OPPORTUNITIES FOR BIOTECHNOLOGY RESEARCH AND ENTREPRENEURSHIP

Editors:
Sagarika Devi
Gokul Shankar Sabesan
Sultan Ahmed Ismail

Bentham Books

Opportunities for Biotechnology Research and Entrepreneurship

Edited by

Sagarika Devi
Guru Nanak College
Velachery, Chennai, Tamil Nadu-600042
India

Gokul Shankar Sabesan
Microbiology Department Preclinical Sciences
Faculty of Medicine Manipal University College
Melaka
Malaysia

&

Sultan Ahmed Ismail
Department of Biotechnology
The New College
Chennai- 600014, Tamil Nadu
India

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Editors: Sagarika Devi, Gokul Shankar Sabesan and Sultan Ahmed Ismail

ISBN (Online): 978-981-5196-11-5

ISBN (Print): 978-981-5196-12-2

ISBN (Paperback): 978-981-5196-13-9

First published in 2024.

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FOREWORD

As a teacher, researcher, and administrator in the field of Biotechnology for the past four decades, it gives me immense pleasure to write a foreword to the book entitled ‘Opportunities for Biotechnology Research and Entrepreneurship’. Biotechnology as a Science has improved employability by combining applied scientific research with business, enterprise, and entrepreneurial skills. Though there are several books in the field of Biotechnology, it is important to capture the link between applied research and entrepreneurship. This book edited by Dr. Sagarika Devi, Prof. Gokul Shankar Sabesan and Prof. Sultan Ahmed Ismail and Published by Bentham Science Publishers is an attempt to develop a solid understanding of science, technology in the business management. Applied and innovative approaches in biotechnology coupled with the entrepreneurship can provide more career and business opportunities in future which is a boon in the era where unemployment problem is of major concern.

The book has 15 chapters and mainly focuses on niche areas of food sciences, medicine, industrial and environmental biotechnology and is authored by global authors representing different countries like India, Vietnam, Thailand and Malaysia. This is Part-1 of the multi series volume. The multi-disciplinary approach of merging diversified areas of Biotechnology in-to one book volume is an appreciable attempt that would help to bring creative ideas in cross-over research and pave the way for new start-ups.

The innovative information and concepts given in the book would not only add value to the existing knowledge but also provide ideas to students, researchers, scientists, entrepreneurs, and policy makers in the area of applied and industrial biotechnology. I congratulate the authors and editors for bringing out this volume with meticulous commitment and amazing teamwork.

K.R.S SAMBASIVA RAO
Mangalayatan University, Jabalpur
Mizoram University
Madhya Pradesh 481662, India

PREFACE

Il n’y a pas des sciences appliquees ´ ... mais il y’a des applications de la science. (There are no applied sciences... but there are the applications of science.) – Louis Pasteur

Opportunities for Biotechnology Research and Entrepreneurship is a culmination of the efforts and vast knowledge of eminent scientists around the globe in different frontiers of biotechnology. The book intends to sheds light and convey recent progress in advancements of scientific knowledge and significant transformations to improve the environment, human health and sustainable industrial applications. Catering to the needs of graduates, postgraduates, scientists, and entrepreneurs in multidisciplines of life sciences, the book contains a series of chapters on new trends in biotechnological applications with specific references to the future prospects for related technologies. We hope that both scientists and non-scientists will find this book a useful source of information. Although a strong technical background may be necessary to assimilate the fine points described herein, we have tried to make the fundamental concepts and issues accessible to readers whose background in life sciences is quite modest. The attempt is vital, for only an informed public can distinguish desirable biotechnological options from the undesirable ones, and those likely to succeed from those likely to result in costly failure.

We extend our sincere gratitude and appreciation to all contributing authors of this book who helped us tremendously through their insightful contributions to put together this peer-reviewed edited volume. We thank the editing and publishing team at Bentham Books, for their generous assistance and persistence in finalizing the edited volume. Special thanks are to our families and friends for their support and cooperation in placing everything together.

Sagarika Devi
Guru Nanak College
Velachery, Chennai, Tamil Nadu-600042
India

Gokul Shankar Sabesan
Microbiology Department Preclinical Sciences
Faculty of Medicine Manipal University College
Melaka
Malaysia

&

Sultan Ahmed Ismail
Department of Biotechnology
The New College
Chennai- 600014, Tamil Nadu
India

List of Contributors

Antony V. Samrot	School of Bioscience, Faculty of Medicine, Bioscience and Nursing, MAHSA University-42610, Jenjarom Selangor, Malaysia
Bibin G. Anand	Department of Physiology & Biophysics, Boston University, Boston, MA 02215, USA
Chaleeda Borompichaichartkul	Department of Food Technology, Faculty of Science, Chulalongkorn University Phayathai Road, Patumwan, Bangkok 10330, Thailand
Chidhambara Priya Dharshini K.	Department of Biotechnology, Manonmaniam Sundaranar University, Tirunelveli-627 012, Tamil Nadu, India
Ch. Satyanarayana	MBRC-Zoological Survey of India, 130, Santhome High Road, Chennai–600 028, India
D. Rajalakshmi	Department of Biotechnology, School of Bio and Chemical Engineering, Sathyabama Institute of Science and Technology, Chennai, Tamil Nadu, 600119, India
Duc-Vuong Nguyen	Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam
Gokul Shankar Sabesan	Microbiology Department Preclinical Sciences, Faculty of Medicine, Manipal University College, Melaka, Malaysia
Hoang-Duy Truong	Faculty of Commerce and Tourism, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam
Hannah R. Vasanthi	Natural Products Research Laboratory, Department of Biotechnology, Pondicherry University, Puducherry, 605014, India
Krishnamoorthy Venkateskumar	Department of Pharmaceutical Technology, Faculty of Pharmacy, AIMST University, Bedong, Malaysia
K. Padmakumar	Centre for Marine Biodiversity, University of Kerala, Kariavattom Campus, Thiruvananthapuram-695581, India
Kamini Vijeepallam	Department of Basic Health Sciences, Faculty of Pharmacy, AIMST University, Bedong, Malaysia
Kunal Kishore	Natural Products Research Laboratory, Department of Biotechnology, Pondicherry University, Puducherry, 605014, India
M. Sathiyasree	Department of Biotechnology, School of Bio and Chemical Engineering, Sathyabama Institute of Science and Technology, Chennai, Tamil Nadu, 600119, India
M. Bavanilatha	Department of Biotechnology, School of Bio and Chemical Engineering, Sathyabama Institute of Science and Technology, Chennai, Tamil Nadu, 600119, India
Putthapong Phumsombat	Department of Food Technology, Faculty of Science, Chulalongkorn University Phayathai Road, Patumwan, Bangkok 10330, Thailand School of Food Industry, King Mongkut's Institute of Technology Ladkrabang, Bangkok 10520, Thailand

