RESEARCH METHODOLOGY AND PROJECT MANAGEMENT IN BIOTECHNOLOGY

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Bentham Books

Research Methodology and Project Management in Biotechnology

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PREFACE

The core concepts of biotechnology rely upon the application of a series of techniques now increasingly available to the researchers worldwide. The prelude to these techniques is essential for understanding their processes and possible applications leading to successful products & practices. A comprehensive textbook that encompasses the frontiers of technological advancements available in the field of biotechnology and integrates these concepts with the scientific method is hence a need of the day. This book will aim to reestablish and update the fundamental knowledge and understanding required for planning and executing fruitful projects for both students and faculty in biological sciences.

This book progresses with introducing the basic concepts of molecular biology techniques, genetic engineering, and bioinformatics, followed by scientific writing, project writing and funding opportunities available for entrepreneurs in biotechnology, guiding further regarding intellectual property rights and biotechnology regulations. The final chapters of the book are comprised of the modern knowledge and updates essential to every biological researcher on genomics, proteomics, and anti-sense technology, keeping in mind the practices of ethics in scientific research. The finale is focused on the applications of biotechnology in the area of molecular medicine.

Unique features of the book:

a. It is a textbook and not a reference book

b. It is comprehensive and includes various subjects and topics essential for biotechnology researchers

c. Each chapter will have learning objectives, self-assessment exercises, bullet points, tables and figures for better understanding and recollection of the subject/topics.

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CHAPTER 1

Techniques in Biotechnology

LEARNING OBJECTIVES

This chapter gives an overview of techniques used in biotechnology for the isolation of nucleic acid. Their handling, precautions in DNA mapping and automated DNA sequencing are discussed.

Abstract: Nucleic acid absorbs UV light maximally at 260 nm owing to its bases. Thus, DNA or RNA yield can be quantified based on this principle. Restriction endonucleases (type II) are one of the most important groups of enzymes for the manipulation of DNA. They are bacterial enzymes that can cut/split DNA of any source at specific sites and were first discovered in bacteria E. coli restricting the replication of bacteriophages, by cutting the viral DNA. This led to differences in the size of restriction fragments obtained due to digestion with specific restriction enzymes. A restriction map is formulated by comparing the fragment size produced in every single digestion with those from double digests. In target amplification, the nucleic acid region around the area of interest is copied many times by in vitro methods. Polymerase Chain Reaction (PCR) is the best-known and the most widely applied of the target amplification methods. Original sample DNA is digested by a restricted endonuclease, separated by agarose electrophoresis, and transferred by agarose electrophoresis, and transferred to a solid support (Nylon or Nitrocellulose membrane) followed by selective visualization of fragments using labeled hybrid

DNA sequence has now become a routine procedure. It is the process of determination of nucleotide or base sequence of a DNA molecule/fragment. A probe is a nucleic acid whose identity is known and is used to reveal the identity or abundance of a target or sample. They are simple to prepare and are labelled with nucleotides that are radioactive, or fluorescent or have attached affinity labels. Also, by using a biotin-labelled primer, single-stranded probes can be obtained. Microarrays represent high-density miniaturized arrays of molecular samples. The technology involves a series of probes immobilized on a glass slide as microdots, which are then hybridized with a mixture of test DNA sequences labelled with a fluorochrome.ization probes.

Keywords: Blotting, DNA chip, Haplotypes, Norther, Oligonucleotide, Polymerase chain reaction, RFLPs, Restriction enzymes, Recombinant DNA technology, SNPs.

Amazing developments in biotechnology in late twentieth century include: decoding of human genome, cloning, gene therapy, progress in stem cell research and RNA interference.

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Many earlier landmark discoveries unveiled the mysteries of genetics and paved way for modern molecular biology. Beginning with the Mendel's experiments with garden peas published in 1866, the concept of genes as discrete units of heredity emerged. Morgan in 1910 revealed chromosomes as units of heredity and Avery in 1944 confirmed through bacterial studies that DNA carried genetic information and with Watson Crick's DNA double-helical model in 1953, Smith demonstrated that DNA can be cleared by restriction enzymes. This facilitated the subsequent development of Recombinant DNA Technologies (Fig. **1**).

With the construction of genetic map using restricting enzymes by Nathans, Southern blot was invented in 1975 to detect specific DNA sequences. This led to the development of DNA sequencing methodologies and the first complete DNA sequence of bacteriophage was discovered. PCR (polymerase chain reaction) was developed by Mullis and co-workers in 1985. Then, simultaneous interrogation of gene transcripts by DNA microarrays became a reality in 1996. The human genome sequence was completed in 2003.

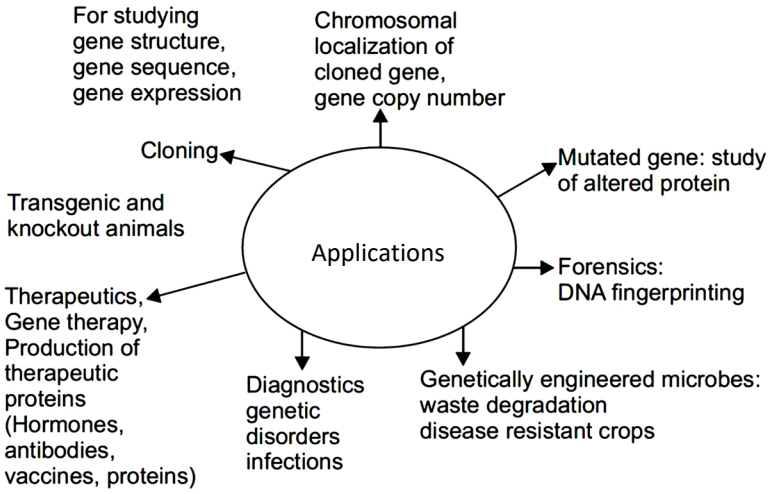

Fig. (1). Recombinant DNA technology applications.

ISOLATION AND SEPARATION OF NUCLEIC ACID

Almost all experiments dealing with gene manipulations require pure forms of DNA, RNA, or both. Thus, there is a need for reliable isolation techniques for nucleic acids (Fig. **2**).

Steps

1.Breaking of cells to expose nucleic acids
2.Separation of nucleic acid from other components
3.Recovery of nucleic acid

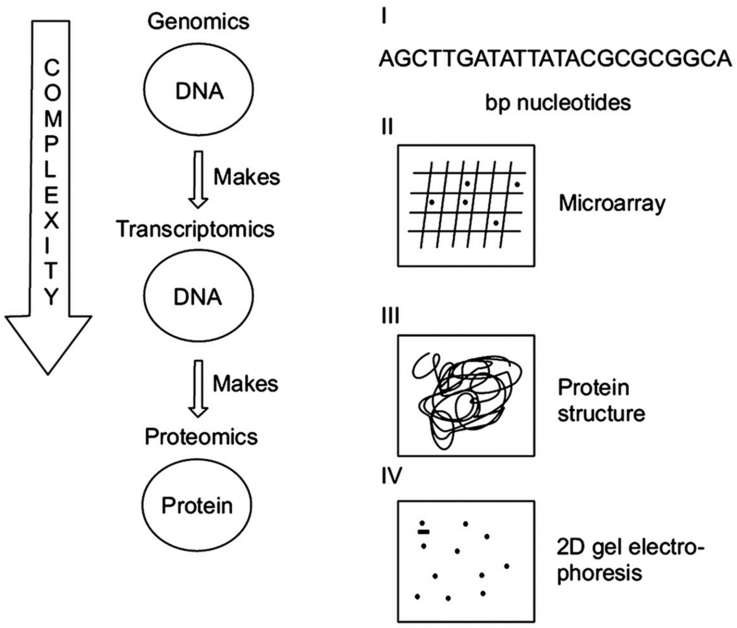

Fig. (2). Genomic data processing.

