthesis, it needs a messenger to carry the genetic codes from the nucleus to protein synthesis sites at the ribosomes. The messenger is another nucleic acid called ribonucleic acid (RNA). Thus DNA induces RNA to make protein. The complete set of the hereditary factors, or the complete genetic material, is called the genome. Human genome is contained in 23 pairs of chromosomes, or 46 DNA molecules, whereas that of bacteria is contained in one single DNA molecule. In some cases the bacterial cell may contain additional small extrachromosomal self-replicating circles of DNA molecules referred to as plasmids (vector). These plasmids may be available in multiple copies and are capable of reproducing multiples of themselves and their genetic information without being influenced by the cell's chromosomal DNA. This fact plays an important role in achieving recombinant DNA technology. The main reasons for selecting unicellular microorganisms, such as *E. coli*, in recombinant DNA are:

- their uncomplicated structure
- availability
- simplicity of their DNA, and
- the ease in which one can isolate and engineer their plasmids to bring about the formation of an existing protein or production of a new one.

To transfer a specific piece of DNA from one organism to another a gene segment is cut or removed from a chain of DNA using enzyme scissors at a specific place along the DNA strand. An opening into the plasmid is achieved by using the scissors. The gene segment is then pasted into the plasmid.

RECOMBINANT DNA TECHNOLOGY

DNA technology began in the early 1970s. DNA is vital in storing all information needed for recreation of living organisms. It consists of a base that includes sugar (deoxyribose), phosphate and one nitrogen base. There are four types of nitrogen bases:

- adenine (A),
- thymine (T),
- guanine (G) and
- cytosine (C).

These four bases exist in pairs, with **A and T** and **G and C** always paired together, but their sequence can be formed in unlimited ways. The resultant structure is termed a double helix. Diversity in organisms depends on the sequence and number of bases. Again, the function of the DNA is not to create an organism, it only synthesizes protein which in turn creates the organism through the messenger RNA (mRNA). When the DNA sequence changes, so does the protein. Recombinant DNA (rDNA) technology refers to that technique which creates composite DNA molecules by joining a piece of DNA taken from one organism with a different strand of DNA (humans and bacteria such as *E. coli*). It involves cutting or isolation of human DNA which carries the genetic code of certain proteins. Cutting the DNA is usually done at a specific site so that each segment contains genes or part of genes to allow reproducibility. A plasmid is extracted from bacterial cells and is cut by using restrictive enzymes, forming a gap in the plasmid ring. The human gene is then spliced into the gap using the enzyme lipase which joins the ends of DNA together forming recombinant DNA. The recombinant DNA molecule, which contains human gene instructions, is introduced back into the cell of the living bacterium. By joining two or more different strands of DNA, a new strand is created. When the cell undergoes mitosis, the recombinant DNA is replicated, and its human genetic instructions are shared between the two daughter cells. Each daughter cell receives an exact copy of genetic information and instructions contained in the desired human gene. The daughter cells, referred to as cloned cells, are cultured in a special medium where they reproduce and manufacture large quantities of the needed therapeutic protein. The therapeutic protein is then purified and formulated into the desired dosage form. When a bacterium is used as the host for preparing recombinant DNA, the method is known as bacterial transformation. Non-bacterial transformation is the method that does not use bacteria as a host. In this case the DNA is injected directly into the nucleus of the cell being transformed.

MONOCLONAL ANTIBODY THERAPY

Monoclonal antibody therapy indicates the use of monoclonal antibodies to target cells with the objective to stimulate the patient's immune response. Monoclonal antibody techniques have resulted in therapeutic proteins that modify the host's response to malignant tumor cells by restoring, improving or potentiating the host's immune system by blocking specific cell receptors.

When an organism is exposed to microbial invasion or to any hostile chemical, it responds by producing antibodies from its B-type lymphocytes. These antibodies bind to an antigen that matches its detector site through the lock and key mechanism. Our bodies contain a large number of antibodies for protection against various antigens. Each antibody is manufactured by different lines of B-cells. Thus, cloning a single B-cell line results in the production of a specific antibody. Fusion of lymphocytes with malignant myeloma cells, for example, forms hybrid-myeloma cells (hybridoma) that are capable of producing lymphocyte-specific antibodies that proliferate rapidly. Isolation of fused myeloma cells can lead to generation of monoclonal antibodies. To produce interferon monoclonal antibody, a liquid containing a low concentration of interferon is injected into a mouse. Within a few days the spleen of the mouse is removed. The B-cells, portions of which will produce antibodies in response to interferon, are fused with myeloma cells to produce hybridoma cells. The hybridoma clones that are separated from each other are capable of manufacturing anti-interferon antibodies. Currently there are twenty-one FDA approved therapeutic monoclonal antibodies. Likewise, numerous such therapies are undergoing clinical trials.

