Understand Biotechnology Research & Development

Lesson objectives

1. What is biotechnology?
2. What are some applications of biotechnology?
3. How are biotechnology products developed?
4. What are some biotechnology career career opportunities in NC?

Nov 4-10:28 AM

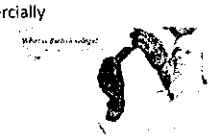
I Biotechnology

A. Although the definition of biotechnology varies, it is simply the collection of technologies that use living cells and/or biological molecules to solve problems and make useful products by humans and animals

a. These products are made through processes called

i. Biomanufacturing - is the manufacturing portion of Biotechnology

ii. Bioprocessing – it is a method to produce a biological material; as in the manipulation of the genetic material o something to make it useful commercially



Nov 4-6:15 PM

b. It is a growing industry within North Carolina

i. There are 16 Biomanufacturing companies in NC

ii. There are also more than 30 other companies engaged in some form of related manufacturing of pharmaceuticals, diagnostics and medical device

iii. These companies, together, employ more than 20,000 people

iv. The types of products produced include:

1. Vaccines for humans and animals
2. Biopharmaceutical
3. Amino acids
4. Industrial enzymes
5. Therapeutics isolated from blood
6. Custom DNA sequences

Nov 4-6:15 PM

c. Major Events in Biotechnology; a timelin

i. 8000 – 4000 B.C.E (Before the Common Era)

1. Humans domesticated crops and livestock

2. Potatoes were first cultivated for fo

ii. 2000 B.C.E

1. Biotechnology was used to leaven bread and ferment beer, using yeast (Egypt)

2. The production of cheese, fermentation of wine begins (Sumeria, China, & Egypt)

Nov 4-6:15 PM

iii. 500 B.C.E. – the 1st antibioti was used: Moldy soybean curds (tofu) used to treat boils (China)

iv. 100 C.E. – The 1st insecticid was used: powdered chrysanthemums (China)

v. 1797 – The first vaccinatio was used: Edward Jenner takes pus from a cowpox lesion, inserts it into an incision on a boy's arm

vi. 1830 – 1833

1. 1830 The first protein are discovered

2. 1833 The first enzym (large biological molecule used in chemical interconversion's that sustain life) is discovered and isolated

vii. 1857

1. Louis Pasteur proposes that microbes cause fermentatio

2. He later conducts experiments that support the germ theory of disease

Nov 4-6:15 PM

viii. 1859 – Charles Darwin publishes the theory of evolution by natural selecti

ix. 1865

1. Gregor Mendel discovers the laws of inheritance by studying flowers in his garde

2. The science of geneti

x. 1915

1. Phages, a virus that is parasiti in bacteri , that only infect bacteria are discovered

2. They are used as vectors in gene cloning, as well as biotechnological uses

xi. 1927 – Herman Muller discovers that radiation causes defects in the chromosomes

Nov 4-6:15 PM

xii. 1928

1. Sir Alexander Fleming discovers the antibiotic penicillin by chance when he realizes that Penicillin mold kills bacteria

2. He shared the 1945 Nobel Prize in Medicine with Ernest Boris Chain and Sir Howard Walter Florey

xiii. 1944 – DNA is proven to carry genetic information by Oswald Avery, Colin MacLeod and Maclyn McCarty

xiv. 1953

1. James Watson and Francis Crick describe the double helical structure of DNA

2. They shared the 1962 Nobel Prize in Medicine or Physiology with Maurice Wilkins

Nov 4-6:15 PM

xv. 1955 – The amino acid sequence of insulin is discovered by Frederick Sanger

xvi. 1982 – Human insulin produced in genetically modified bacteria and is the 1st biotech drug approved by the FDA

xvii. 1958

1. DNA is made in a test tube for the 1st time

2. Sickle cell disease is shown to occur due to a change in one amino acid

xviii. 1966

1. The genetic code for DNA is cracked

2. Three scientists shared the 1968 Nobel Prize in Physiology or Medicine for the discovery, they were Marshall Nirenberg, Robert Holley, & Har Gobind Khorana