The study of purified nucleic acids have led to many key advances in the understanding DNA and RNA. Extraction and isolation of nucleic acid is a key step to subsequent molecular analysis (Fig. **3**).

Depending on the type of specimen, the required volume, yield, purity, the size of isolated nucleic acid, ease of operation, throughput, cost, the use of hazardous reagents, and the automation of the procedure, the most appropriate protocol is selected.

Whole blood, plasma, serum, tissue biopsies, cultured cells, buccal swabs, paraffin-embedded tissues, CSF, amniotic fluid, *etc*. are used. Protocols for DNA extraction can be classified as:

CHAPTER 2

Recombinant DNA Techniques

LEARNING OBJECTIVES

This chapter gives an overview of the basic tools of cloning, gene cloning, gene expression and its analysis, DNA-finger printing, setting up a new lab, quality management in the lab, and lab safety.

Abstract: Following the success of the human genome project with 99.99% sequence accuracy, with no gaps, biotechnology has been revolutionized. Recombinant DNA technology comprises a battery of experimental procedures to isolate (clone) pieces of DNA containing specific genes. The usage of restriction enzymes for manipulating DNA and producing recombinant DNA along with advances in gene editing technology has paved way for diagnosing the candidate disease genes and treating human genetic disorders by restoring functional genes through the modification of the mutant gene or by introduction of a functional gene by Gene therapy. Array technology helps in the validation of recognized sequences, proteins, other biomolecules, drugs, *etc*. on a miniaturized platform. Quality management in the lab along with lab safety plans for biomedical labs requires adherence to various governmental regulations for protecting health and safety of lab employees and for the maintenance of safe working environment.

Genome analysis is carried out by genome mapping. Genetic maps can be linkage, cytogenetic or physical maps. Gene expression can be analyzed by genomics and proteomics Microarrays are emerging as useful closed systems for genomic (DNA microarray) and proteome (protein chip) analysis.

Keywords: Biohazard, DNA Libraries, Knockout mice, Lipofection, Palindromic, Transgenic mice, Transcriptome, Transduction, Vectors.

THE HUMAN GENOMIC PROJECT

The Human Genomic project deciphered 3 billion base pairs that make up the genetic code. In 1988, US National Research Council's special committee formulated a 15-year human genome project, costing some $200 million a year. In September 1994, a genetic map with 1cm resolution was accomplished and a physical map involving 52000 sequence-tagged sites (STSs) was completed in October 1998.

The International Human Genome Sequencing Consortium consisting of investigators from 20 centres located in six countries—UK, US, Japan, France, Germany, and China announced completion of a draft sequence in July 2000. The

final sequence was accomplished in April 2003, with 99.99% sequence accuracy, with no gaps.

HUMAN GENOME

Of the total 3.2 Gb DNA of human genome, 2.9 Gb consists of weakly, staining gene-rich euchromatic proteins and only 1.1–1.4% sequence encodes proteins. The estimated number of genes in the human genome is between 26,000 and 31,000.

With the decoding of the basic sequence, even more difficult task is the elucidation of biological function of these str*etc*hes of DNA.

From the data generated from the Human Genome Project, new disease-associated genes are being discovered every week. Also, it has allowed us to develop a test for molecular diagnosis and development of new targets for the pharmaceutical industries.

Hap Map Project

International Hap Map Project has been launched to study the patterns of linkage disequilibrium and haplotype across the human genome and to characterize SNPs (Single nucleotide polymorphisms).

Encode (Encyclopedia of DNA Elements)

This project aims to identify all the functional elements in the human genome.

Human Epigenome Project

This project aims to elucidate all the methylation sites in 30,000 human genes.

RECOMBINANT DNA TECHNOLOGY

Definition

Recombinant DNA Molecule

It is a vector into which the desired DNA fragment has been inserted to enable its cloning in an appropriate enzyme.

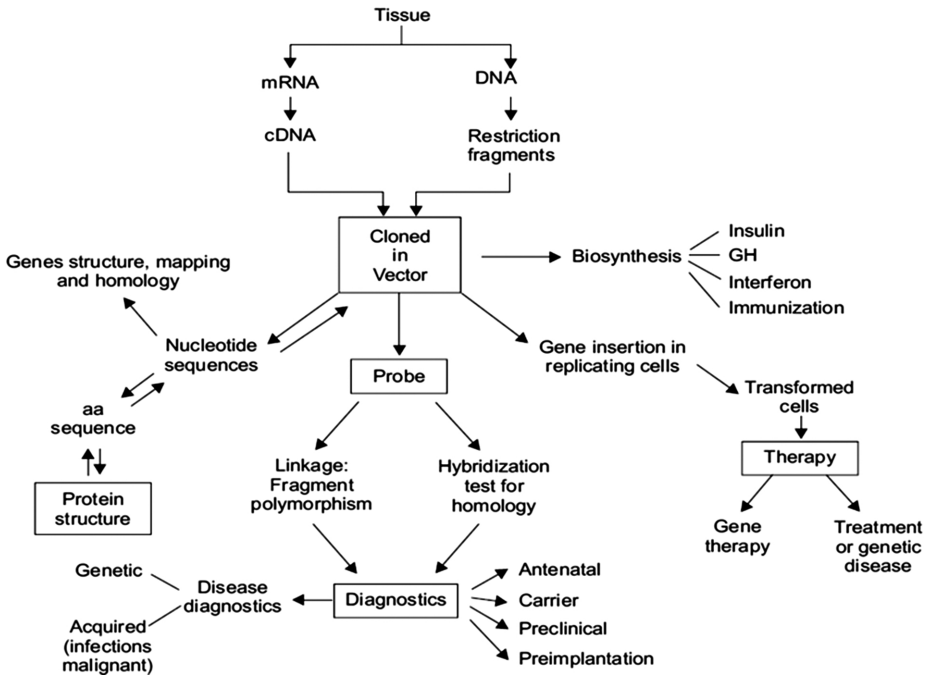

Fig. (1). Applications of DNA technology.

By using restriction enzymes, DNA is cut into suitable fragments and then ligated with appropriate fragments to produce a recombinant DNA.

Objective of Producing Recombinant DNA Molecule

1. To obtain a large number of copies of specific DNA (Fig. **1**).
2. To recover large quantity of protein produced by a gene of concern.
3. To integrate the gene of interest into the chromosome of the target organism.

From Protein to Gene	From Gene to Protein
Isolation of protein (on basis of its molecular function)	Isolation of genomic clone
↓	↓
Determination of partial amino acid sequence of protein	Isolation of cDNA
	↓

(Fig. 2) contd.....