The following are the names of FDA approved products, the first of which was approved in 1986:

(Muromonab-CD3); Abciximab (cardiovascular disease); **Adalimumab** (inflammatory diseases); **Alemtuzumab** (chronic lymphatic leukemia); **Basiliximab** (transplant rejection); **Bevacizumab** (colorectal cancer); **Cetuximab** (colorectal cancer); **Daclizumab** (transplant rejection); **Eculizumab** (inflammatory diseases including paroxysmal nocturnal hemoglobinuria); **Efalizumab** (inflammatory diseases (psoriasis)); **Ibritumomab tiuxetan** (Non-Hodgkin lymphoma); **Infliximab** (inflammatory diseases); **Muromonab-CD3** (transplant rejection); **Natalizumab** (inflammatory diseases); **Omalizumab** (inflammatory diseases, mainly allergy-related asthma therapy); **Palivizumab** (viral infection, especially Respiratory Syncytial Virus (RSV)); **Panitumumab** (colorectal cancer); **Ranibizumab** (macular degeneration); **Gemtuzumab ozogamicin** (acute myelogenous leukemia, with calicheamicin); **Rituximab** (Non-Hodgkin lymphoma); **Tositumomab** (Non-Hodgkin lymphoma); **Trastuzumab** (breast cancer).

GENETIC DISEASES

There are approximately 4,000 known genetic disorders. Fortunately, many are very rare. Cystic fibrosis is one of the most common. A significant percentage of the population has, or may develop, an inherited genetic disorder caused by abnormalities in genes or chromosomes. Such disorders affect all body cells and usually are present since conception. Many do not experience any abnormality, but some may suffer from serious diseases such as cystic fibrosis, hemophilia, muscular dystrophy or sickle-cell anemia. Down Syndrome, Turner Syndrome and Klinefelter's Syndrome are others. In genetic diseases the defective gene usually leads to either absence of enzymes or rendering such enzymes as ineffective. Recombinant DNA technology provides invaluable information about the nature of these diseases. By isolating a gene, which controls all physiologic and biochemical processes in the body, a specific process can be studied and better understood. The presence or absence of genetic defects in a fetus can be verified by using various recombinant DNA techniques. Tests are available to determine if a spouse is a carrier of a genetic disorder. To determine if any unborn child has a disorder caused by a genetic defect, a specific fragment of DNA is used to test a sample of amniotic fluid. These diagnostic tests are accurate and safe to both mother and unborn child.

GENE THERAPY

Gene therapy is defined as replacement of a defective gene with a correct one to treat a genetic and hereditary disease. One approach of such therapy is to join certain parts of DNA, called DNA probes, to another DNA segment. Through these probes, chromosome mapping, gene characterization and diagnosis of infectious diseases, in particular viral ones, may be achieved. Presently, gene therapy is difficult to realize by using recombinant DNA techniques. When gene therapy becomes a reality, it will result not only in curing many genetic diseases, but it will prevent such diseases from developing in the offspring of the patient. There are other methods used in gene therapy. However, there are ethical and therapeutic problems that are faced.

RECOMBINANT THERAPEUTIC AGENTS

Aldesleukin

Aldesleukin is a man-made protein available as a recombinant DNA that has the same action as human interleukin-2. The main function of interleukin-2 is to enhance communication between white blood cells. Additionally, it is important in the body's natural response to infections. The drug is available as a white to off-white freeze-dried cake that is reconstituted with 1.2 ml of sterile water for injection and yielding 1.1 mg (18 million International units) of aldesleukin. The drug is administered by IV infusion in a hospital setting. Aldesleukin is incompatible with the constituents of bacteriostatic water for injection or sodium chloride injection.

This is an antineoplastic drug used in metastatic renal carcinoma and metastatic melanoma. It possesses many serious adverse effects. Consequently, before initiating therapy, the patient must be evaluated to assess the blood chemistry, blood cell counts, cardiac, renal and pulmonary functions. The adverse effects of aldesleukin include flu-like syndrome, increased vascular permeability, hypotension, tachycardia, pulmonary congestion, anuria, oliguria, nausea and vomiting.

