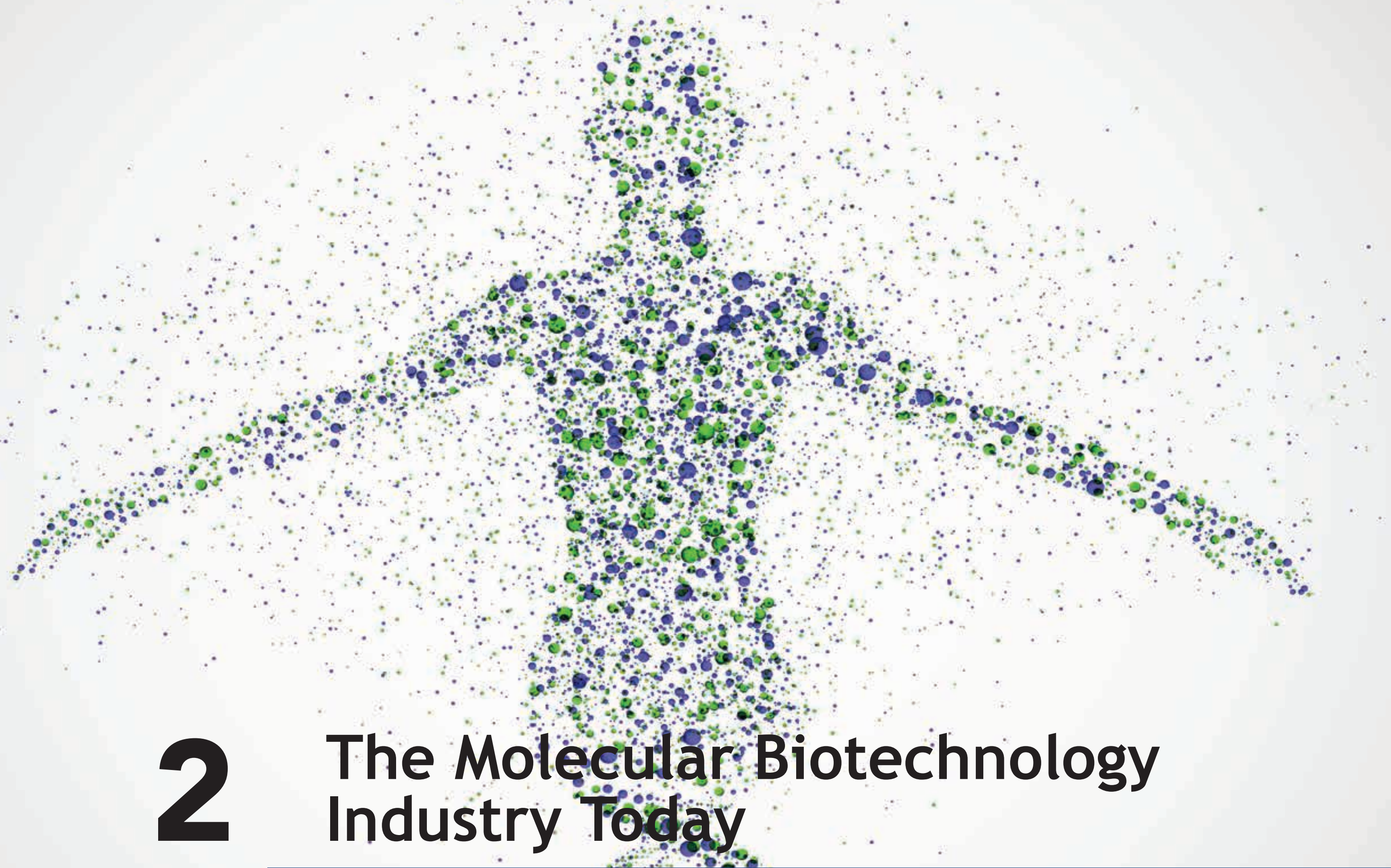

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2 The Molecular Biotechnology Industry Today

LEARNING OBJECTIVES

Upon reading this chapter, you should be able to:

- Describe the interdisciplinary nature of the molecular biotechnology industry.
- Characterize the advances in medicine due to molecular biotechnology and differentiate among biopharma, genetic counseling, and gene therapy.
- Define "genetically modified organism" and explain the basic methods used in their production.
- Provide reasoning for the establishment of seed banks.
- Recall the uses of aquaculture including its role in bioprospecting.
- Recognize the role of industrial biotechnology in consumer products.
- Discuss green biotechnology while explaining bioremediation, biofuels, and conservation methods aided by molecular biotechnology.
- Describe DNA fingerprinting and its role in forensics.
- Identify examples of biodefense.
- Explain the utility of evo devo and provide examples of its potential.
- Detail common activities and objectives of molecular biotechnology professionals.
- Compare and contrast the careers available in the molecular biotechnology industry and associated fields.

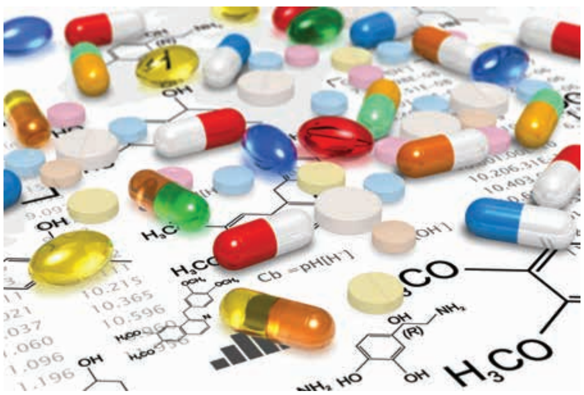
The tools available to the molecular biotechnology industry are essentially universal. The consistency of the genetic code amongst the diverse forms of life on our planet translates to our ability to pick and choose traits, modify genetic sequences, and deconstruct the aberrations that have caused trouble in the past. The technological tools of the industry have allowed for a variety of applications. This makes **molecular biotechnology** an interdisciplinary field, making use of the wealth of knowledge previously discussed and drawing from biology, chemistry, mathematics, computer science, engineering, philosophy, and ethics.

Applying Molecular Biotechnology to Modern Lifestyles

The goals of this field have in large part determined the course of each segment within the industry. Scientists who choose this field as a career may seek to rid the world of its diseases or eliminate pollution from the environment. Or perhaps they are interested in increasing the world's food supply and ridding the world of starvation. They may wish to improve industrial processes in order to make them safer or easier to complete, more cost effective, or more environmentally friendly. Molecular biotechnologists may also focus on the origins of life, the evolutionary relationships among organisms, and how organisms utilize gene expression in the processes of growth and development. The major segments of the molecular biotechnology industry and how they influence modern living are now outlined in brief, with subsequent chapters providing greater detail.

At the Doctor, In Your Medicine: Life Science and Health Care

The Western world has its host of health problems associated with industrialization, such as heart disease, obesity, and cancer. Add this growing list of "first world diseases" to the known inherited diseases and there is an abundance of research material waiting to be studied. A large majority of today's molecular biotechnology industry is devoted to health care applications. Biopharma (bioengineered pharmaceuticals), gene therapy, and genetic counseling are all important areas of research and development.