CHAPTER 3

Bioinformatics and Application of Computers

LEARNING OBJECTIVES

This chapter gives overview of tools and techniques of Bioinformatics; approaches for studying sequence analysis, protein- protein interactions; approaches in studying evolution of life; signal processing and artificial intelligence in bioinformatics; virtual cell and insilico technology; digital technology and robotics in biotechnology.

Abstract: Bioinformatics applications are effective in generating the vast quantity of inputs. Term simulation is the computation for developing algorithms and software, construction of database and curation, and analysis of gene sequence, functions, and structures. Understanding of genetic control of complex dynamic traits has fundamental importance in research fields of agriculture, evolution, and biomedical genetics. The advances in bioinformatics tools have changed research in both basic and applied biological sciences and these tools are enabling scientists to gain knowledge of complex biological systems. Also, they allow implementation of results towards novel developments in biomedical applications and contribute to promoting both individual and population welfare.

Keywords: Aptamers, Biochips, Data mining, Databases, Genomic, Gene expression array, Phylogenetics, Proteome.

BIOINFORMATICS

INTRODUCTION

It is the science of using information to understand biology. It is conceptualising biology in terms of molecules and applying informatics techniques (computer science, applied mathematics and statistics) to organise their information associated with these molecules.

Thus, bioinformatics is concerned with development and application of computer software and hardware to get, store, analyze and visualize biological information. By providing algorithms, databases, user interfaces and statistical tools, comparison of DNA sequences are possible.

The long-term value of bioinformatics and data mining capabilities does not lie so much in developing tools, as it does in connecting knowledge or information into

products like therapeutics, animal, and plant bioreactors in the Fig. (**1**) form of genetically modified organisms, newly discovered genes, *etc*.

Bioinformatics and data mining are two latest areas of research involving computer-assisted management of data generated for biotechnology applications. The information generated in genomics is enormous and its interpretation requires the use of powerful computers and specific software's.

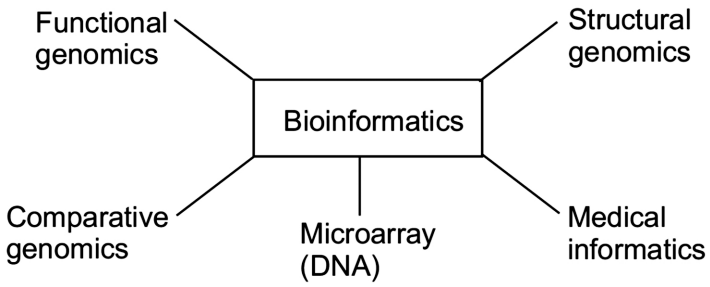

Fig. (1). Recent fields of bioinformatics.

TERMINOLOGY

Genomics

Term genomics has been derived from the word genome, which means haploid DNA content of an organism.

Term *genomics* deals with the genome as a whole and had its origin in the human genome project, which involved determination of the nucleotide sequence of the whole genome.

Today, genomics includes sequencing of genomes, determination of the complete set of proteins encoded by an organism and functioning of genes and metabolic pathways in an organism.

HISTORY OF BIOINFORMATICS

Bioinformatics involves creation, maintenance, and use of databases, to which new data on DNA and protein sequences are constantly added. Bioinformatics came into

existence in 1980s after automated DNA and protein sequencing became possible and computers became central repositories that are accessible world-wide. Four years later, bioinformatics proved itself as a foundation of future biotechnology (Table **1**).

Table 1. Chronology of major events in genome sequencing and bioinformatics.

1962	Pauling's theory of molecular evolution
1970	Needleman-Wunsch algorithm
1971	DNA sequencing
1981	Dolittle's concept of sequence motif, Smith-Waterman algorithm
1982	Sequencing of phage lambda genome
1984–1990	Discussion in scientific community for sequencing genome
1985	Sequence database searching algorithm
1986	Human Genome project proposed
1988	Creation of NCBI (National Centre for Biotechnology Information) at NIH/NLM
1990	Human Genome project started
1988	EMBnet: network for database distribution
1990	BLAST

CHAPTER 4

Scientific Document

LEARNING OBJECTIVES

After going through this chapter, one should be able to appreciate the following:

- How to plan and organize research?
- What is a good research paper?
- How to write an academic report (thesis/dissertation) /review article/ short - communication/abstract/monograph/ report/book?
- Digital technology platforms for documents.

Abstract: Writing a scientific paper, or research report or presenting research data for oral presentation is an art that comes with practice and experience. This chapter intends to make the reader aware of the basic features of scientific writing and digital technology platforms for documents available

Keywords: Research paper, Report, Abstract, Review of literature.

SCIENTIFIC WRITING

Structures

1.Scientific paper
2.Guidelines for writing a scientific paper
3.Review articles
4.Report
5.Thesis and Dissertation

Types of Scientific Documents

Types of scientific articles include primary articles (original research articles, case reports/case series, and technical notes), *secondary articles* (narrative review articles and systematic reviews), *special articles* (letters to the editor, correspondences, short communications, editorials, commentaries, and pictorial essays), and *tertiary and gray literature* (Reports, Proceedings, Dissertations and theses, Registered trials, White papers, Newsletters, Patents).

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Research Paper: its Organization and Writing:

Scientific Paper

A scientific paper is not a technical report or term paper. This is a paper worth writing only if it has general implications for knowledge. One should think of its role as guiding the future efforts of scholars since others will follow with newer data and better models.

Scientists are motivated for writing papers in two ways, namely, to understand the world and to get credit for it. In academic and public sectors, scientific papers are means of expansion of human knowledge. Publish or perish should be the rule for scientists working as individuals for professional survival; if you do not publish, you are out of the field.

Nowadays, the quality of a scientific paper is measured by the citation index. It depends on:

(i)The originality and importance of ideas,
(ii)The effectiveness of communication to flag new ideas,
(iii)The means of communication, the role of advertisement, presentation, communications at meeting, email exchanges, citations, *etc*.

Remember that writing a paper is not merely a description of works, it is the work itself. Suggestions:

(i) Start writing a paper as soon as possible: view it as a tool of your research.

(ii) Write an "introduction" as you engage into your research:

Try to Highlight

•What are you trying to do?
•Why it is important?
•What has been done earlier?

(iii) Write the "methods" when you think they are mature/materialising. Golden rule—Any difficulty in writing means there is a problem with the methods.

(iv) Write "results" and "discussions" after spending enough time on analysing and interpreting results.

(v) Spend a little bit of time daily with your evolving paper. Try to be a critical reader or reviewer to bring the best out of it.

Very few will read your paper in a thorough and deliberate way, from beginning till the end. Remember you must market your paper for casual readers!

1. Title and Abstract—are for search engines and most readers won't go beyond that!
2. Results: Figures + Captions and Table + Footnotes:
(i) Must be self-contained. A lot of readers go through those without reading the text and some look for a brief explanation in the text.
(ii) Make figures attractive.
3. Remember that the take-home message of your paper should be "in your face" *i.e*., in the abstract, introduction, and conclusions. Make sure that everyone gets the message!

Writing an effective paper is not as easy as an essay. A good rule is to write as if your paper will be read by a person who knows about the field in general but does not already know what you did. You should read some scientific papers that have been written in a format which you plan to use and then plan to write a scientific paper.