P. Prakash	Department of Biotechnology, School of Bio and Chemical Engineering, Sathyabama Institute of Science and Technology, Chennai, Tamil Nadu, 600119, India
P. Dhasararthan	Department of Biotechnology, Prathyusha Engineering College, Chennai-602025, India
R. Chandran	Marine National Park, Forest Colony, Jamnagar-Gujarat-361 001, India Centre for Marine Biodiversity, University of Kerala, Kariavattom Campus, Thiruvananthapuram-695581, India General Non-Chordata Section, Zoological Survey of India, FPS Building, Indian Museum Kolkata-700 016, India
R. Senthil Kumaran	Marine National Park, Forest Colony, Jamnagar-Gujarat-361 001, India
Ranjit Singh A. J. A.	Department of Biotechnology, Prathyusha Engineering College, Chennai -602025, India
Raksha Goswami	Natural Products Research Laboratory, Department of Biotechnology, Pondicherry University, Puducherry, 605014, India
Sao-Mai Dam	Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam
S.K. Jasmine Shahina	Department of Microbiology, Justice Basheer Ahmed Sayeed College for Women, Chennai-18, India
Summera Rafiq	Department of Microbiology, Justice Basheer Ahmed Sayeed College for Women, Chennai-18, India
S. Umamaheswari	Department of Biotechnology, Manonmaniam Sundaranar University, Tirunelveli 627012, Tamil Nadu, India
Subramani Parasuraman	Department of Pharmacology, Faculty of Pharmacy, AIMST University, Bedong, Malaysia
Sanjay Preeth R.	Department of Biotechnology, School of Bio and Chemical Engineering, Sathyabama Institute of Science and Technology, Chennai, Tamil Nadu, 600119, India
Saranga Rajesh	Natural Products Research Laboratory, Department of Biotechnology, Pondicherry University, Puducherry, 605014, India
Selva Sudha N.	Natural Products Research Laboratory, Department of Biotechnology, Pondicherry University, Puducherry, 605014, India
Trung-Au Vo	Industrial University of Ho Chi Minh City, Vietnam
Thien-Hoang Ho	Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam
Thanapakiam Ganeson	Department of Pharmaceutical Technology, Faculty of Pharmacy, AIMST University, Bedong, Malaysia

CHAPTER 1

Food Biotechnology – Future Prospective in Food Biotechnology

Antony V. Samrot[1,*], **D. Rajalakshmi**[2] and **M. Bavanilatha**[2]

[1] *School of Bioscience, Faculty of Medicine, Bioscience and Nursing, MAHSA University-42610, Jenjarom Selangor, Malaysia*

[2] *Department of Biotechnology, School of Bio and Chemical Engineering, Sathyabama Institute of Science and Technology, Chennai, Tamil Nadu, 600119-India*

Abstract: The development of biotechnology has led to improvements in the nutritional value and quality of foods consumed by humans, thereby benefiting their health. Globally, foods developed through biotechnology are heavily studied and judged by governments, health authorities, and scientists. By applying food biotechnology, we can reduce the number of naturally occurring poisons and allergies in food. Food biotechnology can be used by farmers and food producers to provide a safe, convenient, and affordable food supply posing new challenges and opportunities for the prevention of disease. It mainly involves the use of genes from plants, microbes, and animals with a view to enhance productivity and nutritional benefits. The interdisciplinary field of food biotechnology employs modern biotechnology principles to produce, process and manufacture foodstuffs. A variety of tools are used in food biotechnology, including traditional breeding methods such as cross-breeding. There are also various modern techniques including genetic engineering which increase the yield. The aim of food biotechnology is to increase the crop yield for the welfare of farmers and to provide nutritional foods for people around the world. There are various concerns associated with the development of food biotechnology. In this paper, the future prospects of food biotechnology are discussed.

Keywords: Agricultural, Food processing, Food biotechnology, Future foods, Food, Fermentation, Genetic engineering, Nanotechnology, Nanocomposites, Production, Shelf life, Yield.

INTRODUCTION

Biotechnology is one of the most promising application domains in the food industry since it allows the creation of new and unique goods [1]. Gene science is being used to develop new products from flora and fauna. In other words, it is a

* **Corresponding author Antony V. Samrot:** School of Bioscience, Faculty of Medicine, Bioscience and Nursing, MAHSA University-42610, Jenjarom Selangor, Malaysia; E-mail: antonysamrot@gmail.com

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scientific approach to create new plants or animals, or innovations with organisms to overproduce any desired products or to improve the quality of the products with some specialised applications [2]. Basically, biotechnology is categorized in two different ways: traditional biotechnology and modern biotechnology. The production of bread, cheese, alcohol, various alcoholic beverages, vinegar, yogurt and other classic biotechnological products are produced through traditional biotechnology whereas modern biotechnology is a field in which biological systems are altered through genetic engineering to produce valuable goods such as human hormones, enzymes, genetically modified foods, insulin and biotech vaccines` [3 - 5]. But both these modern and traditional biotechnology are commercially viable. Genetic engineering is often known as recombinant DNA technology where manipulation of genes is done. The goal of genetic engineering is to add or delete one or more genes in a creature [6], which are called GMOs (genetically modified organisms) having been created to fulfill human needs majorly as food supply [7]. No government allows the export or import of transgenic plants without prior analysis of the consequences caused by the transgenics. Only a few crops and foods have been approved by some nations, while others are still undergoing field testing and marketing challenges. Biotechnology in food has more benefits than drawbacks, it is serving the demands of the growing population by increasing food production. The increased crop yield benefits the farmers and also provides nutrition to people around the world. However, the development of food biotechnology has also raised many concerns.

Impact of Biotechnology on the Food Sector

Food is an imperative link between farmers and supermarkets. A lot of agricultural products are processed after they leave the farm except vegetables and fruits which can be eaten raw. The use of biotechnology can improve the safety of the food supply and nutritional quality at every level of this chain [8, 9]. Using food biotechnology, more food can be grown on less land and it helps to fight world hunger owing to its economic benefits [10]. Biotechnology has been shown to push industrialised countries to achieve maximum growth in the food sector, despite the fact that it is still not widely acknowledged in other countries [11]. To satisfy the world's demand, food production will have to be considerably increased. The potential of biotechnology as a tool to help solve the problem has yet to be completely realised [12]. Less crop yield is widely considered to be the primary cause of food insecurity around the world. People living in developing countries and rural areas tend to be poor and food insecure. Through biotechnology, high-yielding varieties that are resistant to biotic and abiotic stresses can be developed; pest-related losses are reduced, and food nutritional values are improved, which are all vital in rural areas and developing countries

[13]. In order to minimise food insecurity, reducing postharvest waste can be a critical step. Thus, environmental concerns about producing safe foods for human consumption in a sustainable way may need to be addressed [14].

