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Learning objective

This chapter discusses the future prospects of the pharmaceutical industry, especially in the way it affects:

- the chemistry of carbon and silicon
- the impact of pharmaceuticals on longevity
employment opportunities and world market analysis
- drug discovery and drug delivery systems
- personalized medicine
- drug development, especially for an ageing population around the world
- the emerging drug market in the world
- how advanced technology is helping to shape the twenty-first-century pharmaceutical industry.

As discussed in the first chapter, the pharmaceutical industry is highly research based, and there is little to inhibit research. This chapter looks at how future pharmaceutical research will move in different directions, including looking for new molecular entities in pharmaceuticals or biopharmaceuticals, regenerative medicines, personalized medicines, and newer and better drug deliveries.

Key concept terms

AIDS: Acquired Immune Deficiency Syndrome
API: active pharmaceutical ingredient
AZT: azidothymidine, also called zidovudine; drug to treat AIDS
Bioavailability: amount of drug available in blood after administration
Bioinformatics: use of statistics and computer sciences to understand molecular biological processes
Biologic: biotechnology-based drug
Biomarker: indicator of biological state; biochemical characteristics used to measure disease or treatment stage
Biopharmaceutical: drug produced using biotechnological processes
Biosimilar: generic version of a biotechnology drug
Biotechnology: use of living organisms or their products for therapeutic purposes
Brand name: trade name of a drug given by the originator
Carbon and silicon: elements in the periodic table (C and Si)

Controlled release drug: drug that releases over time

DNA: Deoxyribonucleic acid

Enzyme: biocatalyst made of proteins

Excipient: inactive or inert material other than API in medicine

Follow-on biologic: generic version of a biotechnology drug; biosimilar

Gene: functional unit of our heredity (genetic materials)

Gene technology: technology for manipulating genetic material or DNA

Generic name: international nonproprietary name for a drug

Genome: the entirety of an organism’s hereditary information

Genomics: study of genes and their functions

HIV: Human Immunodeficiency Virus

Lipophilic drug: a lipid soluble drug

Mab: monoclonal antibody

Metabolomics: study of metabolites of cellular processes in a biological cell, tissue, or organ

Monoclonal antibody: protein produced from a single clone of B cells

Off-patented: after the expiration of patent

Pharmacogenomics: pharmacology of drugs based on genetic variation

Proteomics: study of proteins expressed by gene, cell, tissue, or organism

RNAi: ribonucleic acid interference

Stem cells: our body’s master cells, which have the ability to grow into more than 200 cell types

Therapeutic: related to treatment of diseases

Vaccine: biological preparation that improves the body’s immunity to fight a particular disease
14.1 Introduction

As long as we are alive, we will be susceptible to diseases. We may eliminate some diseases, but newer ones will come up. Diseases are a part of life, so we will always search for new medicines to treat or prevent new diseases. We need medicines to save injured people because of accidents or natural disasters, and to treat older people whose bodies become more susceptible to illness and injury. The pharmaceutical industry is thus an integral part of our lives (Figure 14.1).

14.2 Carbon and silicon

Carbon (chemical symbol C) and silicon (chemical symbol Si) belong to the same family in the chemistry periodic table. Humans are carbon based and the pharmaceutical industry keeps this carbon factory alive and active.

The chemistry of carbon and silicon are similar but somewhat different (Figure 14.2). Both are in the same group IV of p-block in the periodic table but the property of carbon is more diversified than that of silicon. Carbon is nonmetal and silicon is metalloid. The silicon in computers can contain some manmade viruses, but carbon in humans has natural viruses. It is possible to prevent or protect carbon-based humans from these natural bacteria or viruses, which are also carbon based and often pathogenic and life threatening.
Carbon-based microorganisms and/or their products are the most deadly threat to the healthy living of larger animals including humans. Carbon is the building element of all life forms on this planet and can build biomolecules, such as carbohydrates, proteins, fats, and nucleic acid, but at the end of life these biomolecules degenerate and convert to non-living molecules. As long as we live, we have to fight against diseases using medicines that the pharmaceutical industries discover, develop, produce, and deliver to consumers.