Typical Outline of a Paper

Abstract

Introduction

Materials and Methods

Results

Tables and figures

Discussion

Citations

Reference lists

Genetic nomenclature

Format: flow, abbreviations, tense, third person, parenthesis

Proof-reading.

CHAPTER 5

Scientific Literature

LEARNING OBJECTIVES

The *Scientific literature* includes abstracts, journals, books and data available on the internet. This unit aims to provide knowledge on different types of scientific literature and different modes of research and use this available literature.

Structure

1. Writing an abstract for a scientific meeting.
2. Using the computer in research.
3. Literature.
4. Methodological references.
5. Computer-based searches and other aids to literature.

The scientific programme includes a limited number of spaces for the presentation of abstracts, either as oral communications or posters.

Abstract: Writing a scientific paper, research report, or presenting research data for oral presentation is an art that comes with practice and experience. This chapter intends to make readers aware of the basic features of scientific writing and digital technology platforms for documents available.

Keywords: Literature, Study design, Data collection, Analysis, Research, Encyclopaedias, Reference works, Publications, Journals, and Bibliography.

TYPES OF SCIENTIFIC LITERATURE

Scientists usually communicate their results of research primarily through the *scientific literature.* Scientific literature is a permanent repository of scientific knowledge and records progress in scientific inquiry. Scientific literature can exist in a variety of physical forms such as print publications in the form of books or journal articles, as electronic documents, such as the data on web sites or as personal communications, *etc*.

There are different types of scientific literature, namely, primary, secondary, tertiary and gray literature.

Primary Literature

It is the first-hand account of new/ original research written and reported by researchers who themselves conducted the research.

A *primary article* is a report of a given study and includes introduction to research, methods used, data and results obtained, a discussion of results, and references related to the literature used in the design and analysis of the research in question. These publications can be found in journals, government, and various institutional research reports, and sometimes referenced in books.

Patents, dissertations, and other documents reporting original research, and journal articles are the most widely used primary sources in the field of science.

Secondary Literature

It is a type of scientific literature that is created when other scientists integrate the information from primary literature into review articles or books; these reviews are termed *secondary literature.* It consists of publications that rely on primary sources for information and includes review journals, monographic books and textbooks, handbooks and manuals. Reviews provide a broad overview of a field or ideas generated by many people. Secondary literature is useful for gaining a broad perspective on a topic or a synthesis of ideas about a topic and to find a bibliography of relevant sources. Thus, secondary literature in the sciences summarizes and synthesizes the primary literature. Examples: literature review articles; books.

Tertiary Literature

It consists of published works based on primary or secondary sources which are aimed both at scientists working in different areas from the subject matter of the publication and interested but lay audiences. They are normally written in a popular style and may include a short bibliography; and do not include references of the primary literature. Thus, tertiary literature presents summaries or condensed versions of materials with references to primary or secondary sources. Examples: textbooks, dictionaries, encyclopedia, and handbooks.

There are many types of scientific documents written for various purposes and a few of the main ones are already described in chapter 4. The remaining types are discussed in this chapter.

COMPUTER, INTERNET, AND WORLD WIDE WEB

Computer & Internet

The computer has become an essential tool in biotechnology research. It may be used for routine jobs of word processing and data collection and analysis. Also, when connected to the Internet, it may be used for searching biomedical (biotechnology) literature, accessing information about nucleic acid and protein sequences, predicting protein structure, seeking research methodology and searching databases of genome programs.

By using computers, one can greatly broaden its use to some of the following:

(i)Searching the biomedical literature for pertinent books and journal articles.
(ii)Accessing biological databases that provide nucleic acid and protein sequences and structures.

Once connected to the Internet, many programs are available as freeware.

One can communicate by e-mail. Messages containing text, files and graphics may be sent to anyone who has a computer with an Internet link and e-mail address.

Communication among scientists is now done primarily by e-mail. Also, one can join several discussion groups such as Use Net.

It has become the most rapidly growing component of the Internet since its launch in 1992. It permits the transfer of data as pages in the multimedia form consisting of texts, graphs, audios and videos. The pages are linked together by hypertext pointers so that data stored on computers in different locations may be retrieved *via* the network by one's computer. To access all the resources on web, one needs a browser (that reads hypertext and displays web pages on the computer) and common web browsers are: Internet Explorer, and Netscape Navigator.

World Wide Web

To access web, a web browser is activated and on-screen home page will be displayed. The dialogue box on this page asks for "address", "net site", "location" or "URL" (Uniform Resource Locator); type in the web page address which is usually in the form http://www.

CHAPTER 6

The Basis for Starting a new Project and Preparing R & D Projects

LEARNING OBJECTIVES

This chapter gives information about science funding organizations along with details of national and international funding agencies for R and D projects.

Abstract: Biological resource centres (BRCs) are an essential part of the infrastructure underpinning life sciences and biotechnology. They consist of service providers and repositories of the living cells, genomes of organisms, and information related to heredity and the functions of biological systems. The growing worldwide demand for biological resources provides good reasons for greatly increasing the number and quality of BRCs. BRCs provide essential expertise for the formulation of government policies on biological resources and for information and assurance to the public.

The establishment of national BRCs can help identify and address existing gaps and take advantage of opportunities not currently met by existing ex-situ collections. They can then improve the quality of services offered and achieve efficiencies and cost savings.

A global BRC network would connect national BRCs and provide the framework within which co-ordination, harmonisation and quality assurance could be provided. BRCs need to provide greater quality assurance than is currently ensured by collections and databases.

Keywords: Literature, Study design, Data collection, Analysis, Research, Encyclopaedias, Reference works, Publications, Journals, Bibliography.

FUNDING AGENCIES

Structure	
1. Science funding organizations	
2. Basis and technology for starting a new project	(i) Market survey (ii) Marketing strategies for biotech products (iii) Methodology for starting a new project (iv) Technology

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Biotechnology companies after reaching a certain size become sufficient enough to get much out of their heavy R & D spending as it was for global pharma. Most biotech companies have achieved their success behind just one or two block-busting drugs that were priced boldly and marketed aggressively. The product life cycles are short and by careful planning after considering the skill to draw funding would help in the survival of a company.

All the knowledge gained from market surveys and planning would help in, achieving and sustaining the success of a biotech company.

INTERNATIONAL FUNDING AGENCIES

Organization	**Funding Offered**
1.Alexander von Humboldt Foundation	Research Fellowship and research awards for scholars and scientists of all nationalities not resident in Germany.
2. Arnold and Mabel Beckman Foundation	Supports basic scientific research in the USA in the fields of chemistry, biochemistry, and medicine.
3.Caledonian Research Foundation	Encourages academic research in biomedicine.
4.Dalmo Giacometti Foundation	Private foundation which supports genetic research and biotechnology.
5.Grants Net	Research funding information from the American Association for the Advancement of Science.
6.Swiss national Science Foundation	Support scientific research at Swiss Universities, awards fellowships to young scientists.
7.US civilian R and D Foundation	Promotes scientific research and technical collaboration between US and countries of the former Soviet Union.
8.Wallace Genetic Foundation	Supports interests including agriculture research, preservation of farmland, ecology, plant genetic research.

cont.....

9.Whitaker Foundation	A private funding source for biomedical engineering research and education in US.