Future Foods

The perishability of agricultural products is a big issue. Various strategies for extending the shelf life of crops, particularly fruits and vegetables, have been launched and developed. Delaying the ripening of fruits and vegetables by modifying genes through genetic engineering is one such successful strategy [15]. There are a variety of applications of these genetically modified plants/organisms (Fig. **1**), some are as described below. Transgenic tomatoes, sometimes referred to as genetically modified tomatoes, contain genes modified through genetic engineering. The first commercially accessible genetically modified product was the Flavr Savr tomato, which has a longer shelf life [16, 17]. Humans require vitamin A for vision, development, reproduction, cellular differentiation and proliferation, and immune system integrity. A lack of vitamin A can cause visual or ocular problems such as night blindness and xerophthalmia [18].

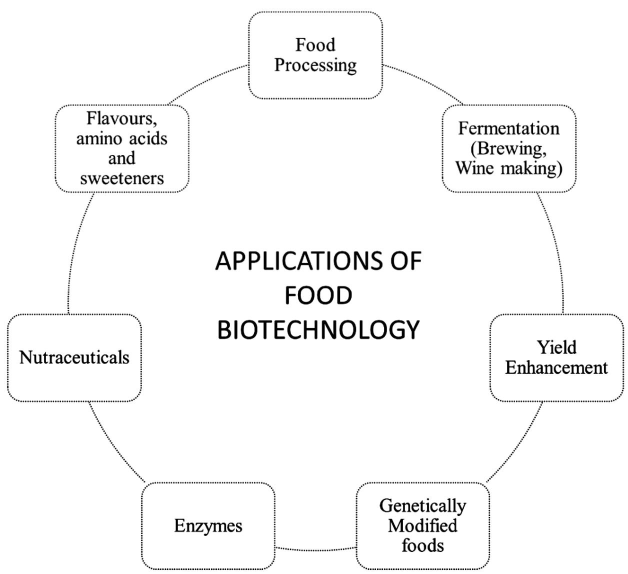

Fig. (1). Schematic representation for application of food biotechnology.

Food Processing

For millennia, bacteria, yeast, and fungi have been employed to make fermented foods [19] and to produce new products or modify existing foods [20]. Applying

CHAPTER 2

Developing Functional Properties of Food Through Biotechnology

Chaleeda Borompichaichartkul[1,*] and **Putthapong Phumsombat**[1,2]

[1] *Department of Food Technology, Faculty of Science, Chulalongkorn University Phayathai Road, Patumwan, Bangkok 10330, Thailand*

[2] *School of Food Industry, King Mongkut's Institute of Technology Ladkrabang, Bangkok 10520, Thailand*

Abstract: Functional foods and ingredients offer health benefits that extend beyond their nutritional value. To develop functional foods, often functional ingredients or supplements are added to create desired properties, especially in the area of health improvement. Many well-known functional ingredients can be obtained from biological processes including probiotics, prebiotics, beta-glucan, enzymes, peptides, antioxidants, medium or short-chain fatty acids, vitamins, *etc.* Therefore, it is necessary to understand the biotechnological process that is used to create high-quality functional ingredients. This chapter gives an overview of functional foods and ingredients in terms of definition, category, biological production, safety, and future functional foods. Functional food can not only prevent nutrient deficiencies but also protect against diseases and promote proper growth and development, as well as enhance health by boosting the intake of important nutrients. Innovations in functional foods and ingredient development would result from understanding more about their biotechnological manufacturing.

Keywords: Biotechnology, Functional food, Functional ingredients, Functional properties, Health.

DEFINITION OF FUNCTIONAL FOODS, BENEFITS AND TRENDS

Functional foods are foods or ingredients that offer health benefits besides their nutritional value. Development of functional foods could contain supplements or other additional ingredients designed to improve health. The concept of functional foods originated in Japan in the 1980s when government agencies started approving foods with proven benefits to the better health of the general population [1]. Some examples include foods fortified with vitamins, minerals, probiotics, or

* **Corresponding author Chaleeda Borompichaichartkul:** Department of Food Technology, Faculty of Science, Chulalongkorn University Phayathai Road, Patumwan, Bangkok 10330, Thailand; Tel: +66(0)22185518, Fax: +66(0)2254 4314; E-mail: Chaleeda.b@chula.ac.th

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fiber. Nutrient-rich ingredients like fruits, vegetables, nuts, seeds, and grains are often considered functional foodsas well. Oats, for instance, contain a type of reduced soluble fiber called beta-glucan, which has been shown to reduce inflammation, enhance immune function, and improve heart health. Similarly, fruits and vegetables are packed with antioxidants, which are beneficial compounds that help protect against diseases. Functional foods are generally separated into two categories: conventional and modified. Conventional functional foods are natural, whole-food ingredients that are rich in important nutrients, for example, vitamins, minerals, antioxidants, and heart-healthy fats. Modified functional foods have been fortified with additional ingredients, such as vitamins, minerals, probiotics, or fiber. These additional ingredients can be obtained from animals or plants by extraction, separation, and purification process. In addition, some useful microorganisms can produce metabolites such as vitamins, oligosaccharides, antioxidants, or micronutrients, which exhibit health benefits as well. The process that utilizes microorganisms is called a biotechnological process. Therefore, by using safe biotechnological processes, it is possible to produce additional functional ingredients like vitamins, probiotics, or fiber for the development of functional foods.

The demand for functional foods is rising. As can be witnessed from the global sales of fortified/functional foods, which reached $292 billion in 2021, up from $274 billion in 2020, per Euromonitor [1]. A Kerry survey of consumers in 16 countries found that 4 in 10 (42%) bought more functional foods in 2021 than in 2020. *Nutrition Business Journal* put U.S. functional food/drink sales at $83 billion in 2021, up 6.8% *versus* 2020 [1]. The reason the demand for functional foods has increased over the years is that consumers have believed in the potential benefits of functional foods. There are several studies that have pointed out the benefits of functional foods such as (1) preventing nutrient deficiencies, (2) protecting against disease, (3) promoting proper growth and development. Consequently, the top 10 functional food trends that are influencing consumer behavior in 2022 are (1) self-defense, (2) fit and ready, (3) sustainably healthy, (4) conditions and connection (5) weighting in (6) plant-based plateau (7) alternatively clean (8) functional cooking (9) mainstream niches (10) inside out [1].