14.3 The role of the pharmaceutical industry in increasing longevity

The average life expectancy around the world is now twice what it was 200 years ago. The world became a healthier place because of improvements in public health because of sanitation and clean drinking water, and the number of vaccines, antibiotics, and other medications produced on a mass scale and distributed to a growing market. The pharmaceutical industry is responsible for these medications. Although many medicines and cures exist in nature and will continue to be discovered, they can only be harnessed to their full potential with the innovation and technology of industry.
The geneticist Chris Morris of the Institute for the Health of the Elderly in Newcastle, England, estimates there will be an increase in life expectancies of five to ten years in the next 30 years, as a result of improved diet and medication. Life expectancies in developed and developing regions around the world between 1950 and 2000 are shown in Figure 14.3, and the life expectancy in the USA between 1950 and 2007 is shown in Figure 14.4.

**Figure 14.3** Life expectancy by birth 1950–2000 around the world by more developed versus less developed region

*Source: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health*

**Figure 14.4** US life expectancy 1950–2007

*Sources: Department of Health and Human Services, CDC, US, and Innovation.org*
Commenting on increased longevity, the former commissioner of the US Food and Drug Administration (FDA), Mark McClellan, said, ‘New drugs are no small part of this medical miracle.’

### 14.4 Aspirin to Avastin

The pharmaceutical industry is developing to meet the need for new medicines to treat more complicated diseases and newer forms of diseases. The synthetic drugs developed in the early twentieth century (e.g. acetylsalicylic acid or aspirin) were simple in structure, but nowadays drugs are more complex (e.g. atorvastatin or Lipitor) and recently even more complex synthetic biologics (e.g. bevacizumab or Avastin) have been introduced to the market (Figure 14.5).

Aspirin has been in use for years as a traditional non-steroidal, anti-inflammatory agent and more recently in low doses as a blood thinner. Aspirin helps maintain blood flow by reducing platelet aggregation or coagulation, which in turn helps prevent heart attacks. Recently developed atorvastatin helps patients with heart diseases by reducing their cholesterol level, thus targeting the root cause of the disease.

The introduction of biopharmaceuticals such as Avastin is a breakthrough development in treatment. Avastin is a monoclonal antibody so can

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**Figure 14.5** The structure of acetylsalicylic acid (aspirin), atorvastatin (Lipitor), and bevacizumab (Avastin)
specifically bind with its targeted protein, in this case vascular endothelial growth factor-A (VEGF-A), and inhibits its activity. VEGF-A is a necessary factor for the growth of blood vessel (angiogenesis). Cancerous tissues need and develop more blood vessels to survive and grow, and Avastin inhibits angiogenesis by selective blocking of VEGF-A, thereby helps controlling cancer. The journey from aspirin to Avastin shows the significant advancement of science and technology in the pharmaceutical industry.

As newer diseases or old diseases in newer forms emerge periodically, such as severe acute respiratory syndrome (SARS), multi-drug resistant tuberculosis, Ebola fever, and hepatitis C, pharmaceutical research is directed to develop newer and better drugs to fight them. However, no anticancer drug yet exists that acts as a magic bullet – as is the case with penicillin and infectious diseases – although drugs are used to treat cancer patients, and in some cases lives have been extended through their use. Nonetheless, the future for developing anticancer drugs looks very bright; one of these is the monoclonal antibody Avastin.

### 14.5 Monoclonal antibody drugs

An antibody is an immunoglobulin, an immune protein produced when an antigen is introduced into the body; monoclonal means produced from a single clone.

Our white blood cells, called B-cells, produce antibodies whenever there are foreign organisms in our bodies, which is how our bodies’ immune systems work. A monoclonal antibody can be made in the laboratory with a specific protein, which can also be used alone or to carry certain drugs or radioactive particles to kill cancer cells. The production of a monoclonal antibody is shown in Figure 14.6.