NATIONAL FUNDING AGENCIES

1.ICMR: Indian Council for Medical Research
2.CSIR: Centre for Scientific and Industrial Research
3.DBT: Department of Biotechnology
4.DST: Department of Science and Technology
5.UGC: University Grants Commission

In life science business environment, new product development is swift, competition is fierce, and the marketplace has multiple distribution channels. To make their position, life science companies need reliable information about their markets regarding research activity of competitors and quantification of the impact of business decisions and goals.

New business creation calls for new ways of designing, developing, manufacturing, marketing, or selling a product of service, which disrupt proven ways of running the business and create dilemmas that have to be managed.

PROCESS OF SELECTING VENTURES

One must first understand (Fig. **1**), Why do ventures succeed or fail?

For understanding how to choose ventures:

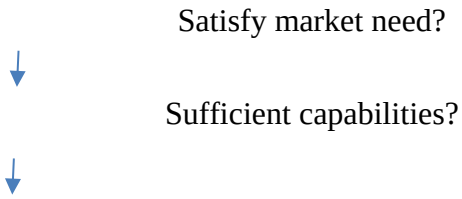

Fig. (1). Process of selecting ventures.

CHAPTER 7

Intellectual Property Rights

LEARNING OBJECTIVES

This chapter gives an overview of intellectual Property (IP), its categories, benefits and management; intellectual property rights (IPR) and filing of patents.

Abstract: Intellectual Property (IP) is the intangible creation arising from the application of human intellect and its legal characterization is intellectual property right (IPR). With the emergence of modern biotechnology, the era of patents, copyright, and IPR have come into being. One needs to be conversant about IPRs and patent systems to protect, license, trade, and market his research and inventions. This chapter aims to prepare oneself to face the legal and ethical challenges of research and trade. IPR appears to play an important role in facilitating production and exchange in certain input markets.

Keywords: Intellectual Property, Patent, Trade secret, Copyright, Trademark.

INTELLECTUAL PROPERTY (IP)

IP is created through the application of intellect and ingenuity and is usually in the form of an idea, concept, design, process, *etc*. to generate a product ultimately. With the emergence of modern technology, intellectual property is the legal characterization and treatment of trade-related biotechnological processes and products.

Under biotechnology, important examples of intellectual property are processes and products that result from the development of genetic engineering techniques (using restriction enzymes) to create recombinant DNA. These IPs can be copied and used by others, thereby reducing the benefits of original inventors.

The right of any individual to derive from intellectual property and to exclude others from doing so is referred to as Intellectual Property Rights. Utility Patents for genetic materials (both plants and animals) that have been allowed in some countries so that patented material cannot be used for further breeding or cultivation (in case of seeds) without paying a fee to the patent holder.

These IPRs affect (both favourably as well as unfavourably) the conservation, availability and use of plant and animal genetic resources (PGR & AGR).

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Also, IPRs may adversely affect:

- food security
- use of evolved agricultural practices
- biological diversity
- ecological balance

CATEGORIES OF IPRs

There are four major types of IPRs application in biotechnology:

1.Trade secret
2.Patent
3.Copyright
4.Trademark

Trade Secret

Trade secrets include private proprietary information or physical material that allows a definite Commercial advantage to the owner over his competitors. A trade secret may protect a formula, production process, microbial strain or cell line, *etc*. However, a manuscript, design, product, *etc*. cannot be protected as a trade secret.

Trade secrets in biotechnology include:

- cell lines
- hybridization condition
- merchandising (corporate) plans
- customer lists

Duration

Trade secrets have an unlimited duration and the process is simpler as compared to patents.

Disclosure of Trade Secret

Disclosure and unauthorised use of a disclosure of a trade secret are punishable by law and the owner may be allowed compensation. Secrecy is ensured through non-disclosure/confidentially agreements.

Advantages of Trade Secret

1.Unlimited duration whereas IPRs are for a limited duration.
2.Easy to obtain - lack of legal formalities and requirements. While a patent is granted in 2-3 years after the application is filed.
3.Involve reduced risk of someone improving upon the process/for mutation, *etc*.
4.Does not require the filing of applications, or paying fees for renewal every year.
5.Does not require contesting and enforcing IPR.

Limitations

1.Its maintenance is costly.
2.It has no protection from independent innovation/invention.
3.It cannot be applied to many IPs.
4.Since it involves non-disclosure, this delays and hampers scientific/ technological progress and further innovations.
5.The title cannot be restored to the owner once secrecy is lost. Does not give rights against public at large unlike IPRs. If secrecy is breached, it becomes open and free to use for all.

Copyright

Copyright is associated with the expression of any idea or information by the author in any tangible form. These IPs include books (authored and edited), computer programs, paintings, sculptures, audio and video cassettes and cinematographic films. A work of copyright cannot be reproduced, in part or total, translated or distributed to the public without the permission of the person holding the copyright (author, editor, publisher, producer).

Copyright is possible only on expressed material (printed, painted, tape/video/computer recorder expressed in any other form).

Copyright rules are modified from time to time. They are territorial in nature and application and there are divergent rules in different jurisdictions. In the case of biotechnology, copyright may cover DNA sequences, computer databases, and DNA instruction manuals. However, the protection of copyright is limited, *e.g*., ideas given in print can be used for any other purposes though photocopy that may not be allowed.

CHAPTER 8

Biotechnology Regulations

LEARNING OBJECTIVES

This chapter gives an overview of the existing patent regime and its application to the field of biotechnology. It also analyses the legal and social implications arising from the interface of biotechnology with IPRs.

Abstract: This chapter introduces patenting and fundamental research, copyrights, trademarks, biotechnological patents, current issues in patenting, Indian response to patent upheaval and bioprospecting along with the existing risk-analysis system for biotechnology products, surveying agency authorities. Regulations in biotechnology apply to the production, sale and use of biotech products and genetically modified organisms and regulatory agencies conduct their functions to protect public health, safety, and the environment.

Keywords: Intellectual property rights, Patent, Economic incentive, Innovative, Bioprospecting, Erythropoietin, Hybridoma, Biopirates.

PATENTING AND FUNDAMENTAL RESEARCH

INTRODUCTION

From the very outset of its use, biotechnology has raised some concerns which led the countries to recognize the need for regulation to ensure the safety of human, animal and plant health and the environment. Regulations apply from the stage of production to sale and the use of biotechnological products and genetically modified microorganisms which are tested and documented before the products enter the market for being used. Medical products and foods are regulated by the government and these regulations have profound effects on the biotechnology workplace. The National Institute of Health (NIH) was the first regulatory body over biotechnology in the USA and from 1984, biotechnology research has become a joint responsibility of NIH, USDA (US Department of Agriculture) and EPA (Environment Protection Agency). USDA makes sure a given organism is safe to grow, EPA makes it certain that it is safe for environment and FDA determines its safety for consumption.

In India, Recombinant DNA Safety Guidelines, 1990 (revised in 1994) were released by the DBT (Department of Biotechnology) which cover areas of research

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involving genetically engineered organisms and these guidelines were further revised in 1994. The Biotechnology Regulatory Authority of India Bill was introduced in 2013 for setting up an independent Biotechnology Regulatory Authority of India (BRAI) to regulate organisms and products of modern biotechnology and it is yet to be passed by the parliament. GEAC (Genetic Engineering Approval Committee) under the Ministry of Environment, Forests and Climate Change (India) is responsible for the approval of genetically engineered products in India.