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Biopharma

The development of pharmaceuticals via genetic engineering, known as **biopharma**, is a primary goal. When dysfunctional genes or gene products are discovered to be the cause of a particular disease, the delivery of a functional gene or gene product may be all that is needed to "medicate" the patient. Since the first biopharma product was introduced in 1982 (see **BOX 2.1**), literally thousands of drugs produced with molecular biotechnology have been researched and hundreds have been approved for market (**FIGURE 2.1**). While biopharma aims to fight against the major diseases affecting humanity, over half of the drugs investigated relate to cancer treatment.

Gene Therapy

Gene therapy is an extension of biopharma technology. **Gene therapy** involves techniques that correct defective genes, or alter their expression, in order to treat or even potentially cure disease. Gene therapy is in its relative infancy but already shows promise in repairing disease-causing alleles. It is encouraging that there is so much still to be discovered. The processes of human cell culture and high throughput screening, to be described in detail, are improving our ability to systematically narrow down potential therapeutics and ensure their compatibility within the human body.

Genetic Counseling

Genetic counseling is also an aspect of the healthcare industry's involvement in molecular biotechnology. **Genetic counseling** involves the identification of disease in an individual's family history and determining the appropriate measures one might take to avoid passing on the disease to his or her offspring. While previously genetic counseling relied heavily upon creating family **pedigrees** to trace the inheritance patterns of disease, today genetic counseling more often involves genetic profiling (**FIGURE 2.2A** and **B**). **Genetic profiling** identifies genetic markers in an individual, some of which are genetic sequences for known disease-causing alleles and mutations associated with susceptibility to disease (**FIGURE 2.3**).

On Your Plate: Agriculture and Food Production

Humans have been selectively breeding plants and animals for thousands of years. We have used microbes such as bacteria and yeast in the production and preservation of food. Although it has been met with its

Box 2.1 Biopharma Begins

Patented in 1982, Humulin (short for "human insulin") was the first genetically engineered human therapeutic approved by the U.S. Food and Drug Administration and thus the first biopharma product on the market. The pharmaceutical was developed by Genentech in the late 1970s but licensed for production through Eli Lilly and Company in the year of its patent. The pharmaceutical giant is credited with guiding Humulin through the FDA approval process, as Genentech was unfamiliar with the regulatory terrain.

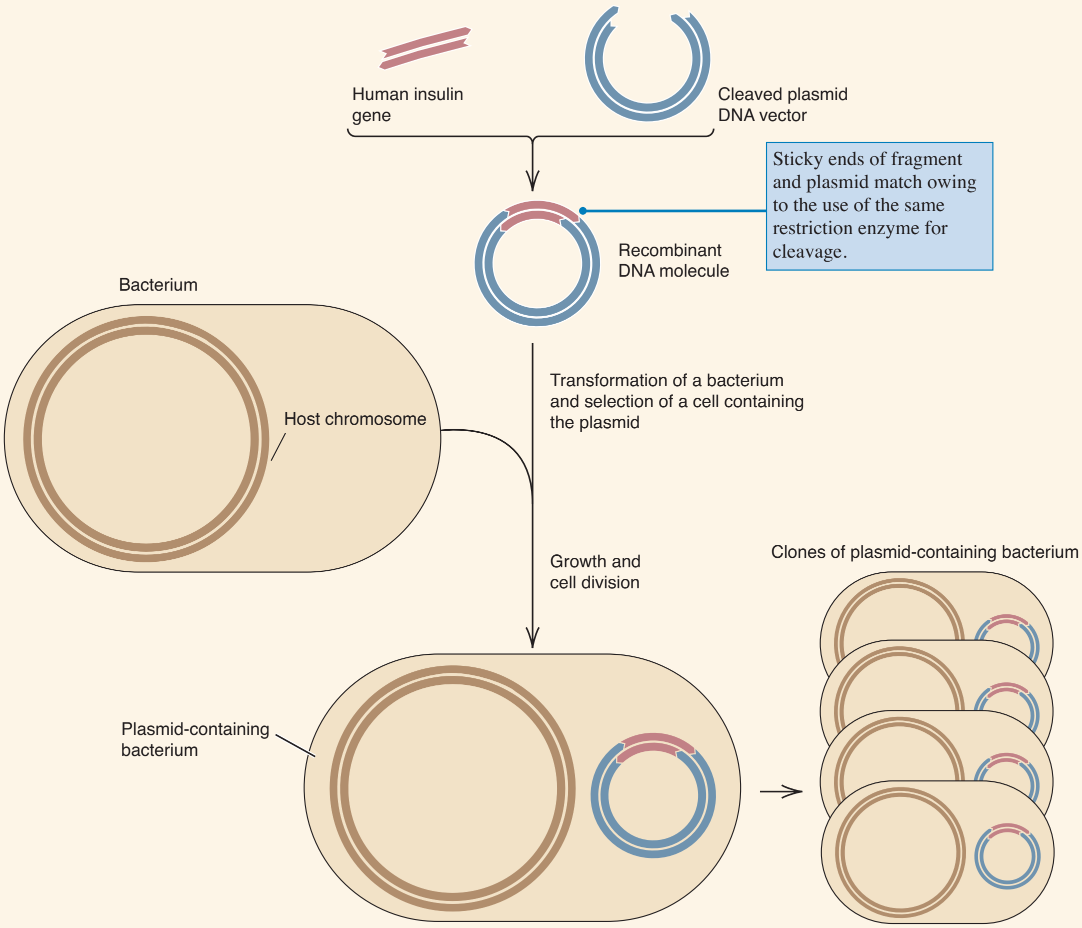


FIGURE 1 **Recombinant DNA and cloning techniques utilized in the process of Humulin production.**

Humulin replaces insulin in diabetes patients who are unable to produce the protein hormone themselves. Creating this drug was simply a matter of identifying the human insulin gene and inserting it into a bacterial host, in this case *E. coli*. Once the *E. coli* was transformed, the human insulin gene could be expressed in endless supply, thus producing a steady stream of human insulin for pharmaceutical consumption.

© PinkTag/iStockphoto.com

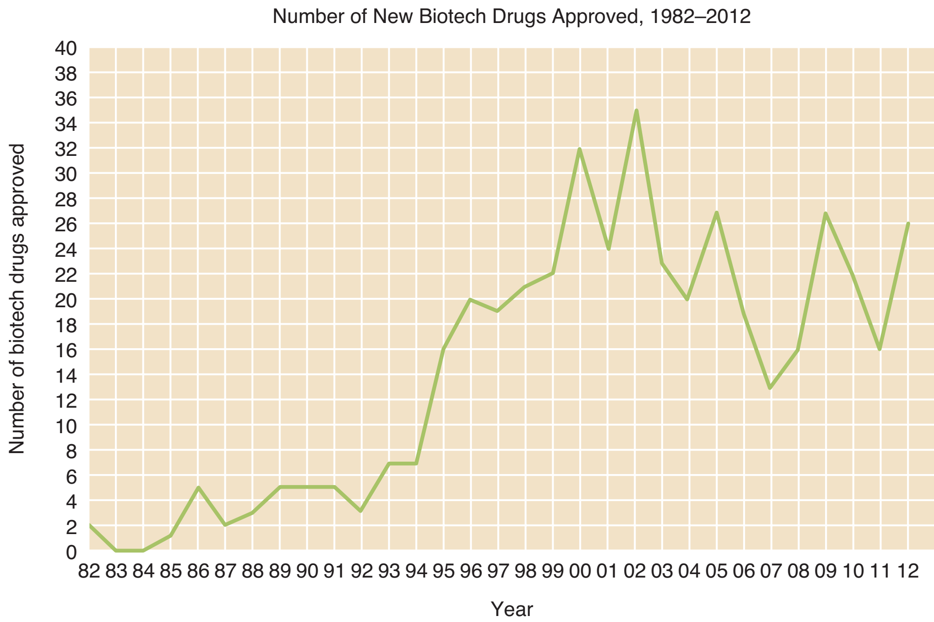


FIGURE 2.1 **The number of drugs produced through biotechnology approved for market has increased steadily since Humulin.**