Monoclonal antibody (mab) drugs are anticancer drugs developed and marketed by biotechnology companies. One innovative idea is to use them to make cancer cells more recognizable as foreign by our bodies’ immune systems, so they can fight against the cancer cells. Rituximab (brand name Rituxan) is a specific monoclonal antibody drug that attaches to a protein CD20 receptor found on B-cells and causes the tumor cells to disintegrate. Certain mab drugs can block the growth signal to cancer cells. Cetuximab (brand name Erbitux) attaches to the receptor of cancer cells, so they do not get the growth signal to multiply. Another mab drug, ibritumomab (brand
name Zevalin), is tagged with a radioactive particle so it can give radiation to the cancerous cells without affecting the normal cells.

These ideas all uniquely reach only the target cancer cells, so are commonly known as targeted therapies. The US FDA has approved a number of monoclonal antibody drugs (Table 14.1) and hundreds more are in clinical trials.

**Figure 14.6** How a monoclonal antibody is produced

**Table 14.1** US FDA approved monoclonal antibody drugs and their uses

| Drug (generic)                      | Company                      | Uses                                      |
|-------------------------------------|------------------------------|-------------------------------------------|
| Alemtuzumab (Campath)               | Genzyme                      | Chronic lymphocytic leukemia              |
| Bevacizumab (Avastin)               | Genentech and Roche          | Breast cancer, colon cancer, lung cancer  |
| Ibritumomab (Zevalin)              | Spectrum Pharmaceuticals      | Non-Hodgkin’s lymphoma                    |
| Panitumumab (Vectibix)             | Amgen                        | Colon cancer                              |
| Rituximab (Rituxan)                | Genentech and Biogen Ideac   | Non-Hodgkin’s lymphoma                    |
| Cetuximab (Erbitux)                | ImClone Systems              | Colon cancer, head cancer, and neck cancer|
| Trastuzumab (Herceptin)            | Genentech and Roche          | Breast cancer                             |
14.6 The future shape of the pharmaceutical industry

When there is a pandemic, or when apparently incurable diseases affect a human population, the pharmaceutical industry has the ability to develop medicines to fight these diseases. It takes time, but ultimately companies are able to develop medicines that can extend longevity if not cure the disease completely.

Acquired Immune Deficiency Syndrome (AIDS) is an example. When this disease began causing health problems and deaths, people were scared, and some thought the world was ending. But the pharmaceutical industry developed a number of medicines and antiretroviral drugs, such as emtricitabine, tenofovir, ritonavir, atazanavir, efavirenz, and AZT, which can prolong lives of AIDS patients when are taken in combination; this strategy is recognized as a highly active antiretroviral therapy (HAART) (Figure 14.7). It is expected that there will be an AIDS vaccine on the market within the next few years.

It takes a long time, considerable staff resources, and therefore huge money to develop a drug. According to Roche, drug research and development resembles a big number game (Figure 14.8).

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**Figure 14.7** Longevity of people with HIV/AIDS, 1990s and 2000s

**Figure 14.8** Statistics of the cost of developing a new drug

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Because of the long time (10–15 years on average) it takes to develop a new medicine to treat a particular disease, millions of people can die before treatment is available. This is what happened to people with HIV/AIDS before AIDS drugs began to be marketed in 1996: about 25 million people died around the world.

### 14.7 Personalized medicine

People don’t always respond to drugs in the same way. One drug does not fit everyone. Recently the US FDA announced a new boxed warning on the anticlotting drug clopidogrel (Plavix), explaining that it can be less effective in people who cannot metabolize the drug to convert it to its active form. So this drug is less effective for people with a variant gene for a liver enzyme, which catalyzes clopidogrel to its active form.