Intellectual Property Rights

According to the official interpretation of the World Intellectual Property Organisation (WIPO), IPR comprises those legal rights, by which the products of intellectual activity over a range of endeavours are defined.

Intellectual Property Rights are property rights over intangible things/products derived from human intellectual activity in the form of innovations and creations. There are awarded for a limited duration (time limited rights) creating the legal right of exclusivity to reward the creator/innovator and help the public at large *via* access and use of such creations/inventions. These are statutory rights, and their extent and scope are defined by the statute and cannot extend beyond that. IPRs apply to all fields of technology and arts.

Biotechnology and IPRs

Biotechnology is the result of the application of human intelligence and knowledge to the biological process. The conjugation between biotechnology and IPRs is not of new origin. Biotechnological research was earlier restricted to academic research only. After biotechnology started giving out commercially viable innovations, it became a matter of necessity to protect its products and creations under IPRs.

The principal objective of modern biotechnology, through the collaboration of academic labs with industry labs or otherwise, is to produce commercial products for economic gain. Investors will be hesitant to invest in high-cost biotechnology ventures if legal protection against unauthorized use by competitors is lacking as the level of uncertainty is very high. Also, society is encouraging industrial innovation. It is for the government to grant exclusive rights to inventors for novel products and processes they develop. These sanctioned privileges are collectively termed as Intellectual Property Rights.

COPYRIGHTS AND TRADEMARKS

Different types of IPRs

Though there are around 7 types of intellectual property rights recognised at the international level, for biotechnology-related inventions and creations, the following types of IPRs are relevant and discussed briefly:

1.Trade secrets
2.Copyrights
3.Trademarks and
4.Patents

Trade Secrets

It comprises confidential information about specific technical procedures and formulations of commercial value that a company wishes to protect from others. The right is automatic, and they are not registered with any government or regulatory body, but the owner takes reasonable security measures to protect the secrecy.

Copyrights

Copyrights protect authorship and ownership of different forms of published work i.e., literary, artistic, musical, dramatic, sound recordings, and cinematographic films from their unauthorized access.

Trademark

It can be either symbols or words that are distinctive and identify a particular service or product of a company.

Patent

For biotechnology, patents form the most important part of intellectual property. A patent is a legal document that provides exclusive rights to the patent holder for implementing the invention commercially.

Though biotechnological products can have connections with copyright, trademarks, and designs, this chapter exclusively discusses the concept of

CHAPTER 9

Genomics and Proteomics

LEARNING OBJECTIVES

This chapter gives an overview of genome sequencing, gene mapping, sequence analysis, DNA sequencing, microarrays, genomics in drug discovery, translational medicine era of 'omics'– single-cell multi-omics, metabolic engineering, epigenetics, protein products and protein expression systems, and microbiome.

Abstract: Genomics is the science of mapping sequences and analysing genomes. This chapter gives an overview of techniques of genome sequencing, gene mapping, sequence analysis, DNA sequencing and microarrays. Genomics offers sequencing, mapping, and analysis of a genome. With the help of computer-based techniques, a human genome was sequenced. Now it is possible to identify the function of genes from protein databases. Since proteins cannot be amplified like nucleic acid, the analysis of protein expression is challenging 2 DGE; MS and protein chips are the most widely used technologies for proteome analysis.

Keywords: Genomics, Proteomics, Metabolomics, Transcriptome, Metabolome Database, Protein expression, Heterologous proteins.

TERMINOLOGY

Bioinformatics	A branch of biology that deals with in silico processing and analysis of DNA, RNA, and protein sequence data.
Genomics	Study of structure and function of genome.
Comparative genomics	Uses sequence similarity and comparative gene order for determining gene function and phylogeny.
Functional genomics	Determines the function of a gene product.
Structural genomics	Determines structural motifs and complete protein structures and their relationship in terms of structure and function.
Proteomics	Study of proteome, *i.e*. the full complement of proteins made by a cell.
Transcriptomics	A study of transcriptome, *i.e*., all the RNA molecules made by a cell, tissue organism.

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cont.....

Metabolomics	Uses genome sequence analysis to determine the capability of cell, tissue or organism to synthesize small molecules.

COMPARISON

Table 1. Comparison of omics.

	Description	**Time dependence**	**Manipulation in cell**	**Measurement in cell**
Genome	Complete DNA sequence of organism	First approximation: none	Genetic manipulation; site directed mutagenesis Genetic screens	Routine high accuracy end complete
Transcriptome	Complete set mRNA transcripts in a cell or a tissue	Reflect the state of gene expression	Indirectly *via* genetic manipulation	Routine cDNA, microarrays SAGE, Northern Blot Quantification, inaccurate, approximate completeness
Proteome	Complete set of proteins present in a cell or tissues	Responsive to all manner of influences throughout life cycle	Indirectly *via* genetic manipulations	Not routine, 2-D-gels with MS. Fusion with reporter proteins (GFP)
Metabolome	All metabolites and their concentrations Defined as organic small molecules, not protein RNA or DNA	Responsive to all manner of influences throughout life cycle	Difficult	Difficult, completeness far away.Net routine, NMR, MS a few other methods. Quantification and resolution difficult.

GENOMICS IN DRUG DISCOVERY

Medical genomics pinpoints the normal and abnormal functions of individual genes and uses the information for the diagnosis and treatment of disease. Functional genomics is the process of determining the function of genes to find those genes that are good targets for drug discovery. Newer proteins discovered through genomics may serve as drugs themselves and they can be proteins or hormones or growth-factors that are under/overexpressed in disease states. Diseases linked to defective, misfolded, and misregulated proteins are good candidates for drug discovery.

A drug target could be a single gene or protein or an entire interacting pathway of proteins. Once a suitable target and compound are identified, the target is validated and the compound is altered so as to improve its efficiency and minimize any side effects, finally generating the compound for clinical trial and approval for their usage.

Functional genomics is becoming increasingly important for genome-based drug discovery.

TRANSLATIONAL MEDICINE

Translational medicine is the integrated application of innovative pharmacology tools, biomarkers, clinical methods, clinical technologies and study designs to improve disease understanding, confidence in human drug targets and increase confidence in drug candidates.

Translational research provides the knowledge necessary to draw important conclusions from clinical testing of diseases and the viability of novel drug mechanisms.

Pathway Analysis

Analysis of metabolic pathways in humans helps to recognize how proteins and other biological molecules are connected to each other and which biological processes they regulate or represent.

How pathways and molecular interactions are explored?

CHAPTER 10

Newer Technologies in Molecular Biology

LEARNING OBJECTIVES

This chapter gives an overview of antisense RNA technology and gene silencing; mRNA surveillance; using biotechnology against bioweapons; molecular cytogenetics; mutation detection, detection of genomic duplications and deletion, mutation database & analysis of human splicing defects;, molecular techniques for DNA methylation studies, pharmacogenetics, pharmacogenomics and nutrigenomics; preimplantation genetic diagnosis and prenatal diagnosis; next-generation DNA sequencing techniques (NGS); single cell biopsy; CRISPR, gene editing; transformative advances in regenerative medicine; Encode, exomic studies, ancestry studies.