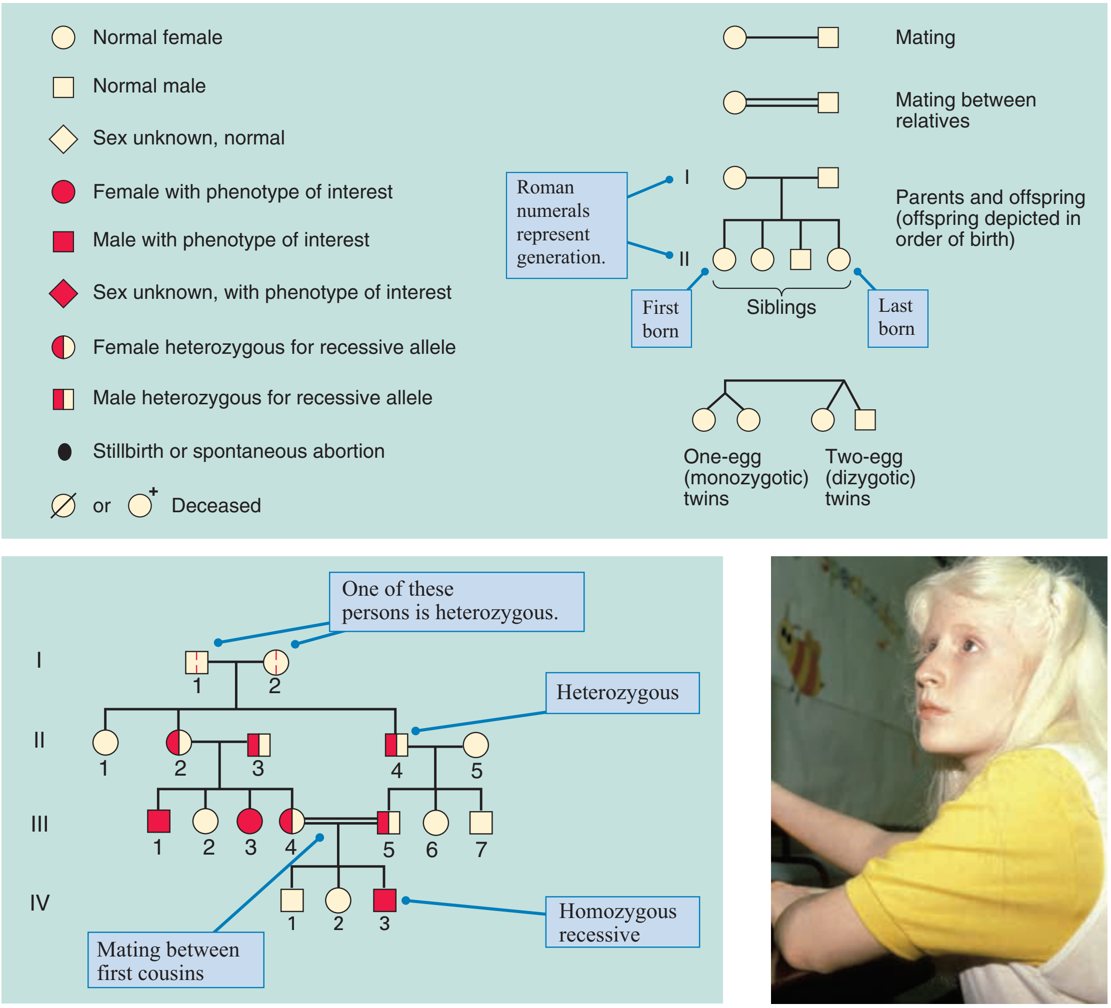


FIGURE 2.2 **(A) The standard icons used in the creation of genetic pedigree charts. (B) A pedigree for albinism.** Note the incidence of inbreeding and how it affects the frequency of recessive alleles. What kind of inheritance pattern does albinism exhibit? © Rhoda Sidney/PhotoEdit, Inc.

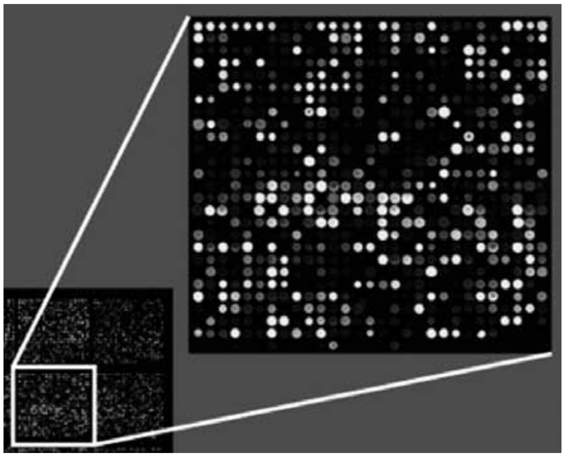
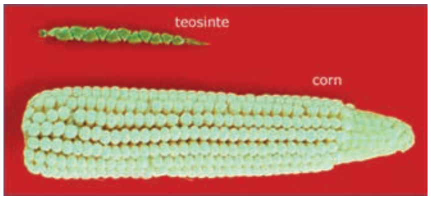


FIGURE 2.3 The outcome of genetic profiling. Each glowing DNA microarray spot indicates a positive match for a genetic marker. Courtesy of Jeffrey P. Townsend and Duccio Cavalieri, Yale University

share of controversy, agricultural biotechnology may be viewed as a further progression of our history of food modification. Genetically engineered plants and animals are a dominant component of agricultural biotechnology. The establishment of seed banks seeks to preserve the biodiversity of the plant kingdom for future generations. Aquaculture methods alleviate pressure faced by the world's natural fisheries.