Nov 4-6:15 PM

xix. 1971

1. The 1st complete synthesis of a gene occurs

2. Discovery of restriction enzyme that cut and splice genetic material very specifically occur

3. This opens the way for gene cloning

xx. 1973

1. Stanley Cohen and Herbert Boyer perfect genetic engineering techniques to and paste DNA using restriction enzyme

2. 1977 sees the 1st expression of a human gene in bacteria

3. Cohen won a Nobel Prize in 1986 for an unrelated discovery

xxi. 1975

1. Georges Kohler and Cesar Milstein develop the technology to produce monoclonal antibodies ; highly specific, purified antibodies derived fr only one clone of cells that recognize only one antibo

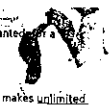
2. They shared the 1984 Nobel Prize in Physiology or Medicine with Neils Jerne

Nov 4-6:15 PM

xxii. 1981

1. The first transgenic animals are produced by transferring genes from other animals into mice (what animal gave the gene?)

2. The 1st patent for a genetically modified organi is granted for a bacteria that can break down crude oil



xxiii. 1983

1. The polymerase chain reaction (PCR) technique, which makes unlimited copies of gene fragments, is conceived

2. Kary Mullis, who was born in Lenoir, NC, wins the 1993 Nobel Prize in Chemistry for the discovery

3. He became interested in science as a child when he received a chemistry set for Christmas

xxiv. 1986

1. The 1st recombinant vaccine is approved for human use: Hepatitis Vaccine

2. The 1st anticancer dru is produced through biotech: interferon

Nov 4-6:15 PM

xxv. 1987

1. The 1st approval for field tests of a genetically modified fo plant: virus-resistant tomatoes

2. 1994 Genetically modified tomatoes ar sold in the US for the 1st time

xxvi. 1990

1. The Human Genome Project, an international effort t map all of the genes in the human genome, is launched

2. 2002 the draft version of the human genom is published

3. Francis Collins, MD., Ph.D. is the Director of the Human Genome Project

xxvii. 1997 – Scientists report the birth of Dolly, the 1st animal cloned from an adult cell

Nov 4-6:15 PM

xxviii. 1998

1. The human embryonic stem cell lines are established

2. They offer hope to many because they may be able to replace diseased or dysfunctional cell

xxix. 2003

1. The SARS (severe acute respiratory syndrome) virus is sequenced three weeks after its discover

2. SARS, which began in China, spreads quickly and spreads fear throughout the Far East and The World

3. The last reported cases occurred in 2004 and resulted from laboratory-acquired infection

Nov 4-6:15 PM

xxx. 2004

1. The 1st cloned pet, a kitten, is delivered to its owner
2. She is called Copy Cat or Cc for short

xxxi. 2006

1. A recombinant vaccine against human papillomavirus (HPV) receives FDA approval
2. The virus causes genital warts and can cause cervical caner

Nov 4-6:15 PM

Find the pairs.

Mar 19-7:45 AM

Find the pairs.

Mar 19-7:45 AM

1 Who Discovered the Laws of Inferitance?

A	Charles Darwin	C	Herman Muller
B	Gregor Mendel	D	Alexander Fleming

Dec 13-3:02 AM

2 Who described the double helical structure of DNA?

A	MacLeod & McCarty	C	Watson & Crick
B	Florey & Cain	D	Mendel & Muller

Dec 13-3:02 AM

b. Present companies and their products, current or in the works include:

i. Biogen Idec

1. Produces biopharmaceuticals to treat cancer, multiple sclerosis and inflammatory disease
2. Its large-scale manufacturing in the Research Triangle Park is one of the largest cell culture facilities in the world

ii. Ajinomoto

1. Is a world leader in the production of amino acids, the building blocks of proteins
2. Like many bioprocessing facilities, the Raleigh plant operates at full capacity 24 hours a day, 365 days a year