The situation is similar to people who are lactose intolerant. Those who have lactase enzyme deficiency cannot digest cow’s milk. The genes control so many things in our bodies’ functions. An analysis of an individual’s genomic data can show possible responses to a particular drug. The future of the pharmaceutical industry depends on who can provide personalized medicine.

Personalized medicine is custom or tailor-made medicine. Treatment or appropriate medicine can be selected to provide the optimum therapeutic value for an individual patient according to their genomic makeup (Figure 14.9).

![Figure 14.9 How a personalized medicine benefits some patients but not others](image-url)
Personalized medicines can ensure personal wellness. Pharmacogenomic analysis can predict health risks for every individual, and manage life styles through:

- early diagnosis of certain chronic diseases
- better diagnosis and choosing the best course of treatment.

It might be possible to provide the right treatment for the right person at the right time in the near future. Before giving a prescription, physicians need to determine a patient’s single nucleotide polymorphism (SNP) profile, compare it with the data bank, and figure out the drug that will work best for the patient. For example, for cancer patients the physician can determine the right dosage of a specific chemotherapeutic drug without using trial and error methods (Figure 14.10). Trastuzumab (Herceptin) is a kind of personalized medicine as the treatment works for a breast cancer patient who has too much HER2 protein in the tumors.

The genetic variant of the enzyme, which is responsible for deactivating the cancer drug, can determine the level of that enzyme. To do this, a DNA sample of the patient has to be analyzed based on SNP profiling. Similarly, cytochrome P450 enzymes are responsible for metabolizing many drugs, such as antidepressants, anticoagulants, and proton pump inhibitors. Some people can metabolize these drugs very quickly; others metabolize them more slowly. The CYP450 test identifies people with genetic

![Diagram](https://example.com/diagram.png)

**Figure 14.10** The role of genomics in avoiding side effects of cancer drugs
variations and physicians can make the correct decision in prescribing drugs and doses.

For tailored treatment or medicine, diagnostic advancement and affordability are very important before personalized medicines are used. Future generations of pharmaceutical and medical students need to understand genome sequencing data. Dr Jeremy Berg, director of the US National Institute of General Medical Sciences, describes this as, ‘when combined with other sources, [having] the power to predict the diseases a person is most likely to develop and how he or she might respond to certain medicines’.5

14.8 Treatment of the increasing ageing population

As the population’s longevity increases, so does the healthcare burden, but some older people are more of a burden than others, depending on how active they are. When they are less active it is usually because they have an age-related chronic illness, such as Alzheimer’s disease, Parkinson’s disease, dementia, arthritis, cancer, a destructive eye disease, or type II diabetes (Figure 14.11). There is no doubt that the demand for better drugs in those areas will continue to be a priority.

Figure 14.11 Diseases commonly found in elderly people

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The objective of advancing drug delivery technology is to improve patient compliance and produce better clinical outcomes. An example of this is the needleless injection – many people are afraid of needles so prefer needleless injections, which are now a reality. Another example is the sustained release tablet. At one time, only simple tablets were available, but now there are sustained release tablets, half of which are released immediately on consumption and the other half released over a longer period. In the near future there will be advancements in nanotechnology-controlled release drugs, especially for orally administered lipophilic drugs. In general these are not very water-soluble, so bioavailability of the drugs is limited.

One of the major possible advancements in drug development and delivery in future relates to gene silencing pathways or ribonucleic acid interference (RNAi) technology. It is known that our messenger RNA (mRNA) carries instructions from the DNA of the cell’s nucleus to build proteins, and all the diseases are linked with either mutated or abnormally regulated gene products.

In 1998 Andrew Fire and Craig Mello discovered a novel phenomenon: short double-stranded RNA can fool the cell to destroy the relevant mRNA before translating its protein. This discovery opened up a new dimension in health science where scientists can selectively eliminate a mutated or unwanted protein that is the root cause of a disease. This discovery won Fire and Mello the Nobel Prize in Physiology and Medicine in 2006. The pharmaceutical industry immediately considered the RNAi as a superior therapeutic modality over the small molecule-based conventional drug discovery protocol because many of the gene targets are not selectively controllable by conventional small molecule drugs, whereas RNAi can selectively remove the disease-causing gene from the system.