Genetically Engineered Food

Artificial selection of plants and animals led to the domestication of crops and livestock during the last 10,000 years of human agriculture. Wild teosinte was bred to become corn and animal husbandry changed aurochs into cows (**FIGURE 2.4**). While these changes took generations upon generations, molecular biotechnology can generate an entirely new line of plant or animal without the need for breeding at all. **Genetically modified organisms (GMOs)** are organisms which contain knockout or inserted genetic material. A gene **knockout** renders a gene inoperable, thereby preventing the synthesis of its protein product(s). Transgenic organisms contain genetic information that is foreign in origin. Genes may be knocked out of or inserted into a food crop or animal in order to confer desirable traits in the organism. A crop such as corn or soybeans may be modified to produce herbicide or pesticide resistance. Fruits and vegetables can be enhanced to yield higher concentrations of vitamins and nutrients (see **BOX 2.2**). Plants and animals may be genetically engineered to increase their growth rates, thereby shortening the time to market and potentially increasing the overall food supply. Genetically modified foods, whether whole or as an ingredient, are the subject of debate and controversy. Although they are deemed safe by the U.S. Environmental Protection Agency (EPA), Food



(A)

(B)

FIGURE 2.4 (A) The relative sizes of wild teosinte and cultivated corn. (B) Aurochs died out approximately 400 years ago. Courtesy of John Doebley; Courtesy of Monk, Inc.

and Drug Administration (FDA), and U.S. Department of Agriculture (USDA), many groups and individuals question their long-term health and environmental effects (**FIGURE 2.5**).

Seed Banks

Concerns over the effects of GM crops have contributed to the establishment of seed banks. As GMO crops continue to be planted more and more, scientists have recognized the potential negative impacts on biodiversity. Genetically modified crops are typically planted as

FIGURE 2.5 A Greenpeace protest in front of the Berlin parliament building in 2003 depicts a killer GMO corn field. © Tobias Schwarz/Reuters/Landov.

Box 2.2 "Pharming: Food as Medicine"

© NiDerLander/iStockphoto.com

Another example of the interdisciplinary nature of molecular biotechnology can be seen in particular genetically modified foods used to deliver drugs and vaccines. Using GMOs as living bioreactors to produce therapeutic proteins is known as "pharming." Pharming entails both the development of a genetically engineered medication or vaccine and the utilization of transgenic plants and animals as edible delivery vehicles. Transgenic goats, sheep, and cattle have been successfully created to yield human therapeutics in their milk. For example, transgenic sheep are used in the United Kingdom to produce the protein alpha-antitrypsin. Normally this protein is influential in maintaining the integrity of connective tissues. In its absence, tissues degrade, such as in the liver where it can lead to cirrhosis. The milk is then consumed as a treatment for liver disease and hemorrhages.

monocultures, meaning a single variety is planted in the entire acreage available (**FIGURE 2.6**). As monocultures contain just one genetically engineered variety, this essentially constitutes a field of clones. Every plant put in the ground is genetically identical. The danger of monoculture practices can be illustrated by the Irish Potato Famine of the 1840s. If Ireland's potato plantings had been more diverse, it would have been less susceptible to blight.

As transgenic crop varieties become more commonplace, the number of unique cultivars growing in the ground and being sold in the store has decreased. In an effort to preserve the genetic information found in the diverse plant species historically used as food, seed banks aim to collect, catalog, and store as many genetic varieties as possible. In fact, routine practice now includes determining the genome sequence of stored seeds. In the event a field of clones falls prey to drought or disease, or if biodiversity decreased by any other means, the seed banks would act as a reserve by which species could be reintroduced. Thus, seed banks act as a modern day Noah's Ark for plant life (**TABLE 2.1**).

Note that a cultivar could be reintroduced by traditional propagation methods as a whole plant, or select genes could be utilized for creating new genetically modified crops. For example, U.S. corn yields were cut in half during the 1970s due to widespread fungal infection. Researchers identified a fungal resistance gene in wild corn preserved in seed banks, and were able to modify the existing corn to express the resistant trait.

FIGURE 2.6 An example of monoculture. © Zoran Orcik/iStock/Thinkstock

TABLE 2.1

The Reasons Behind Seed Banks

Cause of Concern	Negative Impact Alleviated by Seed Banks
Natural Disaster	Existing species may be wiped out.
Disease	Existing species are susceptible and may not adapt fast enough.
Anthropogenic Causes	War and other human-made disasters can destroy existing biodiversity.
Climate Change	Changing patterns in weather, pollination events, and exposure to pests and disease, all of which may be the results of climate change, could alter the viability of existing species.
Timely Research	General trends in biodiversity decline may eliminate species with beneficial properties, such as medicinal compounds.

Data from United Nations. International Treaty on Plant Genetic Resources for Food and Agriculture. Food and Agricultural Organization. Rome 2001

Aquaculture

Much like animal husbandry and selective breeding of crops, aquaculture is not a new technique. **Aquaculture** involves the production of fish or shellfish for human consumption in a controlled environment. Aquaculture accounts for nearly 50% of total fish consumption worldwide, making it a vital source of seafood for humans. As wild fish populations are pressured by commercial fishing enterprises, aquaculture sources will prove more and more valuable to fulfill this need.

Molecular biotechnology plays a role in aquaculture by providing the means to genetically modify seafood species. Through recombinant DNA technology, aquaculture researchers have created disease-resistant strains of oysters. Just as livestock are treated with antibiotics due to their confined living arrangements, vaccines for aquaculture operations have become necessary. Such vaccines have successfully resulted from applications of molecular biotechnology. Genetically modified salmon are another product of aquaculture biotechnology; GM varieties that overproduce growth hormones exhibit a much shorter growing period and allow more salmon to go to market in less time (**FIGURE 2.7**).

Another aspect of aquaculture is **bioprospecting**. The concept is similar to seed banks, only in this case aquatic species are the focus. Aquatic life represents some of the oldest organisms in the evolutionary progression life on this planet. The species found within the freshwater and marine ecosystems, whether unicellular or multicellular, have survived under extremely harsh conditions. This would create the potential for a wide variety of useful genes and gene products that evolved as adaptations for survival. By harvesting and classifying the various aquatic organisms of the world, molecular biotechnologists can create a bank of genetic "tools" for future use. One example of bioprospecting is the marine sponge, which is being explored as a potential source of anticancer compounds (**FIGURE 2.8**).

FIGURE 2.7 A 2010 photo of an 18-month-old GM salmon modified with growth hormone (background) compared to a non-GM salmon of the same age (foreground). © MCT/Landov

FIGURE 2.8 Researchers Murray Monro and John Blunt discovered cancer-fighting properties in this sea sponge off the coast of New Zealand. © Fairfax Media/The Press.

Around the House, At the Superstore: Industrial Biotechnology

This branch of molecular biotechnology is much like a catch-all in that it encompasses techniques and processes from a variety of industries. Those aspects of the field that do not fit in nicely would be found here. When we consider the vast quantity of tangible goods produced in the factories of the world, each manufacturing process might benefit from molecular biotechnology in some way. For example, enzymes produced through biotechnology can act as catalysts in order to speed up many processes. Genetically engineered microbes may be introduced into manufacturing systems as decontaminants to eliminate waste streams. Proteins obtained through molecular biotechnology techniques can act as ingredients to improve different aspects of a product.

Green Biotechnology: Environmental Science and Conservation

Since the early part of the twentieth century, humanity has engaged in a continuous conversation on how to become more environmentally friendly. It is a reaction to the negative side effects of industrialization: air, water, and soil pollution, dwindling of fossil fuels, and mounting evidence in support of global warming and climate change. Ways to minimize our impact upon the natural ecosystems of the world have been outlined, debated, and tabled time and again. The advent of molecular biotechnology is changing our approach to old questions, such as how to reduce pollution and the development of alternative fuels. As biodiversity depletion persists, molecular biotechnology may allow us to preserve threatened and endangered species, or even resurrect those which have become extinct.