Nov 4-6:15 PM

iii. Diosynth RTP

1. Is a world leader in the production of recombinant protein biopharmaceuticals
2. Its state-of-the-art facilities are located in Research Triangle Park

iv. AlphaVax

1. Is developing a new vaccine technology with broad applications against infectious disease, cancer and biodefense threats
2. Its manufacturing plant is located in Lenoir

v. Novozymes North America

1. Is located on 1,600 acres in Franklinton
2. It is the largest multipurpose enzyme manufacturing plan. In the US and employs approximately 350 people
3. Novozymes is the biotech-based world leader in industrial enzymes and microorganisms

Nov 4-6:15 PM

vi. Embrex

1. Is an international egg biotec company that developed the first *in ovo* (in the egg) injection syste
2. It eliminates the need for manual vaccinati of newly hatched broiler chicks.
3. The manufacturing plant is located in Laurinburg

vii. Wyeth Vaccines

1. Operates one of the world's largest vaccine facilities in Sanfor
2. The vaccines that eliminated small pox and polio in the US came from Wyeth laboratories

viii. Greer Labs

1. Is a leading supplier of allergy testing and treatmen materials
2. Its manufacturing facility is located in Lenoir

Nov 4-6:15 PM

ix. KBI BioPharma

1. Is a contract biomanufacturer in Durham
2. The company produces a variety of biopharmaceutical for other companies

x. MWG Biotech

1. Offers products and services for gene research
2. The company produces custom DNA sequences
3. The facility is located in High Point

xi. Argos Therapeuti

1. Is developing therapeuti vaccines in Durha
2. These vaccines are given to treat (instead of prevent) diseases such as cancer and HIV/AIDS

Nov 4-6:15 PM

xii. Biolex

1. Produces hard-to-make therapeuti protein by growing them in the aquati plant Lemna duckweed)
2. The Biomanufacturing plant is in Pitt bor

xiii. Talecris Biotherapeuti

1. Isolates a variety of therapeut protein from human blood and plasma in its Clayton, NC facility
2. The diseases these proteins treat include:
   a. Hemophilia
   b. Clotting disorde
   c. Shock
   d. Burns
   e. Immune disorders
   f. Hepati
   g. Tetanus
   h. Rabies exposure

Nov 4-6:15 PM

xiv. Archer Daniels Midland

1. Is one of the largest agricultural processors in the world
2. The plant, in Southport, NC, produces citric acid

xv. Corn Products Internati na – produces high-fructose corn syrup and starch in Winston-Salem, NC.

xvi. Merck & Co.

1. Broke ground on a new Biomanufacturing facility in 2004
2. When completed in 2008, the Durham facility will produce vaccines for chicken pox and MMR (measles-mumps-rubella)

Nov 4-6:15 PM

B. Practical Applications of biotechnolo

a. Bioprocessing technology

i. Uses whole living cells or components of them to manufacture desired products

ii. Most common whole cells used are yeast and bacteria; one-celled organisms

iii. Most common components are enzymes; proteins that catalyze chemical reaction

iv. Cells isolated from animals and plants also are used to produce desired products

Nov 4-6:15 PM

b. Genetic engineering

i. The technique of removing, modifying or adding genes to a DNA molecule to change the information it contains

ii. More specifically is known as recombinant DNA (rDNA) technology

iii. The product of rDNA technology is known as a genetically modified organism, or GMO

iv. Example: Gene for human insulin inserted into E.coli; bacteria that makes human insulin, a biopharmaceutical

Nov 4-6:15 PM

c. Other Application

i. Agricultural applications – better crops, improved animal healt

1. Improve crop yields by introducing genes that confer resistance to insects, tolerance to herbicides and resistance to environmental stresses; drought, heat, & cold

2. Create disease and insect resistant trees to help meet the demand for wood products

3. Improve animal health through:

a. Better detection of disease

b. More nutritious feed

c. New and more effective vaccines

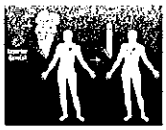
d. Improved treatments for diseases

Nov 4-6:15 PM

ii. Medical and health care applications – new tests, vaccines, medicines

1. New diagnostic tests; example, quick test for strep throat

2. Many new treatments for diseases and condition ; examples, diabetes, stroke, anemia, cystic fibrosis, hemophilia, leukemia and othe cancers; hepatis, rheumatoid arthriti growth deficiencies, transplant rejecti