FERMENTATION PROCESS

The functional ingredients produced from microorganisms through a biological process require an understanding of fermentation. The fermentation process is a microorganism-mediated procedure that requires the transformation of large molecules to small ones or molecular oxidation/reduction reactions. Fermentation technology, which ranges from a small experimental scale to a massive manufacturing scale, depends on microbial components and creates a variety of chemicals. Various bioactive compounds are created during this process, which can provide consumers with significant health benefits [2]. In the fermentation process of functional food production, probiotics and lactic acid bacteria (LAB) are the most commonly employed microorganisms, particularly in dairy processing. This microorganism is well-known in the functional food industry since it provides health benefits and is generally regarded as safe (GRAS). Since several countries have traditionally fermented milk products derived from their agricultural source, fermented milk is the greatest example of fermented functional food. Cheese is a popular fermented milk product made mostly by LAB fermentation of milk curd as a main process [3]. In cheesemaking, microorganisms found naturally in raw milk, natural starting cultures, cyclically generated milk or whey cultures, or selected starter cultures can all cause the fermentation process. The cheese starter, whether natural or selected, is in charge of acidification parameters, cheese taste development, and the decrease of unwanted microbes [4]. According to a study [5], the influence of culture on cheese flavor and texture was assessed in Caciotta-type cheeses by comparing the use of various LAB starters. All settings evaluated resulted in proper acidification, with the attenuated adjunct cultures having a superior overall influence on cheese quality. The result is similar to Gouda cheese reported by another study [6]. Due to the large proteolysis and lipolysis effects, the fermentation of a strain of *Lactobacillus paracasei* chosen from raw milk enabled enrichment and uniformity in the flavor range of cheese with a greater volatile component synthesis. In Cheddar cheese production, it was produced with cow or buffalo milk with commercial and indigenous cultures of *Lactococcus lactis* subsp. *lactis* and *Lactococcus lactis* subsp. *cremoris* sensory features were improved in buffalo milk cheese [7]. As a result, the primary components of the cheese fermentation process are the source of milk and the starter.

FUNCTIONAL BIOTECHNOLOGICAL PRODUCTS

This section will give an example of functional food and ingredient products that can be obtained from a biological process. Brief production or involved technology information, key microorganisms, and suitable conditions of production will be presented.

Probiotics

Probiotics were defined as “live microorganisms which when administered in adequate amounts confer a health benefit to the host” [8]. They can be directly used as a fermentative starter in dairy and non-dairy products such as yogurt, kefir, fermented fish, meat, and vegetables. On the other hand, they can be

CHAPTER 3

The Role of Food Biotechnology Industry in Food Security upon Climate Change, and Future Perspective - A Case Study in Vietnam

Sao-Mai Dam[1,*] and **Hoang-Duy Truong**[2]

[1] *Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam*

[2] *Faculty of Commerce and Tourism, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam*

Abstract: The world's population is expected to reach 9.8 billion in 2050. In order to feed the number of people sustainably by 2050, we need to increase 56 percent of crop production. However, the impact of climate change, including temperature increase, changes in rainfall patterns, and outbreaks of pests and diseases, will affect agricultural productivity and the agricultural industry to adapt to changes in technology and demand for food. Biotechnology has been applied in crop production for many years. However, industrial food biotechnology is still neglected. Advances in the food biotechnology industry can lead to cutting-edge technologies in agriculture adapting to climate change while reducing the impact on the climate. This review brings out the role of industrial food biotechnology in improving food quality upon climate change, especially in Vietnam. This also demonstrates industrial food biotechnology as part of the solution to climate change to reduce greenhouse gas emissions; then, we recommended technological progress in industrial food biotechnology with the future vision: Vietnam's green economy.

Keywords: Agricultural, Agriculture, Biotechnology, Climate change, Food security, Food industry, Green technology, Vietnam.

INTRODUCTION

The world's population is expected to reach 10 billion in 2050. In order to feed the number of people sustainably by 2050, we need to increase 56 percent of crop production. However, climate change has been demonstrated to impact food security globally, negatively, and at local levels [1, 2].

* **Corresponding author Sao-Mai Dam:** Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam; Tel: +84 988 541 415; Fax: +84 283 9940 954; E-mail: damsaomai@iuh.edu.vn

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Since 1850, each of the past four decades has been warmer than any preceding decade. Since 1970, global surface temperatures have increased faster than in any other 50-year period in the last 2000 years. From 1850-1900 to 2001-2020, the average global surface temperature has increased by 0.99 (0.84-1.10)°C. Observational data shows that depending on the continental regions, in the twelve years 1995-2006, there were 11 years (except 1996) with the highest temperature; and the hottest years were 1998 and 2005 [3]. In the ten years 2011-2020, the average global surface temperature was 1.09 (0.95 to 1.20) °C, higher than the relative mean temperature from 1850 to 1900 [4].

Extreme temperatures also tend to match average temperatures, leading to a decrease in the number of cold nights, an increase in the number of hot days, and a decrease in the day temperature range by about 0.07°C per decade. Sea surface temperatures have also tended to increase markedly since the beginning of the 20th century across the oceans. However, the warming rate on land was higher than in the ocean. The increase in temperature on land was (1.59 [1.34 to 1.83] °C), which is greater than over the ocean (0.88 [0.68 to 1.01]°C) from 2011 to 2020. Global warming has caused changes in the land biosphere since 1970 in both hemispheres [4].

The main causes of sea-level rise are rising global surface temperatures, the melting of ice caps, and ice sheets in the earth's polar regions. The rate of sea-level rise since the mid-19th century has been greater than the average rate of sea-level rise for the previous two thousand years. The global mean sea level increased by 0.20 (0.15 to 0.25) m from 1901 to 2018. The average sea level rise rate is 1.3 (0.6 to 2.1) mm /year from 1901 to 1971, which increased to 1.9 (0.8 to 2.9) mm/year from 1971 to 2006, and continued to increase to 3.7 (3.2 to 4.2) mm/year from 2006 to 2018 [4]. Human influence has been the main driver of this increase since at least 1971. Rising sea levels have caused many areas to become saline, and the structure of crops has changed.

Event distribution studies and physics indicate that anthropogenic climate change increases tropical cyclone-associated heavy rainfall. In addition, human influence has increased the likelihood of extreme compound events since the 1950s. Climate change also includes increasing the frequency of simultaneous global heatwaves and droughts; high drought and fire weather in some areas of all inhabited continents; and flooding in some locations [4].