Bioremediation

Bioremediation uses molecular biotechnology to degrade environmental pollutants. Industrial processes lead to the release of harmful chemicals that persist in the natural environment. Left to naturally occurring chemical cycles, these pollutants continue to accumulate because of their extremely slow turnaround. Oil spills act as an extreme example of both monumental environmental damage and the bioremediation techniques employed to alleviate the massive pollution. Beginning with the 1989 Exxon Valdez oil spill off the coast of Alaska in Prince William Sound, scientists have let loose oil-degrading strains of bacteria. The bacteria act as a living sponge, metabolizing the chemicals found within the oil (**FIGURE 2.9**). They thereby break down large molecules into smaller components that can be absorbed by the environment much more easily. However, oil may still be trapped beneath the superficial layers of soil. Long term impacts of the Valdez spill are still apparent over a quarter century later. This technology was improved with the Deep Water Horizon oil spill in 2010, when the oil-eating bacteria were delivered via nanoparticles over the Gulf of Mexico. It is still too soon to tell how effective these treatments were to the Gulf environment. Impact studies continue.

Biofuels

Alternative energy sources continue to be on the forefront of environmental and economic policies. The needs for energy independence, cheaper energy with less price volatility, and cleaner energy have culminated in our desire for technologically advanced alternatives. The decomposition and fermentation of various organisms are being investigated as potential biofuel sources. **Biofuels** are sources of energy derived from biological carbon fixation. Corn and its byproducts, agricultural waste, prairie and switch grasses, and other sources of concentrated cellulose are being investigated as potential fuel sources.

Conservation

The preservation of biodiversity certainly plays a role in seed banks and bioprospecting, as previously presented. Both of these enterprises seek to collect and maintain threatened genetic profiles before they become extinct. An additional area of conservation is seen in projects like the Genome 10K Project, which is assembling a genomic zoo of 10,000 vertebrate species.

Some would even propose reviving extinct species through cloning, as is the case for the Long Now Foundation's Revive and Restore Project. Headed by Stewart Brand, known for his *Whole Earth Catalog*, Revive and Restore maintains a list of potentially revivable extinct species. Whether an extinct species is well-suited for the project depends on criteria such as how desirable and practical the organism is considered to be, and how easily it may be reintroduced into the wild.

Currently, the passenger pigeon acts as the model candidate. The passenger pigeon was iconic until its extinction in the early twentieth century, and its reintroduction would be feasible and practical. DNA from this wild pigeon is readily available from museum specimens and the species has close extant relatives that might ease reintroduction (**FIGURE 2.10**).

FIGURE 2.9 A bioremediation project along an oil-spilled shoreline. Courtesy of the Exxon Valdez Oil Spill Trustee Council/NOAA

FIGURE 2.10 Revive and Restore researcher Ben Novak examines the last living carrier pigeon, Martha. She died in captivity in 1914. © Ryan Phelan/The Long Now Foundation

Protecting Citizens and Nations: Forensics and Biodefense

Techniques of the molecular biotechnology industry are useful in the identification and tracking of organisms. Our ability to confirm the identity of individuals through genetic analysis has dramatically improved the level of confidence in positively determining perpetrators of crime. The technology may even be used to exonerate a wrongly convicted inmate. The tracking of genetic material through space and time can help epidemiologists describe the infection patterns of disease. This has the potential to prevent contamination and the outbreaks that follow. If the inspectors of our food, drug, and water supplies incorporate these tracking abilities, such a practice would constitute preemptive defense of our nation.

Forensics

The term **forensics** refers to science and technology used in the investigation of crimes. The field has exploded thanks to molecular biotechnology. The 1995 murder trial of O.J. Simpson brought this to the attention of the American public when 45 blood samples taken from crime scene evidence were checked against his DNA. Of the 45 samples, 30 were found to be a match with the suspect using restriction fragment length polymorphism (RFLP) analysis. RFLPs are varying lengths of the DNA molecule cut at specific locations with restriction enzymes. The specific length aids in identification. At the time, DNA sequencing was not a part of everyday vernacular and thus likely was not valued as highly as it is today. This may be one reason the jury did not commit Mr. Simpson of murder.

DNA fingerprinting is an additional forensic application. Also referred to as genetic profiling, this technology identifies genetic markers that are unique in each person. For example, genetic markers with variable numbers of tandem repeats (VNTRs) that vary from one person to the next. It is an additional layer of certainty when identifying a suspect of a crime, a victim of a crime or accident, or in cases of paternity.

Biodefense

Molecular biotechnology is being utilized to improve national security, an area known as **biodefense**. Biological contamination of food, water, or medicine has the potential to be accidental or intentional. In either event, our capability to identify the source of contamination can lead to improved security measures for the future. If intentional contamination took place, it would be considered bioterrorism. Biotechnologists have the potential to prevent bioterrorism by closely monitoring all known biological specimens posing such a threat (**FIGURE 2.11**). They can also actively develop treatments such as vaccines in the event a pathogen was released. An additional application in the area of biodefense is the use of biosensors to detect explosives, chemicals, and pathogens in places such as airports or international borders.

FIGURE 2.11 **Biodefense researchers work with the deadliest known pathogens, requiring them to wear biohazard suits.** © Photodisc

Evo Devo: The Development of Life and the Human Family Tree

The data obtained from various DNA sequencing projects can be used to understand both development and evolution. The order of events that transform a single-celled zygote to a full-sized individual entail the development of an organism. Comparisons of DNA sequences, genomes, and proteomes can all offer insight into the evolutionary relationships. We can use this information to understand the place of our species in the tree of life.

Evo Devo

Evo devo is a relatively new branch of molecular biotechnology. The term is an abbreviation of "evolutionary developmental biology." **Evo devo** represents the convergence of study within the fields of evolution and embryonic development. The myriad discoveries in genomics revealed that we share a number of genes with other animals. The fact that these genes were upheld throughout evolutionary eons indicates they share a common purpose across species. These universal genes act as a body-building tool kit that determines the specific timing and intensity of gene expression during development. The toolkit acts as a conductor to orchestrate the complex series of events that tell a developing embryo whether it will be bilateral

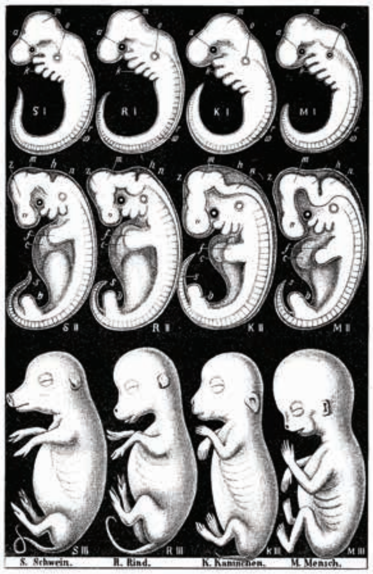


FIGURE 2.12 The comparative anatomy of mammalian embryos. © Photos.com/Thinkstock

or radially symmetrical, if it will have a tail, walk on two or four feet, or fly, and so on. By characterizing the exact pattern of orchestrations occurring during the development of different organisms, researchers can then recognize the differences and begin to establish an order of progression. This order directly correlates to the evolution of various creatures.