Nov 4-6:15 PM

iii. Chemical and environmental applications – bett manufacturing processes and consumer products

1. Produce enzymes used in laundry detergents

2. Use genetically modified microorganisms that break dow industrial waste

3. Develop bio-based, biodegradable plasti

4. Improve manufacturing that reduces the amount of waste products

Nov 4-6:15 PM

II From Lab to Market

A. Clinical Trials – A closer look

a. The Food and Drug Administration (FDA) is the main consumer watch dog for numerous products:

i. Drugs & biologics: prescription and over-the-counte

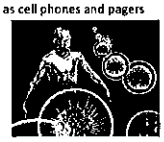
ii. Food

iii. Medical devices

iv. Animal feed and drugs

v. Cosmeti

vi. Radiation-emitti products; such as cell phones and pagers



Nov 4-6:15 PM

b. The evaluation of pharmaceuticals and biopharmaceuti is a highly regulated process requiring many steps to prove a drug is safe and effecti

c. This is known as the drug development process

d. There are a number of steps in the new drug development timeline; they include:

i. Research and development in the lab (basic)

ii. Testing in animals model ; pre-clinical (applied)

iii. Human testi phases or clinical trials

Nov 4-6:15 PM

e. Clinical trials are human studies designed to distinguish a drug's effect from other influence

f. Drugs must be thoroughly analyzed and tested in animal models before they are tested in humans

g. Research and development in the lab

i. R&D involves initial synthesis and analysis of a promising pharmaceutical or development and analysis of a biopharmaceutica produced in living cells

ii. On upcoming slides, the word "drug" applies both to pharmaceuticals and to biopharmaceutical

Nov 4-6:15 PM

h. Pre-clinical testi

i. When new drugs show promise in lab testi , studies are designed to evaluate them further

ii. These studies in animals are referred to as "pre-clinical studies"

iii. Pre-clinical studies help establish boundaries for safe use of the treatments

iv. Many new drugs and treatments are abandoned at this step because they are proven unsafe

Nov 4-6:15 PM

i. Clinical research and development

i. The applicati to the FD to request permission to begin human testi is called an investi ational New Drug applicati or IND

ii. The IND permits the use of an investi ational new drug for th sole purpose of conducti clinical trial

iii. Phase 1 clinical trials

1. The drug is tested for its interacti with the human body
2. The trials are conducted to determine the appropriate dose range with regard to safety and toxicity; not effica
3. The trials are conducted on a limited number (20-80) of normal volunteers or patient ; such as patients with cancer or AIDS
4. Phase 1 trials often take nine to 18 months to complete
5. Many drugs are abandoned in Phase 1 testi because of problems with safety or toxicity

Nov 4-6:15 PM

vi. Phase 2 trials

1. A small-scale, well-controlled trials evaluate the preliminary safety and effica in 100 to 300 patients with the disease or conditi to be treated
2. This phase may focus on dose-response, dosing schedule or other issues related to preliminary safety and effica
3. It often takes one to three years to complete
4. Additional animal testi may be conducted at the same time to obtain long-term safety data
5. If studies show drug to be safe and useful, testi may proceed to Phase 3

Nov 4-6:15 PM

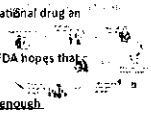
v. Phase 3 trials

1. The most extensive and expensive testi of a dru
2. These trials fully assess safety, efficacy and drug dosa in a large group of patients with the specifi disease to be test
3. Conducted on larger, 100s to 1000s, and more diverse groups of patients with the conditi
4. Make comparisons between the new treatment and a placebo and/or the standard treatment
5. Trials help to better understan the drug's safety and uncover any adverse effect
6. Trials often take two to five year to complete

Nov 4-6:15 PM

vi. New Drug Applicati (NDA)