Vietnam is one of the countries most affected by extreme weather events [5]. In the world, Vietnam ranked 8th in population exposure to extreme weather events from 1996 to 2015. Vietnam also is the fourth in a proportion of the population exposed to the risk of river inundation. From 2007 to 2011, on average, 430 people died from natural disasters every year; economic losses are expected to equal 1% of GDP in the same period [6]. It is not a new phenomenon: the average annual loss in 2005-2010 was 460 deaths, 908 injuries, 32,689 homes destroyed, and an estimated annual economic loss of nearly 1 billion. USD. From 1989 to 2016, storms and floods claimed the lives of nearly 15,000 people and injured nearly 17,000. Damage to homes, infrastructure, and economic activities was also severe.

The pattern of storms, floods, and other climate disasters varies widely in different parts of the country. People living in low-lying areas near rivers such as plains and coastal plains are used to the annual flood season and consider it a part of their life. Consequently, they have adjusted their production system to adapt. However, together with changes in flood duration and intensity, changes such as the loss of mangroves are increasing the environmental impact of storms, floods, saltwater intrusion, sea-level rise, and overexploitation of groundwater also impacts climate change. Many mountainous and highland areas in the North and Central regions of Vietnam are vulnerable to flash floods and landslides. For example, flash floods in the Central Highlands region claimed the lives of more than 730 people in 1999; 58 people died from flash floods in Binh Dinh and Quang Ngai provinces in 2003, and 38 people were dead or missing, many houses and roads were destroyed in the northern mountainous areas after flash floods and landslides in July 2009. There have been many similar events in recent years, such as flash floods in the northern mountainous region that claimed the lives of at least 27 people and caused much damage to houses and infrastructure in August 2017; similar to the years 2016, 2015, and most of the previous year's [7, 8].

Flash floods in mountainous areas occur quite often but do not always cause severe storms and floods. Vietnam, almost every year, has to face tornadoes. From 1961 to 2014, 295 significant storms (category 6 to 12) occurred in Vietnam [9]. The frequency increased, with an average of 5 storms/year from 1961 to 1999. However, the total number has increased to 7 storms a year since 2000.

In 2004, Reuters news agency wrote, "Floods and landslides have claimed the lives of at least 40 Vietnamese people and 42 others are missing. Flooding caused by heavy rains from Typhoon Muifa last week inundated 170,000 homes in five provinces, destroyed roads, and hindered food supplies to many areas. Thousands of people have been displaced and an official said 270,000 people in one of the affected provinces need urgent assistance" (Reuters November 29, 2004). Similar storms and floods occur almost every year in the coastal areas of Vietnam, especially in the vulnerable central coastal provinces [7, 8].

CHAPTER 4

Potential and Challenges of Applied Biotechnology in Mushroom Bio-based Products in the Food Industry

Trung-Au Vo[1], **Thien-Hoang Ho**[2] and **Sao-Mai Dam**[2,*]

[1] *Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam*

[2] *Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam*

Abstract: Mushrooms are popular because of their high nutritional value. Biotechnology provides powerful tools for the sustainable development of mushrooms. Many advances in the non-meat-based food industry represent the significant role of mushroom biotechnology. Mushrooms are a rich source of proteins and have low or zero fat and cholesterol. In addition, some mushrooms are a source of bioactive compounds. Therefore, mushroom-based products have become widely accepted foods worldwide. The new techniques used to meet the consumer requirements of the mushroom increase the quality and convenience to use new product development. Technological developments have generally witnessed increasing crop production capacities in cultivation technologies. Besides that, new mushroom-based food products are developing; and the production techniques are innovated to improve the quality of final mushroom-based goods. The mushroom-based products are mainly produced as a result of contributions from mushroom cultivation in developing countries such as China, Europe, India, USA, and Vietnam. The challenge is finding opportunities to increase mushroom and mushroom-based product consumption capabilities with increasing world population and non-meat-based food consumption. This chapter reviews the recent advances and challenges for sustainable production of mushroom-based products as a non-meat food source in the food industry.

Keywords: Bioactive, Food industry, Nutrients, Non-meat based, Mushrooms.

INTRODUCTION

Mushrooms have long been known as exceptional food and are macrofungal; it plays an essential role in modern life today. There are about 22,000 species found and identified, of which about 2000 species are safe for consumption, and more than 700 species have been known to possess pharmacological properties [1].

* **Corresponding author Sao-Mai Dam:** Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam; Tel: +84 988 541 415; Fax: +84 283 9940 954; E-mail: damsaomai@iuh.edu.vn

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Mushrooms are grown mainly in Asian, Northern, and Central American countries with China and India as top cultivators [2].

Edible mushroom is an essential food in the world after meat and vegetable. Mushrooms were arranged in a group of plants or meat, but they stayed in the separating group [3]. According to FAOSTAT (2018) data, the total world production of mushrooms and truffles was near 9 million tons. The total area harvested was near 68 thousand hectares (ha) in China with 6.67 million tons, 21 thousand hectares of area harvested in Europe with 1.3 million tons, 45 thousand ha, and USA with 416 million tons [4]. Technology makes mushroom cultivation active and cultivable all over the world. So far, there are five main types of mushrooms grown and account for 85% of the world's mushroom production, including species or genera: *Agaricus bisporus* contributes about *30%, Pleurotus sp. (27%), Lentinula edodes (17%), Auricularia (6%),* and *Flammulia (5%)* [5].

Edible mushrooms have many medicinal properties that promote health. Some studies show that medicinal substances from mushrooms play an essential role in treating some diseases, such as: preventing cancer, anti-aging, regulating the digestive system, and strengthening immunity [6 - 9].

The mushrooms are fast-growing and can be harvested in the form of fruiting bodies or mycelium finding their way in pharmaceuticals (for their medicinal properties and in functional food industry (as an abundant source of nutrients). From previous studies (Table **2**) it is evident that mushrooms have a very high nutritional content, including group vitamins B, D, and E, minerals, proteins, and amino acids. In addition, mushrooms also contain active ingredients that are good for health, such as β-glucans, Glucan, Ganoderic acids, Lentinan, Cordycepin, and polysaccharides [10]. The main medicinal properties ascribed to mushrooms include antibiotic, antitumor, antiviral, immunostimulant, and hypolipidemic activities [11]. In addition, several researchers have explored that the isolated compounds and mushroom extracts may contain anti-elastase, anti-collagenase, anti-hyaluronidase, and anti-tyrosinase activities [12, 13].