RNAi activity is mainly achieved through two pathways: short interfering RNA (siRNA) and miRNA. siRNA are double stranded, and can selectively shut down a gene by cleaving the relevant mRNA. miRNA are single stranded, and cannot eliminate a specific mRNA but can inhibit translation of several mRNAs. Many RNAi products are in clinical trial stages and will be on the market in the near future. Figure 14.12 illustrates RNA interference in the body.

Recently Mayo researchers have used RNAi methods in mice models to demonstrate that it is possible to silence the gene that produces alpha-synuclein, which is believed to be the primary cause of Parkinson’s disease.
Boston Children’s Hospital has developed a completely new approach to drug delivery systems. Researchers used a tiny, subcutaneous implantable device containing a membrane-based nanogel embedded with magnetite nanoparticles, which releases the drug by turning a magnetic field on or off. In an article in *Nano Letter*, the researchers showed that the drug dose delivered was directly proportional to the duration of the ‘on’ pulse. The main objective of drug delivery systems is to deliver the intact medication to specifically targeted parts while causing little toxicity. The pharmaceutical researchers are now trying to use nanotechnology to target specific drug delivery using different vehicles, such as biodegradable polymers, dendrimers, electroactive polymers, and modified C-60 fullerenes.

**14.9 Controlled-release drugs using a magnetic field switch**

**14.10 The world pharmaceutical market and employment**

The pharmaceutical market is growing every year (Figure 14.13). According to the forecasts of the Intercontinental Marketing Services (IMS), the world...
pharmaceutical market will grow 5–8% annually through 2014 and sales will reach US$1.1 trillion in 2014 from US$808 billion in 2009.

As the market is steadily growing, we should be able to expect more employment opportunities in this industry, but the world economic crisis may lead to job cuts. Figure 14.14 shows the number of people employed

Figure 14.13 Yearly growth of global pharmaceutical market, 2002–2009 (US$ billion)
Source: IMS Health Market Prognosis, March 2010

Figure 14.14 Number employed in the UK pharmaceutical industry, 1980–2007
Source: The Association of British Pharmaceutical industry
in the UK pharmaceutical industry from 1980 until 2007. Though there is a steady increase in R&D employment, the numbers employed in the industry overall changed little.

The US Bureau of Labor Statistics reported that there were 289,800 pharmaceutical employees in the USA in 2008, and this number is expected to increase by 6% between 2008 and 2018. As a result of the economic crisis that started in early 2008, several industries have down-sized; the pharmaceutical sector has not down-sized but there have been job cuts in the sector.

14.11 Stronger generics markets in future

Saving costs on healthcare is an important concern in developing countries and developed countries. Though the cost of medicines is not a major part of the overall healthcare cost in developed countries, it is significant, especially for those who are chronically dependent on them.

Generic drugs are exact copies of the original brand name drugs in their active ingredient(s), strength, dosage form, purity, quality, stability, safety, and efficacy, but excipients such as colors, flavors, and fillers may be different. IMS Health figures show there has been a steady growth of generic markets from 2004 to 2009 (Figure 14.15).

![Figure 14.15 Global generic market sales (US$ billion) and generic and pharmaceutical growth, 2004–2009](source: Redrawn with permission from IMS Health)
As a result of the economic crisis in early 2008, the growth of generic markets dropped significantly, but generic markets will be stronger in future because some of the blockbuster drugs will soon be off-patented. Once the patent is off, generic companies launch generic equivalents. In Europe, a generic market is growing, and generics make up almost 50% of volume sales with a fraction of the dollar value of non-generic drugs (Figure 14.16).