1. Submitted to the FDA once all or most of the proposed studies are completed
2. Submitted if company believes adequate positive informati has been obtained to warrant a request to market the drug
3. The NDA contains extensive data on the investi ational drug an results of the clinical trials
4. The NDA is many thousands of pages long. The FDA hopes that eventually they will be submitted electronically
5. By law, the FDA has 60 days to decide if there is enough informati n to conti with the NDA review
6. By law, the FDA is required to made a fi al decision within 180 days
7. In practice this timeframe often lengthened, considerably, by mutual agreement



Nov 4-6:15 PM

vii. New Drug Application (NDA) Revie

1. The Center for Drug Evaluation and Researc (CDER) reviews applications for pharmaceutical

2. The Center for Biologics Evaluation and Researc (CBER) reviews applications for biopharmaceuticals, vaccines, blood and blood product

3. **What is the difference between biopharmaceutica and a pure pharmaceutical compan ? "A biopharmaceutical plant uses processes that typically include fermentation or cell cultur using genetically engineered cell lines to make the active drug substanc . A pharmaceutical plant uses processes that typically include chemical synthesis to create the active drug substanc . Many companies have both types of manufacturing plant."**

Nov 4-6:15 PM

viii. Phase 4 Clinical trials

1. Companies sometimes continue clinical trial of a drug after it has been approved for marketi

2. Phase 4 trials may be performed to learn more about side effects and long-term risks and benefi

3. Companies also may evaluate different formulati of a drug, like sustained-release, or test the drug for a different indicati Propecia (finasteride) used in Prostate disease and can be used for alopecia. (what is this?)

4. And, the FDA sometimes requires companies to conduct phase 4 trials

Nov 4-6:15 PM

ix. Post-marketing surveillanc

1. The company must continue to repor information about new findings and problem after drug approva

2. Health care providers can report new findings to the company or directly to the FDA; consumers can report informati to the FDA as wellxi. A typical timetabl from test tube to patient is as follows

1.	R&D and preclinical	3.5 years
2.	Phase 1	1.0 years
3.	Phase 2	2.0 years
4.	Phase 3	3.0 years
5.	NDA evaluati	2.5 years
6.	Total	12.0 years

Nov 4-6:15 PM

B. Producing a Pharmaceutical or Biopharmaceuti

a. The Manufacturing Process

i. Process development

1. Scientists and engineers begin to figure out how to "scale up" production of a drug even before it receives FDA approval

2. Manufacturing processes might be quite different than the small-scale lab procedures

ii. Producti

1. Production of a pharmaceutical or biopharmaceutical involves ma different, complex and lengthy step ; which include:

a. Synthesis
b. Purificati
c. Formulati
d. Final dosage form preparati – liquid, tablets, capsule, suppository, injectable, or intravenous

Nov 4-6:15 PM

2. The step processes

a. Step 1: Synthesis

i. Order the raw materials needed to make the product

ii. Test all raw materials to be sure they meet quality standards

iii. For Biomanufacturing, equipment and materials need to be sterilized to avoid contaminati to the cell cultures

iv. The product then is created

1. For pharmaceutical , there are chemical processes involved; chemical synthesis

2. For biopharmaceutical , cell culture or fermentati is involved

3. The product is referred to as the "active ingredien."

Nov 4-6:15 PM

v. For the biopharmaceuti , the original cell culture is started in small bottl ; around the size of large soda bottl

vi. As the cells grow and multipl , they are introduced into a small bioreactor

vii. Eventually they are grown in large bioreactors, which can be several stories tall

viii. Biosynthesis – a small bioreactor in the foreground, with a larger one behind it

Nov 4-6:15 PM

b. Step 2: Purifiati

i. Afte the active ingredient is synthesized, it must b purifi

ii. Purifiatin involve removing the chemicals used in the process

iii. For biopharmaceuticals, purifiatin involves separati the cells from the cellular nutrients and byproducts, the sou, they grew in

iv. The end result of productin is called the bulk product

v. The bulk product may be sold as is, processed further at the same plant or shipped to another plant for further processing