Mushrooms are considered a functional food and a source of nutraceuticals because of their bioactive and nutraceutical compounds. These compounds have beneficial effects on human health [3]. However, mushrooms are easily susceptible to weight loss, mechanical damage, and enzymatic browning. In addition, high moisture content, high respiratory rate, and high nutrient contents generate mushrooms' rapid loss of quality if the post-harvest stage is not sound. For example, the shelf life of *Pleurotus ostreatus* and *Agaricus bisporus* mushrooms is from one to three days at 20-25ºC temperature and up to five to seven days under a refrigeration [14]. However, the post-harvest shelf life of *Lentinula edodes* mushrooms is three days at 20-25ºC and three to five days at 40ºC. Differences in the higher respiration rate between mushroom species, and greater perishability occur causing differences in their shelf life [14].

Nowadays, post-harvest technology and modern processing technology are applied in preserving and processing mushrooms. Many products have been developed from mushrooms. New processing methods such as drying, canning, pickling, freezing, and sterilization are applied. Food technology produces new products based on mushrooms combined with meat, tea, bread, cake, and biscuits. Mushrooms are also used in cosmetics, pharmaceutical, and aquaculture industries [15].

Moreover, mushroom products not only have become important in the world diet but also, can be used to replace some types of meat because of its nutritional content, and helping to reduce the harmful effects of animal meat. The substrate or compost used in mushroom cultivation also can be used to produce compost to reduce agricultural waste [16].

This chapter summarizes relevant studies about mushroom-based products and their bioactive properties in the food industry and other industries.

MUSHROOM PROPERTIES

Nutritional Value

Edible mushrooms contain a lot of nutrients and play an important role in the human diet today, the nutrients source can be detected in the body and cap fruit, such as proteins, carbohydrates, fats, minerals, and vitamins [17, 18]. In addition, the previous research found that polysaccharides such as β-glucans, monosaccharides, disaccharides, proteins and peptides, phenolic acids such as chrysin, naringenin, myricetin, quercetin, rutin, p-coumaric, cinnamic, ferulic, corgallic, protocatechuic, and others and have been demonstrated [19].

Several works evidenced that using mushrooms comprises a low-calorie diet. About 1 kg of fresh mushrooms can supply around 250-350 calories [20]. Some results of previous research from 1972 to 2005 are depicted in Table **1**. Mushrooms have three main macronutrients: 50-65% total carbohydrates, 19-35% proteins, and 2-6% fats [21]. *Auricularia auricula* has a high content of carbohydrates with 82.8g/100g, then *Flammulina velutipe*s with 73.1 g/100g, and *Calocybe indica* and *Pleurotus sajor - caju* with 64.26/100g, and 63.4/100g respectively. Nevertheless, their calorie was different, the highest in *Agaricus*

CHAPTER 5

Potential and Challenges of Applied Biotechnology in Aquatic Products Production - A Case Study in Vietnam

Sao-Mai Dam[1,*], **Duc-Vuong Nguyen**[1] and **Hoang-Duy Truong**[2]

[1] *Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam*

[2] *Faculty of Commerce and Tourism, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam*

Abstract: Biotechnology is making essential contributions and poses significant challenges to aquaculture and fisheries' new product development via enhancing taste, shell life, nutrition, and quality and reducing waste. Aquatic products biotechnology might be regarded as reliable for enhancing and expanding the production and processing of sustainable food products created for the future of the expanding global population. Aquatic product biotechnology consists of (1) new technological applications in aquatic farming to improve productivity and feed utilization, (2) commercial packaging technology for preservation, and (3) effective use of by-products or wastes and the process of product innovation. Some insights into the biotechnological development of aquatics production in Vietnam are reviewed in this chapter.

Keywords: Aquaculture, Aquatic farming, Aquatic product, Biotechnology, By-products, Fisheries, Nutrients, Packaging, Vietnam.

INTRODUCTION

In 2050, it's predicted that there will be 10 billion people on the planet. In order to sustainably feed the world's population, we must increase food production by 56% by 2050. However, climate change has been demonstrated to impact food security globally, negatively, and at local levels [1, 2].

The Mekong Delta produces 50% of Vietnam's seafood and contributes significantly to the country's total exports. Therefore, the fisheries industry is

* **Corresponding author Sao-Mai Dam:** Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam; Tel: +84 988 541 415; Fax: +84 283 9940 954; E-mail: damsaomai@iuh.edu.vn

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considered a key economic sector of the provinces, especially the southern provinces of Vietnam.

The seafood processing industry is becoming one of the critical economic sectors, leading to international economic integration. In Vietnam, fisheries contribute 3.4% of the national GDP and 24.4% of the agricultural GDP making positive contributions to agricultural and rural economic restructuring that makes an essential contribution to national security protection.

According to the report of the Directorate of Fisheries, it was estimated that in 2021, the growth rate of aquaculture production value reached 3.01% compared to 2020; total production will reach 8.73 million tons, an increase of 1.04% compared to 2020 (8.64 million tons), and 7.12% compared to 2019 (8.15 tons). The exploitation output reached 3.92 million tons, leading by 1.03% compared to 2020 (3.88 million tons), and aquaculture reached 4.8 million tons, leading by 0.84% compared to 2020 (4.76 million tons) [3, 4].

Seafood export turnover in 2021 was estimated at 8.89 billion USD, increased by 5.71% over the same period in 2020 (8.41 billion USD), and by 3.37% compared to 2019 ($8.6 billion). In 2021, export turnover was expected to reach 104.59% of Vietnam's expected target ($8.5 billion). With the inclusion of fishmeal and aqua feed (US$685.2 million), the total seafood export value in 2021 reached US$9.57 billion, equaling 107.65% compared to 2020 (8.89 billion total) USD) [3, 4].

According to the Vietnam Association of Seafood Exporters and Producers, in 2021, the export seafood industry has experienced ups and downs because of the Covid-19 epidemic. In the first half of the year, seafood exports were quite good, thanks to the recovery of the market and stable domestic production. However, in the third quarter of 2021, seafood production and export came to a standstill because of social distancing and the “3-on-the-spot” production regulation to control the Covid-19 epidemic. From the beginning of October, Resolution 128/NQ-CP dated October 11, 2021, of the Government with an adaptive and flexible anti-epidemic policy, has brought a new breath of life, helping seafood production and export recover [3].

In addition, when the fishery industry has achieved the planned targets for 2021, the total output of the fishery industry has increased but has not yet reached the set target. With catches continuing to increase, although there is no increase in the number of fishing boats, this made it more challenging to achieve the “Fishery Development Strategy” target. (The goal of the “Fishery development strategy” is: to gradually reduce the number of unsafe fishing vessels and the quantity of aquatics; to increase the quality of the fishing process).