Comparative embryology is not a new pursuit; Charles Darwin engaged in comparing various embryos in attempts to determine their evolutionary relationships (**FIGURE 2.12**). What makes evo devo unique is that we now add a molecular understanding: how genes and environment interact to produce a new organism. It is analogous to the initial theory of natural selection as an evolutionary mechanism and the eventual modern synthesis. While Darwin and Alfred Russel Wallace were able to conceive the mechanism of natural selection by observing species at the organismal level, the modern synthesis nevertheless added depth to the concept of evolution. In the same vein, comparative embryology can draw conclusions based upon organismal observations, but evo devo is layering molecular events onto existing principles.

The Human Family Tree

The field of evolutionary biology has benefitted tremendously from molecular biotechnology. As the DNA of more and more species are sequenced, the data are used to determine the step-by-step progression of one species giving rise to another wherever possible. Specific segments of DNA, including particular genes, can be honed in on for small changes over time. Then a phylogenetic tree is created, which is a visual schematic of evolutionary relationships (**FIGURE 2.13**).

As previously discussed, projects such as the Genographic Project are using this information to learn more about our own species and where we fit in the grander scheme of life. Anthropologists are using DNA evidence in concert with archaeological evidence to piece together the story of our past. By sampling populations around the world, the project has constructed a map of human migration out of Africa, showing how our species came to populate the continents of Earth (**FIGURE 2.14**).

Molecular Biotechnology Industry Practices

The molecular biotechnology industry follows its interdisciplinary nature when it comes to practice as well. Research scientists often begin the flow of work when they identify a gene or gene product. This leads to the development of genetic engineering in some form. Moving from the initial discovery to a final product involves a number of steps.

Funding: Public and Private

There is no getting around the associated costs to conduct research. Money must come from somewhere, and the source may be public or private. Funding is awarded based on the viability of the product or information

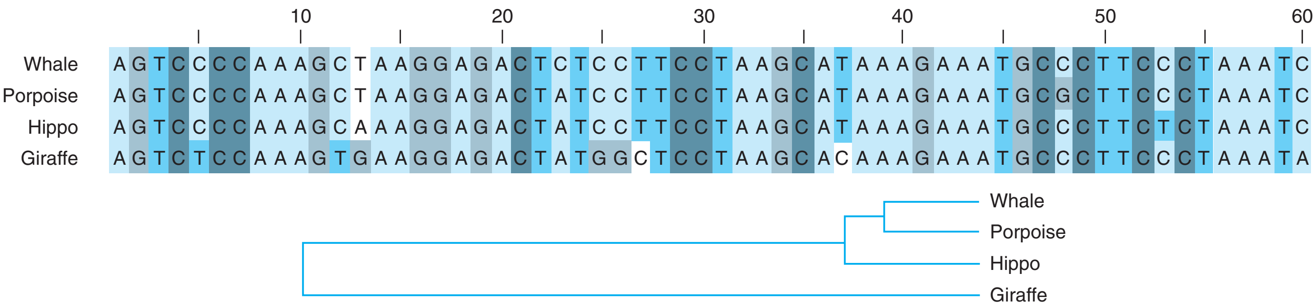


FIGURE 2.13 Evolutionary biologists used DNA sequence comparisons to construct a phylogenetic tree linking hippopotamuses and giraffes with their aquatic cousins, whales and porpoises.

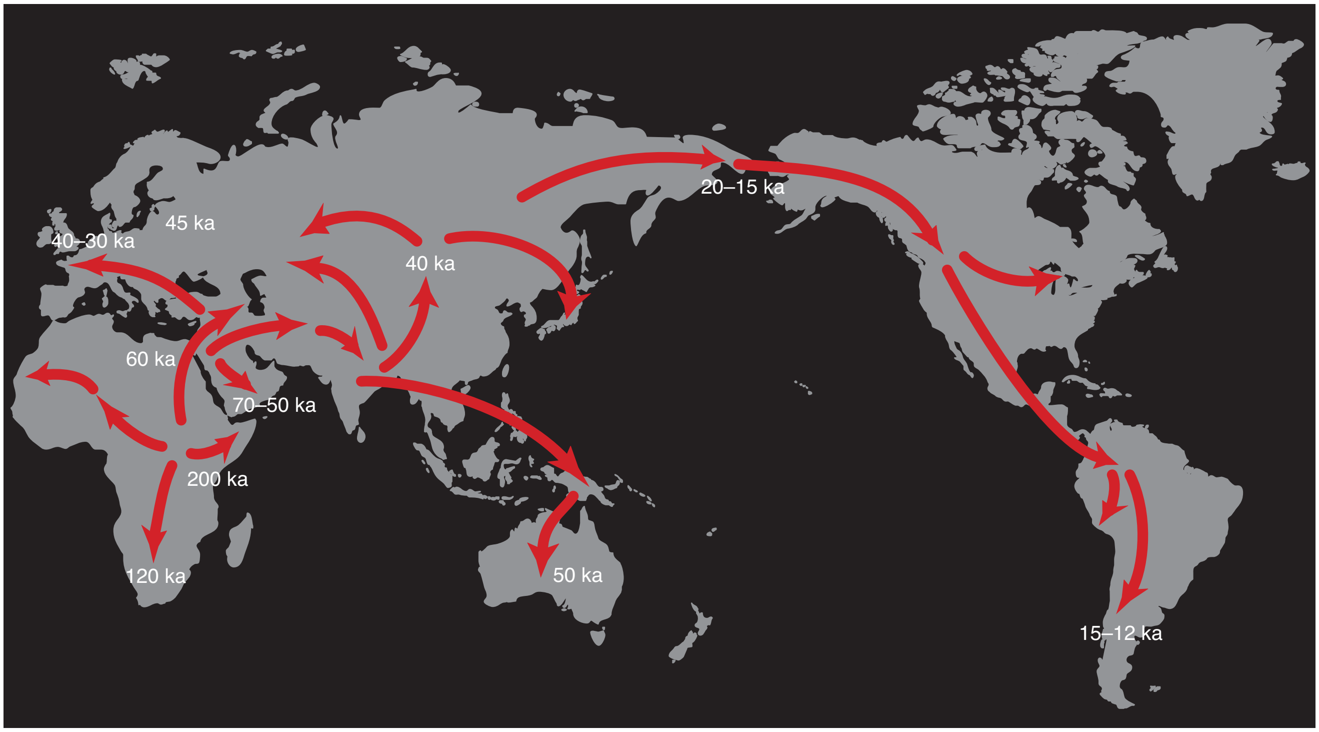


FIGURE 2.14 The Genographic Project has pieced together the migratory patterns of *Homo sapiens* out of Africa.

to be obtained through the research. The value of the research is also considered, both in terms of the educational value of the knowledge gained and in terms of the profitability of the project's output.

Research scientists may work in a publicly funded laboratory at state colleges and universities or state or federal agencies such as the National Institutes of Health or the Center for Disease Control. Public and private companies may also draw funding through grants from federal sources. Alternatively, private entities, such as venture capital firms or pharmaceutical corporations, may fund research for a laboratory as well.