Nov 4-6:15 PM

c. Step 3: Formulati

i. Several other operatins are required to get bulk product into its fial for

ii. Formulatin involves chemical mixing operatin to blend the actie ingredien with other substances, such as filer , needed in the fial for

iii. The fial form may be a solid (tablet or capsule), liquid, gels/creams or aerosols

iv. Biopharmaceuticals usually are sold as sterile liquids or sterile powders

Nov 4-6:15 PM

d. Step 4: Final dosage form preparati

i. The formulated preparatin is made into its fial for

ii. The fial form is dispensed into containers

iii. The containers are labeled and packaged

Nov 4-6:15 PM

b. Quality Matte

i. The standards of quality are high because the stakes are so high

ii. Poor quality products can harm or even kill consumers

iii. Companies must conform to the stringent Good Manufacturing Practie (GMP) regulatins established by the FDA

iv. Ensuring quality – manufacturers have three departments that ensure quality, they include:

1. Quality Control (QC)
2. Quality Assurance (QA)
3. Validati

v. Quality Control – QC employees sample and test the raw materials and the product during many stages of the manufacturing process

Nov 4-6:15 PM

vi. Quality Assurance

1. QA ensures product quality by setti up and checking the systems o standard operati procedure (SOPs) and of documentati

2. SOPs guide every task by defii each procedure in detail so it can be performed exactly the same way every ti

3. Companies are required to prepare and follow SOPs by the FDA

4. Any deviati from the SOP must be documented and approved by the QA department

5. Critical deviati that could affct product quality are investigated furth

6. Documentatin proves that a company has done what it said

7. A company is required to have a traceable, writtin record of all processes and checks

8. "If it isn't writtin down, it doesn't exist. If it isn't writtin down, it neve happened."

Nov 4-6:15 PM

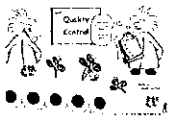
vii. Validati

1. Validati proves that a manufacturing process will consistently produce the product to predefied specifiati

2. The operatin of every part of the plant that affects quality must be validated

3. If a manufacturing process is changed or if a new product is introduced, all processes and equipment that affect quality must be validated

4. Validatin scientists and engineers hav extensive experience because they must be very familiar with the regulatin



Nov 4-6:15 PM

viii. Five rules for quality

1. Understand customer needs

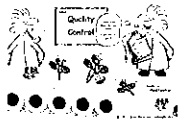
   a. Companies have internal customers, fellow employees, as well as external customers

   b. For a process technician, your internal customer is your coworker at the next stage of the process

2. Say what you do – write down the procedures

   a. Standard procedures and forms are required for every step

   b. Batch records define the steps required to manufacture the product, the materials used, etc.



Nov 4-6:15 PM

3. Do what you say – follow the procedures

   a. Manufacturers are required to consistently and exactly follow procedures

   b. SOPs are vital, and there are SOPs for every step

4. Prove it – keep records

   a. Companies must have traceable, written record of all processes

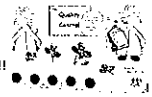
   b. Again, "If it isn't written down, it doesn't exist. If it isn't written down, it never happene ."

5. Improve it

   a. Companies must continually evaluat its processes and procedures

   b. They should take steps to make them bett.

   c. Of course, new procedures must be validated!!!



Nov 4-6:15 PM

c. Standard Operating Procedure

   i. SOPs define a particular process in detal so it can be performed in the same way, every tim

   ii. Lengthy regulations related to manufacturing are found in the *Code of Federal Regulation*

   iii. Good Manufacturing Practic (GMP) regulates methods, equipment, facilities and control

   iv. What is included in SOPs?