Abstract: Technical advances began with the advent of array comparative genomic hybridization and single nucleotide polymorphism arrays and are enabling researchers to identify disease-associated genetic variants by virtually scanning the entire genome. With the help of these technologies, it is now possible to screen for common genetic variants and even rare small deletions and duplications *i.e.*, microdeletions and microduplications. This has led to a virtual explosion of gene identifications. This chapter aims to provide an overview of new technologies.

Keywords: Antisense RNA, Antisense therapy, Gene silencing, Jumping gene, Bioterrorism, Bioweapons, cytogenetic, DNA methylation, Pharmacogenetics, Pharmacogenomics, Nutrigenomics.

ANTISENSE TECHNOLOGY

Antisense RNAs

Antisense RNA is an RNA molecule that is complementary to mRNA and binds to mRNA, preventing its translation. Antisense RNA is occasionally used in gene regulation both by bacteria and eukaryotes.

The antisense RNA approach is designed to specifically interfere with the virus replication. A complementary DNA strand of a gene can be inserted in reverse orientation (3′ → 5′) and is termed as an antisense gene. The antisense gene produces mRNA complementary to mRNA synthesized by the normal gene. Both of these mRNAs hybridize, blocking the normal translation of mRNAs. Antisense approach can be useful in both single-stranded RNA viruses and DNA viruses.

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Antisense Therapy

This refers to the inhibition of translation by using a single-stranded nucleotide (antisense oligonucleotide). Also, it is possible to inhibit both transcription and translation Figs. (**1** and **2**).

For Cancer Therapy

Antisense RNA molecules are more frequently used in cancer therapy.

Two Ways of Inhibition of Translation by Antisense RNA

(i) Antisense cDNA is cloned and transfected into cells to synthesize antisense mRNA. This antisense mRNA binds with the specific mRNA and block translation.

(ii) Antisense RNA is directly introduced into the cells which hybridize with target mRNA and blocks translation.

For HIV Prevention

Antisense therapy can prevent HIV infection. Target cells for HIV infection are genetically engineered to contain a gene that can express a complimentary copy of the HIV genome and antisense RNA. When cells with antisense RNA are infected with HIV, a double-stranded RNA hybrid molecule is formed that cannot be used by the enzyme reverse transcriptase.

Antisense technology in conjunction with emerging technologies will make a significant impact on the future of healthcare.

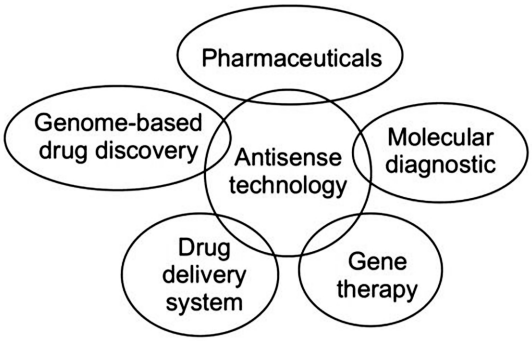

Fig. (1). Antisense technology and biopharma industry.

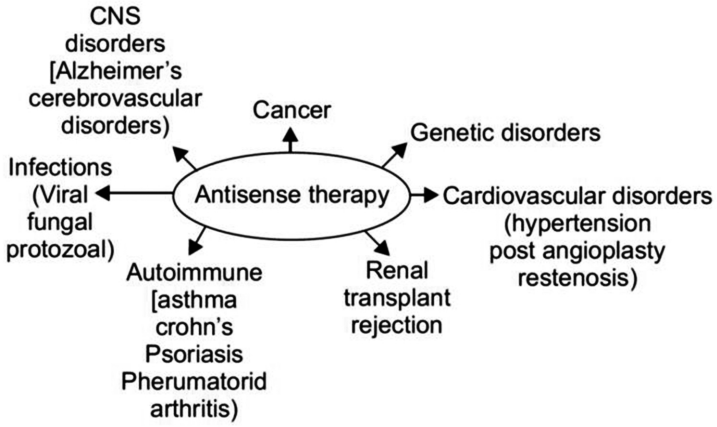

Fig. (2). Potential clinical applications of antisense therapy.

Theoretically, all infections and diseases due to genetic overexpression should be amenable to antisense approaches.

Antisense therapy interferes with the expression of disease-causing proteins, thus offering a direct and selective intervention in the disease process. Other key antisense technologies that have an impact on drug discovery and molecular diagnostics are antisense gene therapy ribozymes, triple helix-forming oligonucleotides and peptide nucleic acids (PNA).

Antisense approaches are compatible with emerging trends in drug development, genomic-based therapeutics, and the integration of diagnostics with therapeutics Fig. (**3**).

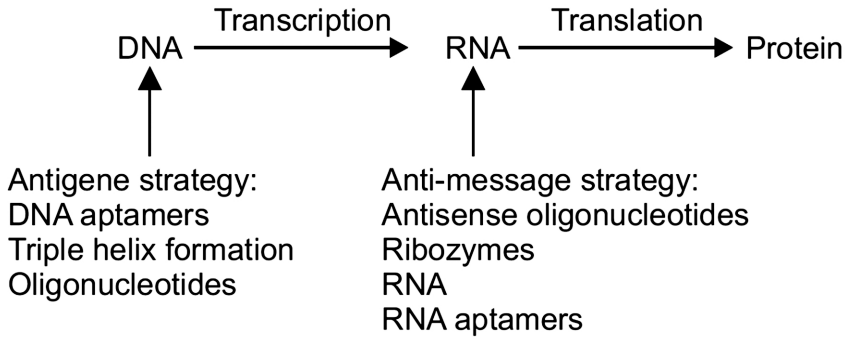

Fig. (3). Antisense strategies.

CHAPTER 11

Ethics in Science & Technology

"History of the world civilizations shows that societies have risen to a higher level not through mechanical or technological efficiencies but by practising sound moral and ethical values".

— Swami Bodhinanda (Gita & Management)

LEARNING OBJECTIVES

This chapter gives an overview of ethics, values, and morals concerning research; Indian research at a glance and violation of ethical issues in India and worldwide; Virtual embryo – virtual life, artificial bacteria -ethical issues; ethics in the era of covid19 and challenges in precision medicine. Also, the ethical responsibilities of scientists, technologists, institutions, firms, policy-makers, governments, international organizations and citizens are discussed.

Abstract: This chapter discusses conceptual issues in arguing for the ethics of science and technology. Since we live in a world where scientific knowledge and new technologies are continuously challenging our values, and we have to live our daily lives and make decisions based on the fundamental values of human dignity in our civilisation, scientists are no exception. Governments and private sectors have recognized the importance of ethics required to reconcile the human imperatives of development and sustainability. It is necessary to conduct both in-depth research on ethics and strengthen ethics education in science and technology to solve the problems brought about by rapid developments in the field. Stem cell research, genetic testing, and cloning are giving human beings new power to improve health and control development processes of all living species. Concerns about the social, cultural, legal and ethical implications of such progress are the most significant debates of the past century and a new word has been coined to encompass these concerns, *i.e.* bioethics.