Alteplase

Alteplase is a recombinant DNA human tissue plasminogen activator (TPA). To produce recombinant TPA, the human gene is inserted into a mammalian cell line, such as a Chinese hamster ovary cell. The endogenous human TPA is secreted by vascular endothelial cells. It aids in the dissolution of blood clots encountered in acute myocardial infarction, pulmonary embolism and acute ischemic stroke. Alteplase is not absorbed orally. It is practically insoluble in water. Consequently arginine is included in the formulation to enhance solubility. Sterile water for injection should be used for reconstitution. Due to the absence of preservatives, the drug must be used immediately after reconstitution, or within

eight hours if stored properly.

Alteplase exerts its thrombolytic activity by hydrolyzing the arginine-valine peptide bond in plasminogen to form active proteolytic enzyme plasmin that causes the disintegration of fibrin, fibrinogen, and the coagulant factors V, VIII and XII. Side effects of alteplase include bleeding, hypersensitivity reactions, arrhythmia, nausea, vomiting and cerebral edema. During therapy, thrombin time should be monitored. The drug is contraindicated in patients with active internal bleeding, aneurysm, cerebrovascular accident and use of oral anticoagulants. The recommended dose is 0.9 mg/kg infused over 60 minutes.

Epoetin Alfa

Erythropoietin is a hormone produced mainly by the kidneys to promote the formation of red blood cells in the bone marrow. It also initiates the production of hemoglobin. The level of erythropoietin in the blood is useful in the study of bone marrow and kidney disorders. It is almost impossible to collect human erythropoietin in large quantities to meet clinical needs. However, this could be achieved by utilizing recombinant DNA technology and using mammalian cells of Chinese hamster ovary. The resultant recombinant DNA molecule inside the cell carries the gene instructions for producing human erythropoietin. The cells are grown in cultures where they multiply and produce human erythropoietin.

Epoetin alfa is a recombinant DNA form of the hormone erythropoietin which is used in therapy. This drug possesses biological activity similar to that of the endogenous hormones. Epoetin alfa stimulates the cells of bone marrow to produce red blood cells, increase hemoglobin and hematocrit. Deficiency of erythropoietin leads to the development of normocytic and normochromic anemias. It is used to treat anemias especially those associated with kidney failure. Adverse effects of epoetin include hypertension, increased incidence of clotting at vascular access site, seizures, nausea, vomiting and constipation. Epoetin alfa is available as a sterile, colorless liquid contained in a single-use container with no preservative. It can be used intravenously or subcutaneously at 50 to 300 units per kilogram.

Dornase Alfa

Dornase alfa is a purified solution of recombinant human deoxyribonuclease, an enzyme that cleaves DNA. It is a form of human enzyme deoxyribonuclease I. The drug is produced by cultures of mammalian cells that are genetically modified Chinese hamster ovary cells. Modification of the mammalian cells is achieved by the addition of plasmids that contain human deoxyribonuclease gene obtained from human pancreas.

Dornase alfa hydrolyzes the DNA present in the sticky mucus of patients who suffer from cystic fibrosis, and other pulmonary diseases, thereby reducing its viscosity and promoting expectoration and breathing. Furthermore, improvement of the condition results in minimizing infection. Dornase alfa is administered by inhalation through nebulizers. The oral inhalation solution should not be diluted, nor administered with other medications from the same nebulizer. It is important that instructions for proper use of nebulizers be given and explained to the patient. The usual oral inhalation dose is 2.5 mg once daily. Each ampule contains 2.5 mg of the drug in 2.5 ml of undiluted solution. Adverse effects of dornase alfa, which in most cases are mild and transient, include sore throat, voice change, hoarseness, chest pain, rash and conjunctivitis. If the patient experiences increased difficulty of breathing as well as chest pain, immediate medical attention should be sought. The drug should be stored in the refrigerator and protected from light.

Filgrastim

Filgrastim is a human granulocyte colony-stimulating factor (G-CSF) produced by using recombinant DNA technology and cultures of genetically modified *E. coli*. It is a hematopoietic drug that stimulates the production of neutrophils within the bone marrow and may have some effect on other leukocytes. Filgrastim is used to prevent the development of chemotherapy and bone marrow transplantation-induced neutropenia, increase neutrophil counts in adults with various types of neutropenias, myelodysplastic syndromes, and aplastic anemia. Furthermore, it is used to increase the number of hematopoietic stem cells in the blood for use in stem cell transplantation. Filgrastim is well tolerated. Its adverse effects are minimal and include medullary bone pain, nausea, vomiting and transient rash.