   1. Effective da
   2. Purpose
   3. Scope
   4. Responsibility
   5. References: other SOPs
   6. Materials and equipment
   7. Procedures
   8. Approval signatures

Nov 4-6:15 PM

III Biotechnology careers

A. Biotechnology generates opportunit

   a. R&D (Research & Development) expenditures amounted to $16.4 billion in 2001, which was about 10% of all industry that year in the US

   b. These industry groups are expected to be one the fastest growing industry groups between 2002 – 2012; which is a 70% in the projected output growth for the US

   c. The top occupational groups with the highest projected percentage increase in employment, in this time frame, include life, physical and social occupation

   d. The life sciences are expected to grow by 18%, which will be led by a 19% increase in the biological sciences; with biological techs expected to increase by 19% as well

   e. There is also an expected increase in employment in the pharmaceutical and medicine manufacturing area, between 2004 – 2014, by 26%

Nov 4-6:15 PM

f. The most research intensive industries in the US is in the area of Biopharmaceutical

g. This sector employed more than 406,000 individuals across the US in 2003

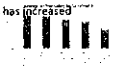
h. Each job that was directly created in the biopharmaceutical area, there were an additional 5.7 jobs create in the overall economy, well above the average for all other industry, this equated to an additional 2.72 million jobs Why?

i. This sector was also directly responsible for $63.9 billion in real output in 2003, which was up from $8 billion in 1992. This made the total output more than $172 billion in a ripple effic across when other sectors were figured into the equatio

j. More and More states are exploring the Biomanufacturing arena in an effort to spur their economic growth

k. Biotechnology careers are diverse, with excellent employment opportunit in numerous areas, such as writers and marketing specialis to genetic counselor , which usually do not require training in biology

l. However filing Biomanufacturing positions has been a challenge due-to th maturation of the fil and the need to manufacture these products has increased



Nov 4-6:15 PM

B. Seizing the opportunity

   a. If you are qualified and have the desir , you will be an excellent candidate to enjoy the unique opportunit and benefits that these sectors provide biopressing, pharmaceutical and chemical manufacturing

   b. These sectors will provide you with the opportunity to work in a growing and thriving industry; with skilled and competent individuals who are valued and in great demand

Nov 4-6:15 PM

c. Some of advantages by working in these sectors include:

i. Product pride with the satisfaction you will feel, when making th product, knowing that it will improve lives and boost the economy; these products will:

1. Will make it possible to help feed the world through increased food productio

2. Will reduction and prevention of diseas in children and infants

3. Will bring about the relief of painful symptoms, fighting disease and saving lives

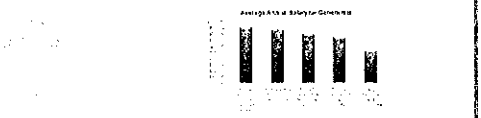
Nov 4-6:15 PM

ii. The ability to receive higher wages – employees in the bioprocessing, pharmaceutical and chemical manufacturing arenas can earn an average wage well above other manufacturing industries

iii. The ability to achieve stability in employment – As the industry rapidly increases, the demand and opportunity for the skilled, competent professional will increase as well. Your expertis is your unemployment insurance. This expertise in manufacturing technology is also portable; if your company does downsize, you are more than likely to acquire employment with another company.

Nov 4-6:15 PM

iv. You will work within a modern and professional atmosphere – most facilities are high-tech, compute-controlled, efficient environments th are staffed with well-educated and professional technicians, engineers and scientists, which use the team approach to encourage their employees to consistently strive for higher levels of responsibility in problem solving



Nov 4-6:15 PM

v. The ability for a variety of job and career advancement – many employees are able to cross-train, learn other jobs in other parts of the manufacturing process and thus possible move from one department to another. As employees gain more experience, they also have the ability to advance in their career; managerial tracks, more supervisory responsibility, or the ability to advance in the scientific or engineerin arenas

vi. There are also companies who have reward programs for their employees knowledge and skill levels and tuition reimbursement as wel

(All the above information in this section came from the following

Nov 4-6:15 PM

C. On the job – career opportunities in the manufacturing aren

a. Production positio are individuals who work on product production and are required to be involved in many different , complex, and lengthy steps toward the final produc

i. These positions require a high school diploma, a process technician certificate or an associate degree in applied science; this also includes those who work on the floor as technicians in the Biomanufacturing facility, including (homework – look up responsibilities) Entry-level positio