Keywords: Ethics, Plagiarism, Ecological issues, Policy issues, Global ethics experiences, Society for Scientific Values.

ETHICS VALUES MORALS

Ethics are a set of principles and a sense of purpose which are fundamental to a civilized society. It is said that science is ethics–neutral but scientist is not! Ethics can be universal or functional and profession dependent which cannot be taught but must be cultured and nurtured through experience, analysis, introspection, and a sense of responsibility.

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Ethics can be exercised at the level of individuals, communities, professions, and countries. At a philosophical level, ethics include abortion, genetic testing, organ transplant, gene therapy, etc. At the professional level, ethics include research integrity and scientific values. At the regulatory level: biosafety, bioethics, EIA, clinical trials, and field trials are the main concerns. The fields of biotechnology and bioethics have coevolved and impacted each other.

Professional Ethics: Issues

Plagiarism

Duplicate publication

Author credit and accountability

Research supervision

Data: quality and integrity

Special Facilities: Sharing and use of peer review.

IPR

Development, acquisition and commercialisation of technology

Ecological issues

Professional Ethics: Secondary Issues

Policy issues

Interaction with the public and media

Science vs Society

Science vs market forces

Regional, communal and caste factors

Political interventions

Recruitment and assessment

Corruption and kickbacks

Issues Regarding Scientific Values and Research Integrity in India

Favouritism and victimization in:

Recruitments and promotions

Grants, awards, peer reviews

Caste, region, religion

Feudal work culture

The bureaucratic, non-transparent system, poor accountability

Corruption

Plagiarism, false data/claims, authorships, conflict of interest

Public Protests Against Biotechnology

Since biotech is one of the battlefronts in the fight against globalization, liberalization, capitalism and privatization. However, biotech needs to be democratized and negotiable.

INDIAN RESEARCH AT A GLANCE

In India about one lakh scientists, engineers and technologists are working in various S & T Institutions, producing around 20,000 research papers/articles. Also, 3,000 PhDs are produced every year, most of which flock to the west.

Science and technology Institutions in India

>250 universities

> 100 deemed to be universities

8 IITs

CHAPTER 12

Medical Biotechnology

LEARNING OBJECTIVES

After completing this chapter, you should be able to:

- Provide examples of current applications of biotechnology in medical sciences
- Understand the purpose of gene therapy, regenerative medicine, pharmacogenomics

Abstract: Medical biotechnology incorporates many of the topics that have already been discussed in this book. Right from developing new drugs to prospects of stem cell use and cloning, the possibilities are enormous.

Keywords: Homologs, Personalize medicine, nanodevices, Nanoparticles, Regenerative medicine, Xenotransplantation, Biocapsules, Stem cells.

DETECTION AND DIAGNOSIS OF HUMAN DISEASES BY MOLECULAR BIOLOGY

Molecular biology offers powerful tools for diagnosing and combating human diseases. Mice, rats, worms, and flies have played critical roles in helping scientists study human diseases.

Various model organisms are used for the identification of disease genes and testing of gene therapy and drug-based therapeutic approaches.

Homologs

Many important genes are conserved from species to species and genes identified in model species have been related to human genes termed as homologs.

The human genome project and comparative genomics studies have demonstrated that human beings share a large number of genes with other organisms *e.g*., humans share 50% of genes with fruit flies and about 61% of genes mutated in 289 human disease conditions are found in fruit flies. This group includes genes involved in leukemia, cystic fibrosis, pancreatic cancer, prostatic cancer and other human genetic disorders. Heart disease, and HIV model organisms are used by scientists to study disease processes and test therapies to combat the disease. Molecular biology offers possible biomarkers for the detection of diseases at an early stage,

e.g., in the case of cancer, early detection is critical for treatment and improving patient survival.

Biomarkers are proteins produced by diseased tissues or their production is increased when the tissue is diseased. They are released into body fluids such as blood, urine, and body cavity fluids. Also, the detection of genes or gene expression patterns also provides important biomarkers for early detection and diagnosis and monitoring of diseases and microarray offers promising results in this regard.

GENETIC DISEASES

Many different genetic diseases have been detected by molecular biology techniques. Until recently, fetal genetic testing was done more for fetal sex detection than the detection of genetic diseases. Amniocentesis and chorionic villus sampling are used for the detection of genetic diseases. Karyotyping, FISH (fluorescence in situ hybridization) and spectral karyotyping are useful in identifying missing or extra chromosomes. A number of diseases due to chromosomal abnormalities occur when a portion of a chromosome is deleted or swapped from one chromosome to another, *e.g*., chronic myelogenous leukaemia where DNA is exchanged from chromosome 9 to 22 and vice versa and this exchange can be detected by FISH.

Mutations in specific genes also result in many genetic diseases and require more sophisticated techniques for their detection in both fetuses and adults.

RFLP (restriction fragment length polymorphism) pronounced "*riflips*" analysis can detect genetic diseases in embryos and adults from amniotic fluid and blood respectively. Also, RFLPs are used for DNA fingerprinting. Another approach is allele-specific oligonucleotide (ASO) analysis that allows the detection of a single nucleotide change in the gene. In the ASO technique, DNA is isolated from cells and amplified by PCR using primers flanking genes of interest. This technique can be used to screen gene defects from single cells from 8 to 32 cell-stage embryos created by in vitro fertilization, termed as *Preimplantation Genetic Testing*.

SINGLE NUCLEOTIDE POLYMORPHISMS (SNPS), EXOME SEQUENCING

SNPs, single nucleotide changes in DNA sequences, (pronounced "*snips*") are the most common genetic variations in humans. SNPs occur in approximately every 1,000 to 3,000 base pairs (bp) in the human genome and over 1.4 SNPs have been identified. Most SNPs occur in introns (non-protein coding regions) and have no

effect on a cell. But, when an SNP occurs in a gene sequence, it may cause a change in the protein structure that produces diseases or influences traits in a variety of ways, including conferring susceptibility for some types of diseases. Since SNPs occur frequently throughout the genome, they serve as a valuable genetic marker for identifying disease-related genes.

HapMap

Hap is an abbreviation for haplotype and Hap Map is an international effort to identify and catalogue chromosomal locations (loci) of >1.4 million SNPs present in 3 billion bp of the human genome. Many SNPs on the same chromosomes are clustered in groups called haplotypes and this may have a role in diagnosis and treatment.

Microarray analysis using DNA microarrays, and protein microarrays will also play an important role in the detection of genetic and other diseases.

Applications of Biotechnology

Major areas of medical biotechnology are the identification of novel drugs and developing new ways for the treatment of diseases. Different proteins, *e.g*., insulin, human GH have been produced using recombinant DNA technology and are used to treat human diseases. Also, therapeutic proteins such as monoclonal antibodies, blood products and enzymes produced by living systems can be thought of as biotech drugs (Table **1**).

Biotechnology proteins have revolutionized the healthcare and pharmaceutical industries. Newer strategies for treating different types of cancer are promising and oncogenes and tumor suppressor genes are getting attention.

Work is going on to identify proteins made by these genes are targets. For inhibition and activation to fight the disease.

Table 1. Recombinant therapeutics.

Protein	***Application***
Monoclonal antibodies	Therapeutics: cancer, Rheumatoid arthritic Diagnostic

SUBJECT INDEX

A

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