The British Generic Manufacturers Association estimates that the price of the generic version of a drug often undergoes a reduction of 90% of the original cost of the brand name drug within a few weeks. Two factors gain generic drugs immediate access to the market: reduced cost for consumers, and guarantee by a drug control authority of their safety, quality, and efficacy. For example, the US FDA and the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK are government bodies responsible for approving generic versions of medicines after carrying out extensive reviewing processes.

### 14.12 Generic biologics and biosimilars market potential

Biologics are biotechnology-based drugs or the generic versions of biotechnology-based drugs, known as biosimilars or follow-on biologics. Most biologics are very large and complex molecules or a mixture of molecules. There are debates about whether it would be difficult to make
the equivalent generic versions of biologics because, unlike small molecule drugs, they are usually protein, and even a minor variation in the production and processing procedure affects the final 3D conformation and thereby their functionality. This also affects the efficacy and safety of the relevant biosimilar.

More than 150 biopharmaceutical products, including cytokines, hormones, clotting factors, vaccines, and antibodies, have been marketed around the world, but patents on some of the biologics have already expired or will expire in 2011, and the introduction of generic versions to the market is fast approaching. Currently, biotechnology-based drugs, especially large molecules such as monoclonal antibodies, are very expensive and not affordable for many patients. Prices can be reduced if the regular approval process is carried out for biosimilar products after their patents expire.

The patent of Amgen’s blockbuster biologic epoetin alfa (brand name Epogen, known as EPO) expired in the European market in 2004, and the company’s US patent will expire in 2013. Generic versions of EPO are available in China, India, Peru, and Brazil, and Amgen itself is selling generic EPO in China and South America. Biosimilars are also available for GSK’s Engirix B, a hepatitis B vaccine, and Eli Lilly’s Humulin, a human insulin. Developing countries will be a big market for future biosimilar products because of the low cost of the biologics. Figure 14.17 shows some blockbuster biopharmaceuticals with high market potential as biosimilar products. Table 14.2 lists the differences between pharmaceuticals and biopharmaceuticals.
14.13 Emerging new markets

For many years, the USA, European countries such as Germany, UK, France, Italy, and Spain, and Japan were the leading global pharmaceutical markets, but more recently countries from Asia and Latin America have emerged with remarkable market growths. IMS figures show that China, Brazil, Russia, and India in particular have emerging new markets. In 2009, the pharmaceutical markets of Asia, Africa, and Australia grew by nearly 16% whereas those in North America and Europe grew by only about 5% (Figure 14.18).

China and India both have populations of more than one billion people, and as the countries develop economically the ‘pharmerging’
(pharma-emerging) markets are poised for significant growth. According to a report by PricewaterhouseCoopers, India will join the top ten countries by 2020 with a market value of US$50 billion.14

14.14 Biotechnology – a way forward

Modern biotechnology has widespread applications in the production of biopharmaceuticals, vaccines, and diagnostics. In the field of biopharmaceuticals, biotechnology applications include drug development, genetic testing, gene therapy, and pharmacogenomics. Human insulin was the first biotechnologically produced medicine, developed and produced by Genentech and marketed by Eli Lilly. The first modern biotechnology company, Genentech (acquired by Roche in 1999), had great success in producing a number of biopharmaceutical products (Table 14.3).

According to a report by the Pharmaceutical Research and Manufacturers of America (PhRMA), in 2008 there were 633 new biotechnology medicines under development. These included 254 medicines for cancer, 162 for infectious diseases, 59 for autoimmune diseases, 34 for HIV/AIDS and related conditions, 25 for cardiovascular disease, and 19 for diabetes and related conditions. Most were waiting for the US FDA’s approval.15
Every cell in the body originates or stems from stem cells. After receiving instructions from the body, stem cells start to divide to make certain genes or new proteins. This process is how different types of cells, such as nerve, blood, muscle, bone, and skin cells, are produced during early life and growth (Figure 14.19). A cell’s gene controls the internal signals and external signals come from chemicals, such as hormones secreted by other cells.