1. Process Technician
2. Manufacturing Prep Process Technician
3. Formulation/Fill Technicia
4. Packaging Technician

Nov 4-6:15 PM

ii. These positions require a bachelor of science degree in engineering (homework – look up responsibilities) Entry-level positio

1. Process Engineer in Process Development
2. Process Engineer in Manufacturing

b. QC, QA and Validation Positio (homework – look up responsibilities); some of these positions require prior work experience, while it is possible to be promoted into these positions as well

I. A Quality Control Assistant requires a 2 year degree – A.A.S; Entry-level positio

ii. These positions require a B.S. or B.A. four year degree; Entry-level positio

1. Quality Control Associate
2. Quality Control Engineer (B.S. in engineering)
3. Quality Assurance Associate

Nov 4-6:15 PM

iii. These positions are non-entry-level and require at least a four-year degree and job experience in the industry (homework – look up the responsibilities

1. Process Quality Inspector
2. QA Auditor
3. Validation Specialis (A.A.S./B.S), Engineer (B.S. in engineering) or Scientis (B.S.)

Nov 4-6:15 PM

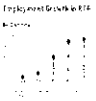
c. Manufacturing Support include a variety of positions that includes maintenance of the plant and all its utilit such as electrical systems, water purifcation syste and heating, ventilation and air conditi ; as well as waste products management

i. These positions require a high school diploma, a specialized certification or associates (2yr) degree (homework – look up the responsibilities) Entry-level position

1. Instrumentation/Calibration Technici
2. Manufacturing Support Technician
3. Environmental Technician

ii. These positions require a four year engineering degree (homework – look up the responsibilities) Entry-level positi

1. Maintenance Engineer
2. Process Control Engineer
3. Environmental Engineer



Nov 4-6:15 PM

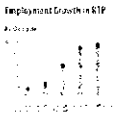
d. R&D scientists work in labs and generally are not a part of the manufacturing facility

i. These positions require a two or four year degree (homework – look up the responsibilities) Entry-level positi

1. Research Assistant
2. Research Associate

ii. These positions require a doctorate or master's degree plus work experience (homework– look up responsibilities) Entry-level positi

1. Research Scientists in Drug Discover
2. Process Development Scientis



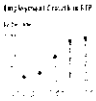
Nov 4-6:15 PM

e. Other division positions include those employees who may work in an offi within the facility or in some other locati

i. These positions may be entry-level or require some industry experience (homework – look up responsibilities

1. Customer Support Specialist (a 4 year degree)
2. Clinical Trials Associate (CRA – 2 to 4 year degree or a certification the fi ld

ii. These positions require a minimum of a 4 year degree and industry experience, which include a Regulatory Affairs Specialist homework – look up responsibilities



Nov 4-6:15 PM

Resources for pictures and videos

1. biotech_feature.jpg
roche.com
2. anil1p.jpg
bangor.ac.uk
3. bioprocessing.jpg
ncl.ac.uk
4. genetic-engineering-2824.jpg
scienceclarified.com
5. Genetic-Engineering.jpg
b4tea.com
6. genetic-engineering.jpg
cellsighttech.com
7. 1297251928_genetic-engineering.jpg
american-business.org
8. 381819_506565882702009_1588542956_n.jpg
facebook.com
9. Biotech-ETFs-Biotech-Stocks-IBB-XBI-Clinical-Trials.jpg alphaprofit.com
10. Mouse Held By Researcher_web.jpg
amprogress.org
11. Clinical+Trials.jpg
sjcofthynet.blogspot.com
12. pharmaceutical_img.jpg
ferrymachine.com
13. QCIL-pics-2-copy.jpg
afro-ip.blogspot.com
14. farmwars3.jpg
fourwinds10.net
15. 5132VrKWQeL._BO2,204,203,200_PIsitb-sticker-arrow-click,TopRight,35,-76_AA300_SH20_OU01_.jpg
amazon.com

Nov 12-9:38 AM