On the other hand, due to the impact of the Covid-19 epidemic, the inspection of the fishery's legal regulations' accomplishment and the local fishers' training have not been implemented to ensure the plan. Furthermore, the monitoring and synthesis of the local production situation are not timely due to the incomplete software system and the incomplete and timely updating and reporting of the localities. As a result, product preservation has not improved, and the efficiency of exploitation is relatively low.

However, Vietnamese seafood processing companies also face increasingly strict technical barriers regarding food safety, traceability, sustainable development factors and anti-dumping lawsuits (typically the case of pangasius, basa and shrimp). Moreover, the shortage of high-quality labor in fishing and aquaculture has been common in many localities. In addition, the European Commission keeps a warning for Vietnam's seafood, causing difficulties for seafood exports to the EU market.

Although Vietnam's seafood exports have achieved remarkable achievements in the world market, there are still many limitations compared to the products of other prominent seafood exporting countries such as the EU, China, Norway, Thailand, *etc*. There are few convenient items, poor design and packaging, no market development strategy for essential products, and no mighty brand name for processed seafood products. Moreover, the technology for high-end processing products has not been developed.

Besides, domestic seafood processing mainly focuses on serving food processing. Meanwhile, the development potential in medicine and some other fields has not been exploited. Moreover, the application of science and technology in fishing and aquaculture has not been potent, so it has not contributed to improving the value of products.

To solve these problems, the application of scientific and technological achievements, especially biotechnology, is the optimal solution toward the goal of sustainable and comprehensive development for the seafood processing industry.

Currently, there are many applications of microbial technology, such as the production of microbial biomass, production of microbial metabolites, production of microbial enzymes, and production of recombinant products.

In recent years, Vietnamese scientists have closely followed the need for technology development in aquafeed nutrition, farming techniques, product preservation techniques, and seafood processing technologies. At the same time, it is necessary to coordinate with manufacturers and businesses to produce many new products.

CHAPTER 6

Potential and Challenges of Applied Biotechnology in the Plant-Based Food Industry

Duc-Vuong Nguyen[1] and **Sao-Mai Dam**[1,*]

[1] *Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam*

Abstract: Recently, many advances in plant-based food biotechnology are a wide-ranging science that uses modern technologies to produce food products. Biotechnologists and food scientists' new instruments, methods, industry, and products enhance taste, shell life, nutrition, and food quality. Food biotechnology is as ancient as civilization, *via* fermentation, to produce food products such as beer, wine, vinegar, sauce, fermented vegetables, *etc.* Besides that, genetically modified (GM) yeasts and bacteria are used to enhance the products' quality and produce enzymes for improving the quality of plant-based food products. This chapter summarizes the roles and some of the applications of biotechnology in plant-based food processing and food preservation.

Keywords: Biotechnology, Enzyme, Fermentation, Food processing, Plant-based food.

INTRODUCTION

In food processing technology, research and development of food products is a strategic activity, promoting the development of the food industry and related sciences to provide high-quality food products. It results in meeting the growing consumers' needs and bringing further benefits to people and society, further improving the quality of life, and meeting the needs and changes in human needs. The development of plant-based foods has been studied and applied for a long time and until now continues to receive more attention from scientists and experts. The cause belongs to nature, nutrition, function, harmony with tastes, and meeting the needs of consumers. In essence, plant-based agriculture and food industry are sectors of the economy that create surplus value through high use-value products that directly meet consumer demands. Therefore, plant-based foods and food ingredients play an important role when considering agro-food. Besides products

[*] **Corresponding author Sao-Mai Dam:** Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam; Tel: +84 988 541 415; Fax: +84 283 9940 954; E-mail: damsaomai@iuh.edu.vn

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from animals and microorganisms, plant-based food products are increasingly receiving consumer attention. Applying biotechnology, such as a microbial and enzymatic method in food processing technology helps increase efficiency, reduce raw material and production costs, and competitive product prices. Simultaneously, with biotechnology, food product quality is stable and developed to meet consumer demand. Many new and valuable products protecting consumers' health are developed from available raw materials or even by-products of the traditional food processing industry.

This chapter presents scientific publications and implementation results in the plant-based food processing industry based on microbial and enzyme technology. The main content includes the following sections:

- Research and development of food materials from plants and agricultural products.
- Research and development of plant-based food products.
- Some related case studies in Vietnam.

RESEARCH AND DEVELOPMENT OF PLANT-BASED FOOD MATERIALS

Raw materials play an essential role in food products' composition and quality in production and processing. Therefore, materials studies are essential both in basic research and applied research. With the development of science, technology, and engineering, scientists and production experts have published valuable results in raw materials research on food from agricultural products with people's increasing needs. The food materials studied and used can be obtained directly from agricultural products and plants, or combined with some changes in composition to enhance the superior properties of that material. Plant materials have significant applications in food processing technology, as starch, vegetable oils, proteins, bioactive compounds, antioxidants, antibacterial, anti-inflammatory agents, *etc.* For example, starch materials can be extracted from plants or fruits such as wheat, rice, cassava, corn, potatoes, sweet potatoes, sake, bananas, *etc.* Of course, starches' structure and technical properties vary depending on the source of origin. However, after being obtained, the starch can be modified by suitable techniques to create modified starch with different properties, for example, resistant starch.

Starch

Starches are the third most abundant natural polymer after cellulose and lignin [1]. Starch is a polysaccharide of glucose through linkages α-1-4 and α-1-6. Starch exists in the granules where carbohydrates are stored in an insoluble and tightly packed form and are composed of two types of chains, amylose and amylopectin [2]. Starch exists in various forms of cereal grains (wheat, rice, maize, *etc.*) or endosperms of legumes, tubers (cassava, potatoes, sweet potatoes, *etc.*), unripe fruit (bananas, mangoes, *etc.*), and many other storage organs of plants. Starches range in size from 1 to 100 μm and vary in shape (circle, oval, lenticular, and angular) depending on the plant origin. Starches can be classified *via* physicochemical properties or origin. They also can be classified on their ability to interact with enzymes and degree of digestibility. In this way, starch can be divided into three categories: Rapid Digestion Starch (RDS), Slow Digestion Starch (SDS), and Resistant Starch (RS) [3]. RDS is found mainly in starchy foods cooked with moist heat. RDS is strongly correlated with the glycemic index based on postprandial glycemic response [4]. SDS is a starch that takes a long time to digest and is completely digested in the small intestine. SDS is starch with an amorphous physical structure inaccessible to digestive enzymes. Food rich in SDS is beneficial because it delays the onset of metabolic syndrome, diabetes, and cardiovascular diseases in humans [5]. In an *in vivo* trial study, Englyst H.N *et al.* (1992) showed that cereal starch, such as corn starch, is a material rich in SDS. After eating, there is a slow release of glucose. SDS can be enriched by altering the starch molecules' molecular structure, including denaturing starch with 1-octenyl succinic anhydride (OSA), forming cross-linked starches, and modified starches α-1.6 by the enzyme [6].