Filgrastim is administered intravenously and is available as a sterile preservative-free solution supplied in single-use vials and prefilled syringes.

Interferon Alfa

Interferon is a man-made protein that resembles the one produced by peripheral blood leukocytes, fibroblasts and epithelial cells in response to infection. It enhances the immune system to combat diseases. It may slow the growth of cancer cells. There are at least 23 structurally similar types of human interferon that have been identified. Interferon is marketed as:

1. interferon alfa-n3—a mixture of naturally occurring human interferon, and
2. interferon alfa-2a and interferon alfa-2b—which are produced by recombinant DNA technology and prepared from cultures of genetically modified *E. coli*.

Genetic modification is achieved by incorporating plasmid that contains genes from human leukocytes for synthesis of human interferon alfa.

Interferon alfa is available as a sterile, preservative-free, and white to off-white, lyophilized powder. Once it is reconstituted, it may be administered subcutaneously, intramuscularly or intralesionally. The powder is packaged in vials that should be stored at 2-8° C. At room temperature, the vial is stable for one week. It is used in the treatment of Kaposi's sarcoma, chronic myelogenous leukemia, selected cases of chronic hepatitis B virus infection, and infection of chronic non-A, non-B hepatitis and some cases of chronic hepatitis D, melanoma that has spread to the lymph nodes, and Non-Hodgkin's lymphoma.

Adverse effects are common and include flu-like symptoms, myalgia, arthralgia, anorexia, nausea, vomiting, diarrhea, anxiety, irritability, headache, mild myelosuppression, increased level of hepatic enzymes (SGOT and SGPT), rash, transient alopecia, proteinuria, and hypotension.

Hepatitis B Virus Vaccine Inactivated

Hepatitis B virus vaccine inactivated is a noninfectious vaccine that contains hepatitis B surface antigen (HBsAg) using recombinant DNA technology. It is produced by the genetically modified yeast *Saccharomyces cerevisiae*. The yeast is altered to incorporate the hepatitis B virus gene coding for the surface antigen. The HBsAg produced by the yeast is collected, purified, inactivated with formaldehyde, and reacted with aluminum hydroxide. It is used to prevent Hepatitis B viral infection. It has advantage over conventionally prepared vaccine in that it triggers the production of protective antibodies, without exposing the body to infectious diseases.

The vaccine is well tolerated and the adverse effects which may be encountered are usually mild and transient. Local adverse effects at the site of injection include soreness, induration, pruritus, swelling, warmth and burning. Systemic adverse effects include fatigue, weakness, headache, cough and fever. The vaccine is usually administered by intramuscular injection, but in some cases it may be given subcutaneously. The vaccine is recommended to military personnel, persons engaging in high-risk sexual activities, laboratory workers, abusers of illegal injectable drugs and persons who frequently receive blood and blood products.

Sargramostim

Sargramostim is a recombinant granulocyte-macrophage colony-stimulating factor (GM-CSF). This hematopoietic agent is produced by recombinant DNA technology utilizing a yeast expression system of *Saccharomyces cerevisiae*. The endogenous human GM-CSF is a hormone produced by T-cells, macrophages, fibroblasts, and endothelial cells. The drug mainly stimulates the production of leukocytes (leucopoiesis).

The drug is available in sterile lyophilized powder that is packaged in vials and should be stored at 2-8°C. It is administered by both intravenous and subcutaneous injections. Sargramostim is used to accelerate recovery from autologous bone marrow transplantation. It has been used to treat neutropenia in a limited number of adults with acute lymphocytic leukemia and chemotherapy-induced neutropenia. The drug is well tolerated in recommended doses, but adverse effects such as flu-like syndrome, headache, nausea, edema, transient rash, mild phlebitis and mild bone pain have been reported.