The funding process starts with the submission of a research proposal, which a panel of scientists and biotechnology professionals then reviews. Funding decisions may also be subject to government regulation. For example, the 1996 Dickey-Wicker law limited federal funding in stem cell research. While funding decisions are based on the criteria previously mentioned, personal relationships and political influence have a way of influencing the outcome.

Publications and the Peer-Review Process

As with any scientific endeavor, part of the research process is to communicate your findings. The nature of science involves the collaboration of diverse interested parties. Communicating information is a necessary step that is carried out through professional journal articles. A wealth of journals pertain to the field of molecular biotechnology, including *Cell*, *Journal of Molecular Biology*, *Nature*, *Genetics*, *Molecular and Cellular Proteomics*, and the *American Journal of Public Health*.

Peer review is a process associated with journal article publication to ensure the accuracy and validity of a proposed paper. Once the author(s) submits a paper, a journal editor sends advanced copies to experts on the particular subject. The experts review the paper and return comments and suggestions to the editor, which the author is usually then privy to for the purposes of modifying the original work as needed.

Scientists are also on the receiving end of this communication. It is crucial to stay current with the cutting edge to know what events are taking place in your field, who amongst your colleagues is contributing knowledge and technology, and how the newly published information can be used in future studies.

Conferences and Seminars

While it is standard practice for biotechnologists to read journals, it is also beneficial for them to meet face to face on a regular basis. Conferences draw large numbers of participants in vast exhibition halls. Members of industry and academia convene to discuss the latest developments in their areas of expertise. Conferences include visiting booths of different vendors to learn more about the latest products and technologies and sitting in on talks and symposia led by scientists and industry executives. Conferences are usually several-day-long events that require travel and associated costs, such as entry fees.

Seminars are more intimate in nature and tend to be much less commercial than conferences. They are smaller gatherings at colleges and universities typically held within a single department. Seminars may also be held at organizational or association meetings. They offer researchers, in some cases including student researchers, the opportunity to present information on topics related to their projects. Seminars are usually free and open to the public, unless membership is required.

Intellectual Property

Any knowledge obtained from biotechnology research could yield intellectual property that may be patentable. Once patented, the owner now holds rights to the information and can incur licensing fees toward any researcher seeking to use it. Any additional technologies discovered or invented would then be subject to royalties due to the patent holder(s).

Patenting becomes tricky when the intellectual property originates from living organisms. It raises ethical implications when something that could be construed as public domain becomes private property. Regardless, in 2011 a federal appeals court ruled that human genes can be patented. In 2013 the Supreme Court overturned this ruling; at present, human genes are not patentable. Until this recent verdict, the molecules found in each of our cells could essentially have part ownership—what's yours was not yours. Unfortunately, if this pipeline to profit was eliminated, many players in the biotechnology industry might lose their incentive to conduct additional research.

Careers in Molecular Biotechnology

As we have seen, the molecular biotechnology industry spans a growing number of endeavors. By virtue of its interdisciplinary nature, the number of careers pertaining to the field is likewise increasing. There are comparatively few areas of occupation that do not involve some aspect of the science, technology, engineering, and mathematics (STEM) required of molecular biotechnology. Collectively, the public and private sector occupations related to STEM disciplines involve these four elements. A career in molecular biotechnology is included in the rapidly growing STEM industries.

When considering a career in molecular biotechnology, there are a number of roles to choose from. Not surprisingly, many require advanced education beyond the bachelor's degree level. Medical and Doctor of Philosophy degrees are common among biotech professionals. A higher degree obtained correlates to a higher earning potential. Jobs are concentrated around technology centers such as colleges, universities, and research parks.

> **FOCUS ON CAREERS**
>
> In this chapter, an overview of the various careers available pertaining to molecular biotechnology is presented. Throughout the remainder of this text, be sure to notice the *Focus on Careers* features. These features will relate to the specific topics being presented in each chapter and will provide a more detailed look into the type of work being done within each field utilizing molecular biotechnology. *Focus on Careers* includes up-to-date, relevant information such as educational requirements, day-to-day activities, and performance expectations. Through *Focus on Careers*, you will be exposed to real life professionals and institutes of excellence along with the strides they are making to innovate science, technology, and society.

Careers in the Laboratory

Laboratory Managers

Laboratory managers act as overseers of the day-to-day operations performed within the lab setting. They are responsible for hiring decisions, budget management, and regulatory compliance. When a research project is initiated, the laboratory manager searches for the necessary personnel and orients new employees to the good laboratory practices (GLPs) and standard operating procedures (SOPs) of the particular project. It is an ongoing process to maintain a sufficiently trained and functional team, which the laboratory manager must ensure takes place. This position may require someone to conduct trainings on laboratory safety and the laws pertaining to that lab, or facilitate the presentation of such trainings. The laboratory manager must also keep the lab running smoothly by keeping materials and supplies well stocked, maintaining the working order of all tools and instruments, and providing a regulatory compliant environment. As a budget manager and the buyer for the laboratory, this person often cultivates relationships with vendor representatives and maintenance servicers. They may attend trade conferences for such purposes as well. The same is true when performing duties as a regulatory compliance officer. A laboratory manager is in regular contact with the agencies of government which regulate his or her lab and may need to attend meetings or conferences to stay current with regulations. The position may also include keeping permits current and filing regular paperwork with government agencies as necessary.

Principal Investigators, Senior Research Scientists, and Medical Scientists

Principal Investigators, Senior Research Scientists, and Medical Scientists are all terms that refer to the lead role of a research team. They may work in a college, university, or hospital setting, or find employment in government agencies or private companies. The team lead is responsible for steering the course of research and determining the objectives of each project. Other responsibilities of the team lead include:

- Design of the project and its experiments
- Delegation of tasks to the research team
- Participation in grant proposals and patent applications
- Report on the progress of each project
- Troubleshoot unexpected results and modify procedures as needed

Principal Investigators, Senior Research Scientists, and Medical Scientists nearly always have a PhD, MD, or both. They tend to be highly specialized in one or perhaps a handful of areas within the field of molecular biotechnology. As the number of biotechnology enterprises continues to grow, the level of specialization is expected to increase as well.

Laboratory Technicians and Technologists

Laboratory technicians and technologists act as the support team to the principal investigators of a research project. They perform the day-to-day work of experimentation and laboratory management. Depending on the exact nature of the laboratory, duties of laboratory technicians and technologists vary widely. They can be involved with equipment maintenance, preparation of materials, carrying out experiments, and assembling data. One may become specialized in certain tasks with a distinct division of labor assigned to each member of the support team.

Due to the growth of this industry, the availability of jobs with less educational requirements is increasing. However, these tend to be the lowest paying biotechnology-related jobs as they may require a bachelor's degree, or even an associate's of science degree in some cases. It bears repeating that when it comes to careers in molecular biotechnology, the more education the better. Two- and four-year degrees limit opportunities for advancement and minimize income potential in this highly technical and specific field.

Crime Lab Technicians

Forensic investigation now relies heavily upon biotechnology techniques and crime lab technicians perform this work. It is a rewarding role for individuals interested in both science and criminal justice. Crime lab technicians use their knowledge of biotechnology to analyze biological evidence such as hair, skin, and blood samples. They report their findings to members of law enforcement and may also testify as experts in court trials.