There are two types of natural stem cells: embryonic and adult stem cells. Embryonic stem cells are extracted from the embryo right after fertilization and are pluripotent, which means they can produce any types of fetal or adult cell of the animal under investigation. In contrast, adult stem cells are isolated from mature tissues and are multipotent, which means they can produce limited types of cells. The first human clinical trial using stem cells began in October 2010. The US FDA has approved a study by the biotech
company Gernon to investigate the injection of embryonic stem cells into patients with spinal injuries to restore their motor functions.

Medical and pharmaceutical researchers believe that stem cell therapy has the potential to cure chronic diseases. Current stem cell therapies include bone marrow transplants to treat leukemia and other cancers. Leukemia is a cancer of white blood cells, leukocytes, made up of bone marrow; these cancerous leukocytes grow abnormally and cannot fight against infections. The treatment includes chemotherapy and/or bone marrow transplant, where healthy bone marrow from donors is given to the patient.

In future researchers expect to use this technology to treat different cancers, Parkinson’s disease, spinal cord injuries, Alzheimer’s disease, multiple sclerosis and muscle damage, diabetes, burns, osteoarthritis, rheumatoid arthritis, and heart diseases. Current stem cell transplant methods have one major drawback, however: the patient’s body can reject donor stem cells, even though they are screened for matching.

Scientists are conducting research to regenerate new tissues in the laboratory after collecting healthy adult stem cells from the patient and then transplanting the cells back into the same patient. As the regenerated tissue is genetically identical to the recipient’s cells, graft rejection will not occur.
The availability and isolation of desired adult stem cells are very restricted, so this kind of regenerative medicine is practically very restrictive for many diseases. The recent discovery of induced pluripotent stem cell has shown the light to overcome this limitation. In this process, any cell, such as a fibroblast, can be reprogrammed to a pluripotent stem cell, which then can be used to differentiate to the desired cell type for the treatment of a patient. The technology is not risk free, however. The cells may divide in an uncontrolled manner and generate tumors. Scientists are working to fine tune the process of this type of treatment so this technology can be used clinically.

14.16 Technology and automation

In 2010 television news programs showed how robots were used at a depth of 5,000 ft below the surface of the ocean to stop the gushing oil spill in the Gulf of Mexico. Drug discovery processes in the pharmaceutical industry have also greatly benefitted because of the introduction of automation and robotics with the ability to identify new drug candidates out of millions of compounds. In addition, the use of advanced bioinformatics helps scientists create computer-aided design of new drugs, and understand the molecular pathways of diseases and the three-dimensional structure of proteins.

General practitioners are pleased whenever they find a broad spectrum drug (one that has wide coverage) because they can prescribe it based on symptoms without any clinical diagnosis. Patients can save money and time in such a situation. However, if a patient’s treatment using broad spectrum drugs is to be effective and free from side effects it is essential that the disease is detected at its earliest stages, before symptoms appear, with an extremely accurate diagnosis.

Biomarkers are biochemical characteristics used to a measure disease or treatment stage. They are powerful tools, which could be used in future to diagnose, treat, monitor, and prevent diseases. Diagnostic tests currently used to identify a disease need to offer a more precise assessment for specific personalized treatments. The early detection of diseases and an understanding of their causes may help physicians start a new form of treatment. Once biomarkers for chronic diseases, such as cancer, HIV, cardiovascular diseases, Alzheimer’s and Parkinson’s, are developed and validated, drugs can be developed more specifically and effectively for a particular genetic trait.

The science of nanotechnology, using microscopic devices at the atomic and molecular levels, is soon going to revolutionize the diagnosis and treatment of diseases. Gene chip technology, which is already in use, can examine and analyze genetic sequences very quickly, and identify active genes in diseased tissue.
14.17 The future pharmaceutical R&D work force

R&D has always been a primary sector in the development of the pharmaceutical industry and will remain so. Medical treatments will gradually shift from the traditional towards personalized treatments. Pharmacogenetics will replace the conventional path of diagnosing diseases, and there will be an evolution of newer drug development strategies and screening methods towards making the right kind of biopharmaceuticals. The future pharmaceutical R&D work force will remain multidisciplinary but more inclined towards areas related to molecular genetics (Figure 14.20).