Human Insulin

Insulin is a hormone which affects metabolism and causes most of the body's cells to take up glucose from the blood. It is a peptide that consists of 51 amino acid residues. Insulin is formed in the beta cells of the Islets of Langerhans in the pancreas. Human insulin is the first animal protein to be used as a medication resulting from recombinant DNA techniques. It is produced either biosynthetically by *E. coli* or *Saccharomyces cerevisiae*, or semisynthetically by transpeptidation of pork insulin. The resultant insulin has a structure identical to that of the natural molecule produced by the human pancreas. The process of manufacturing biosynthetic insulin involves inserting human DNA encoded for human insulin into the bacterium cells. The cells are grown by fermentation to produce millions of genetically identical daughter cells which are capable of producing proinsulin, whose connecting peptide is cleared enzymatically, resulting in human insulin. Semisynthetically prepared human insulin involves enzymatic modification of pork insulin. The only difference between pork insulin and pancreatic human insulin is in position 30. Pork insulin contains alanine at that position, whereas human insulin

contains threonine. Selective substitution of these amino acids is achieved by trypsin-catalyzed transpeptidation of pork insulin in the presence of an ester of threonine.

Human insulin is used to manage diabetes mellitus. Unlike pancreatic human insulin, insulin prepared by recombinant DNA technology is free of contamination with glucagon and proinsulin.

Somatrem

Somatrem is a growth hormone secreted by the anterior portion of the pituitary gland and used in children who have a deficiency. It stimulates body growth in general and the growth of long bones and skeletal muscle in particular. Hyposecretion of growth hormone in children leads to pituitary dwarfism. Gigantism occurs when the pituitary gland over-secretes during childhood. If the overproduction of the growth hormone occurs during adulthood, the syndrome that results is referred to as acromegaly, which is enlargement of bony areas particularly the feet, fingers and face. Because of the difficulty encountered in obtaining sufficient quantities of human growth hormone for therapeutic purposes, recombinant DNA technology is used to produce the hormone by utilizing *E. coli*. Adverse effects include headache, muscular pain, and fatigue.

SUMMARY

Biotechnology is the technique that employs a part of the cellular and submolecular components of living organisms to produce new products to be used in treating human diseases and improve quality of agricultural crops or livestock. Such products include drugs, vaccines, diagnostics, foods, and chemicals needed in various industrial processes.

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

| | | |
|--|-----|----|
| Describe history & development of biotechnology techniques | Yes | No |
| Define "biotechnology" & list its subclasses | Yes | No |
| List main components of the cell | Yes | No |
| State principles of recombinant DNA technology | Yes | No |
| Describe genetic diseases as well as genetic therapy | Yes | No |
| List examples of recombinant therapeutic agents, their use & adverse effects | Yes | No |

2. Was the program independent & non-commercial Yes No

| | | | | | | | |
|-----------------------|------|---|---------|---|-----------|---|---|
| | Poor | | Average | | Excellent | | |
| 3. Relevance of topic | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

Please Select the Most Correct Answer

- | | |
|--|---|
| <p>1. "Green" biotechnology deals with: A. Medical processes designed to produce drugs B. Industrial processes designed to produce chemicals such as biofuels C. Agricultural processes designed to produce transgenic plants D. Marine & aquatic environment</p> <p>2. Genetic information is stored in: A. Cytoplasm B. Cell membrane C. Phospholipids D. Chromatin</p> <p>3. Replacement of a defective gene with a correct one is termed: A. Recombinant DNA treatment B. Genomics C. Gene therapy D. Monoclonal therapy</p> <p>4. Recombinant DNA technology is associated with a technique that creates composite DNA molecules by joining a piece of DNA from one organism with a different DNA strand. A. True B. False</p> <p>5. Monoclonal antibodies are all produced by the same line of B-cells. A. True B. False</p> | <p>6. DNA is located in which part of the cell? A. Cytoplasm B. Nucleus C. Mitochondria D. Cell membrane</p> <p>7. Alteplase is: A. A thrombolytic agent B. An antineoplastic agent C. An increase in hemoglobin level D. Used in treating cystic fibrosis</p> <p>8. Recombinant human deoxyribonuclease is known as: A. Filgrastim B. Dornase alfa C. Epoetin alfa D. Aldesleukin</p> <p>9. Which of these is not a common side effect of interferon alfa? A. Flu-like symptoms B. Increased level of SGOT & SGPT C. Myalgia D. Tachycardia</p> <p>10. Pancreatic human insulin contains which amino acid in position 30? A. Threonine B. Alanine C. Phenylalanine D. Tryptophan</p> |
|--|---|

Contributing Author

Farid Sadik, Dean Emeritus
University of South Carolina
College of Pharmacy
Columbia, SC

Contributing Author

William J. Feinberg, BS Pharm, MBA

Executive Editor

William J. Feinberg,
BS Pharm, MBA



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