Quality Control Analysts

Once a biotechnology product is researched and developed, the manufacturing division steps in to create the final product. Quality control (QC) analysts act as part of the manufacturing team by testing the product within a laboratory, both during the process of manufacture and upon its completion. QC analysts also test the quality and efficacy of each ingredient involved in the manufacturing process. They collect and analyze data from their tests and present reports of their findings. If any specifications are not met, QC analysts will alert management and work to find a solution. In such an event, they are then responsible for updating operating procedures and communicating the information to the appropriate personnel.

Non-Laboratory Careers

Many aspects of the biotechnology industry take place outside of the laboratory. While the science and technology is initiated and refined in the laboratory, the resulting products will go nowhere without the assistance of a downstream pipeline. Professionals outside of the laboratory contribute to the necessary elements of completion both prior to release and aftermarket of their product. Educators of biotechnological pursuit would likewise be considered professionals outside of the laboratory, as would the technicians and engineers that provide the tools and instruments needed in the laboratory itself. Careers outside of the laboratory are among the highest paying of all STEM employment.

Educational Careers

Professors, instructors, and teachers can specialize in biotechnology education. These educators must be well-versed in the various disciplines that contribute to the study of biotechnology, such as molecular biology, biochemistry, genetics, and immunology. They provide the knowledge necessary to educate the upcoming biotechnology workforce and can act as mentors for budding biotechnologists. Therefore, they must stay abreast of current events in the field and may have outside interests or relationships with industry. An educational career may be divided between laboratory and non-laboratory duties, as university professors may also perform research.

Management Professionals

Positions in management exist in several realms of molecular biotechnology. They represent the highest paying STEM career of any, with an average salary of over $130,000 per year. All branches of molecular biotechnology require individuals to manage operations. A management professional could perform a leadership role in research and development, project management, clinical trials, manufacturing, or sales, among other areas.

Biostatisticians

The role of a biostatistician straddles the fields of biology, mathematics, and computer science, making it a highly technical career. Analyzing the massive amounts of data generated in DNA sequencing requires information technology and highly specialized computer programs. Biostatisticians extract useful information from the billions of nucleotide base pairs routinely generated in the world of molecular biotechnology. This type of job usually requires a PhD, but with sufficient computer and math skills, it is possible to obtain employment at the bachelors or masters level.

Clinical Research Associates

Clinical research projects determine the effectiveness of experimental medications in human subjects. The clinical research associate designs, executes, and manages these research projects. Individuals with a medical background are usually preferred for these roles, such as registered nurses with experience dealing with patients and FDA regulations. Knowledge of the regulations governing clinical trials is a necessity for this career path.

Sales and Marketing Professionals

Around 400,000 sales and marketing professionals are employed in scientific and pharmaceutical organizations across the United States. Among the highest paying careers in the biotechnology industry, sales and marketing roles are attractive to individuals with a scientific background but who do not wish to work in a laboratory.

SUMMARY

- The tools of biotechnology have allowed for a variety of applications. Molecular biotechnology is an interdisciplinary field that incorporates a broad base of scientific disciplines. It draws upon biology, chemistry, mathematics, computer science, engineering, philosophy, and ethics and influences a number of fields including medicine, agriculture, justice and defense, environmental science, and anthropology.
- A large majority of today's molecular biotechnology industry is devoted to healthcare applications. Biopharma is the name given to bioengineered pharmaceuticals. Gene therapy is a form of medical treatment that removes or replaces defective gene(s) in order to treat or even cure injury or disease. Genetic counseling involves the identification of disease in an individual's family history and determining the appropriate measures one might take to avoid passing on disease to his or her offspring. It may include the use of pedigrees and/or genetic profiling.
- Genetically modified organisms (GMOs) are organisms that contain knockout or inserted genetic material. Genes may be knocked out of or inserted into a food crop or animal in order to confer desirable traits in the organism. A gene knockout renders a gene inoperable, thereby preventing the synthesis of its protein product(s). GMOs may also possess inserted genetic information from a separate species.
- Seed banks serve the purpose of collecting and preserving a diverse assortment of plant seeds. The establishment of seed banks maintains biodiversity for future prospecting, which may be useful in the event of famine or crop disease. This threat is particularly acute as monoculture becomes more prevalent in agriculture worldwide.
- Aquaculture produces fish and shellfish for human consumption under controlled and sustainable conditions. In addition to serving as a food source, aquaculture also provides products from aquatic organisms such as pearls, adhesives, and pharmaceutical compounds. Bioprospecting includes harvesting and classifying the various aquatic organisms of the world, allowing molecular biotechnologists to create a bank of genetic "tools" for future use.
- Industrial biotechnology is a broad class of applications involved in manufacturing processes and production of consumer goods. Examples include enzymes created by GMOs used to enhance the productivity of manufacturing processes as well as vitamins and drug compounds produced through microbial fermentation.
- Green biotechnology seeks to reduce pollution, develop alternative fuels, and conserve biodiversity. Bioremediation utilizes living organisms to decompose chemical pollutants and other human-made waste. Biofuels such as corn ethanol

and biodiesel are being investigated as potential fuel sources. Conservation is aided by biotechnology through DNA and tissue preservation and enhanced breeding methods.

- DNA fingerprinting has innovated the field of forensics by adding the additional layer of genetic evidence to crime scene investigation and cases of identity such as paternity. Also known as genetic profiling, DNA fingerprinting is a nearly indisputable method used by forensic analysts as it provides an insurmountable level of certainty.
- Biodefense is the application of molecular biotechnology to defending peoples and places of a nation. Examples of biodefense include detecting and tracing biological contaminants and/or weapons, developing vaccines against biological warfare, and the creation of biosensors.
- Evo devo combines the study of evolution and embryological development. Evo devo has the potential to contribute knowledge of evolutionary relationships among organisms. The field may also lead to advances in medicine as we develop a greater understanding of the molecular and cellular mechanisms which make us who we are as a species.
- Molecular biotechnology professionals are often involved in obtaining funding for their projects, performing research and development under applicable laws and regulations, and communicating their findings in peer reviewed journals, meetings, and conferences. The molecular biotechnology industry spans a growing number of endeavors. By virtue of its interdisciplinary nature, the amount of careers pertaining to the field is likewise increasing. Positions may be set in a laboratory or non-laboratory setting and are typically divided into institutional and private sector occupations.

KEY TERMS

Aquaculture
Biodefense
Biofuels
Biopharma
Bioprospecting
Bioremediation
DNA fingerprinting
Evo devo
Forensics
Gene therapy
Genetic counseling
Genetic profiling
Genetically modified organism
Knockout
Molecular biotechnology
Pedigree

DISCUSSION QUESTIONS

1. What area of molecular biotechnology do you foresee having the greatest impacts on society and why?
2. Select a career path in molecular biotechnology that interests you most. Research current prospects for this career. Parameters to search include average salaries, necessary education and experience, available job postings, and companies that employ individuals in this career.
3. Search the U.S. Patent and Trademark database for recent patents in molecular biotechnology. Describe a patent awarded in the past year. Include the characteristics which granted the technology or product a patentable status.

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