![Figure 14.20 A twenty-first-century pharmaceutical R&D work force](image)

![Figure 14.21 Current and future treatment methods in medicine](image)
Practice questions

1. Is DNA a monomer or polymer? If a polymer, what is its monomer, or vice versa?
2. What are the nucleotides in DNA and RNA? Mention the base pairs for both.
3. Which of the following are biotechnology products?
   (a) bread (b) beer (c) yogurt (d) wine?
4. Can fermentation be considered the same as biotechnology?
5. What was the first successful biotechnology medicine?
6. Name a few biotech companies.
7. How many electrons, protons, and neutrons are there in carbon and silicon?
8. Write the electron configuration of carbon and silicon.
9. How many bonds can carbon and silicon make? Give examples.
10. Carbon is considered the building block of life. Can you name a few biomolecules? What elements other than carbon are present in those biomolecules?
11. Which kind of molecules, carbonaceous or non-carbonaceous, can generally be disease-causing? Explain with examples.
12. Why are there two molecules in the structure of atorvastatin?
13. Structurally, what kind of molecule is bevacizumab (Avastin)? The generic name of this kind of drug always ends with mab. Why?
14. What is the basic difference between an aspirin and Avastin molecule?
15. What kind of side effects can Avastin produce?
16. How do you differentiate between pharmaceuticals and biopharmaceuticals?
17. Are there any biosimilar products on the market?
18. Were there any blockbuster biologics in 2009?
19. Why are generic biologics called biosimilars and not biogenerics?
20. Explain your ideas about courses you should take to prepare yourself for a potential pharmaceutical career.

Answers to some practice questions

2. For DNA, adenine, thymine, guanine, and cytosine are the nucleotides. The base pairs are adenine and thymine, and guanine and cytosine. Find out the answer for RNA.
3. They are all biotechnological products.
5. Human insulin is the first biotechnologically manufactured medicine developed by Genentech in bacterial cells.
6. Amgen, Biogen Idec, Cephalon, Chiron, Eli Lilly, Genentech, Genzyme, Invitrogen, J & J (USA); Seron and Roche Group (Switzerland); GSK (UK); Novo Nordisk (Denmark); Boehringer Mannheim (Germany); Chugai (Japan).
7. Look at Figure 14.2. Carbon has atomic number 6 and atomic mass 12. Therefore, carbon has 6 protons, 6 electrons, and 6 neutrons. Now figure out those numbers for silicon.
8. Electron configuration of Si is 1s^22s^22p^63s^23p^2. Find out electron configuration for carbon.
9. Both are tetravalent. Find out examples.
10. Carbohydrates, proteins, fats, and nucleic acids; figure out their composition.
12. Atorvastatin is produced as calcium salt and calcium is +2 positively charged.
13. Protein molecules are drawn this way. ‘Mab’ is abbreviated from monoclonal antibody.
14. Aspirin is a pharmaceutical and synthetic drug but Avastin is a biopharmaceutical and biologic.
15. It can inhibit normal blood vessel growth.
16. The answer is given in tabular form in Table 14.2.
17. Recombinant human insulin is on the market.
18. Find out from Chapter 1.
19. Biologics are produced from biological sources or using recombinant DNA engineering. They are complex protein molecules and very difficult to duplicate exactly. It could be similar and not an exact duplication of the originator.
20. Traditionally chemists, biochemists, biologists, and microbiologists with some pharmaceutical background used to have easy access to the pharmaceutical industry and its marketing and sales jobs. To make a career in twenty-first-century pharmaceutical jobs, students need to equip themselves with further knowledge of emerging sciences, especially ‘omics’ such as genomics, proteomics, and metabolomics, because treatment methods will change (Figure 14.21).
Notes

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