The term “Resistant Starch” (RS) was coined by Englyst H.N *et al.* (1992) to describe a small fraction of starch resistant to hydrolysis by α-amylase and *in vitro* treatment with pullulanase. Compared with RDS and SDS, RS is not hydrolyzed to glucose in the small intestine within 120hrs after ingestion but is fermented in the colon. RS is a linear molecule of α-1-4 D-glucan derived primarily from the degraded amylose chain. In general, the RS composition of starch granules is positively correlated with amylose content. Nevertheless, there are exceptions, such as pea starch, where the amylose content is moderate, but the RS component is very high.

Amylose has unique functional and nutritional properties. Thus, amylose-rich starchy crops such as potatoes, barley, and high-amylose wheat are developed [7]. The unripen banana powder is a rich source of RS, 78% α-glucans from undigested green banana starch in the small intestine [8]. High-interest trends are perspectives on nutrition and consumer health, research and development of low-carbohydrate food ingredients and products, and increasing RS ratio. Researchers and manufacturers have gathered to find the source of RS-rich materials and their applications. The mobility of this starch in the small intestine for a long time helps delay hunger in people with diabetes. It produces a large amount of stool in the large intestine, which will help people reduce the diseases often present in the

CHAPTER 7

Potential and Challenges of Microalgae Peptides- An Overview

Thien-Hoang Ho[1] and **Sao-Mai Dam**[1,*]

[1] *Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam*

Abstract: Microalgae technology has made significant advances in recent decades. Initially, Microalgae attracted the interest and attention of the scientific community as a renewable resource for biofuels. Besides, it also has the potential to accumulate lipids and biomass significantly in a short period. Recent studies have shown that microalgae's bioactive peptide could be well-suited with great potential in human nutritional support. Therefore, a bioactive peptide derived from various strains of microalgae could be a potentially significant source for developing novel nutraceuticals and functional foods that can reduce the risk of cardiovascular disease, cancer, and arteriosclerosis. The bioactive peptide has also been used in anti-wrinkle and anti-aging skincare products, where it serves to stimulate the creation of proteins in the skin. Although some microalgae have reported antimicrobial and antivirus peptides, the understanding of peptides with these properties is still unclear and not described. Interest in microalgae-derived peptides is overgrowing. This review highlights and discusses the cutting-edge features of their research and applications to develop new therapeutic drugs, cosmetics, and other valuable products. It is also exploring the technology for microalgae peptide extraction and purification.

Keywords: Antioxidant, Anti-inflammatory, Anti-diabetes, Anti-cancer, Antimicrobial, Bioactive peptides, Microalgae.

INTRODUCTION

Microalgae are single-celled organisms that can be grown in large quantities in aquatic habitats using sunlight and carbon dioxide as their primary energy sources. They also are renewable sources with a vast and diverse range of species and belong to a sizeable polyphyletic group, including prokaryotic (Monera) and eukaryotic algae (Protista). These algae are divided into "microalgae" and "macroalgae" based on their pigments, shape, cell wall, cellular division, and str-

* **Corresponding author Sao-Mai Dam:** Institute of Biotechnology and Food Technology, Industrial University of Ho Chi Minh City, Thành phố Hồ Chí Minh, Vietnam; Tel: +84 988 541 415; Fax: +84 283 9940 954;
E-mail: damsaomai@iuh.edu.vn

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uctural organization. Macroalgae (seaweeds) are multi-cellular macroscopic nonvascular plants that multiply; contain chlorophyll pigment, with lengths of up to 60 meters. Microalgae are split into three groups based on their chlorophyll pigmentation: Chlorophyceae, Rhodophyceae, and Phaeophyceae; unicellular forms are called microalgae [1]. Microalgae, unlike macroalgae, are microscopic unicellular creatures that are invisible to the naked eye. Microalgae can be found in both terrestrial and aquatic environments [2]. Microalgae require sunshine, atmospheric CO_2, and minerals to create biomass, biofuels, food feed, and bioactive components due to their rapid growth. In addition, algae can take up nutrients from their environments, which can be inorganic, such as iron, or organic such as nitrogen. So that it can be applied in pharmaceuticals, nutraceuticals, cosmeceuticals, biofuels, and pollution control for wastewater treatment, food additives, and aquaculture [3 - 6]. Compared to standard food proteins *(e.g*., fish, egg, and soybeans) the microalgal biomass produced competes in quantity and quality and is a significant food protein source [7, 8].

The benefits of microalgae are many and varied. The most obvious benefit is that they are a great source of protein, containing all nine essential amino acids in the proper proportions for human nutrition. Microalgae can be used to supplement any diet or provide an excellent vegetarian alternative to a meat-based diet [9]. Protein hydrolysates from microalgae are an excellent source of nutritional quality and are available at affordable costs. Several microalgae species are notable as proteins, hydrolyzed proteins, or peptides that are significantly involved in biological functions and are rich in nutrients. These benefits have been demonstrated by numerous studies conducted on animals and humans. They have been significant in antioxidant [10], antihypertensive [11], immune-modulatory anti-cancer [12], hepatoprotective, anti-atherosclerotic anti-coagulant, anti-UV radiation, anti-osteoporosis, and antimicrobial activities [13]. Microalgae create about 7000 tons of dry matter per year. Notably, *Chlorella* sp. has been used in many countries as a source of nutrition and medicine. *Chlorella vulgaris* is the most widespread and commonly utilized industrial species, with a high protein and essential amino acids including lysine, tryptophan, and tyrosine. Currently, the production of cultivated algae in large quantities includes *Arthrrospira* spp (world annual production amounts to 5000 tons of DW), *Nannochloropsis* spp, and *Haematococcus pluvialis* [14, 15]. However, despite these benefits, a peptide from microalgae is still not widely consumed due to several challenges associated with its production.

The first challenge is harvesting. Currently, microalgae are harvested *via* filtration, centrifugation, or flocculation. These methods require large volumes of water and result in significant losses of biomass. Another challenge is the cost of producing microalgae. Current cultivation systems require large land areas, sophisticated equipment, and highly skilled labor.

Furthermore, the current method of extracting microalgae peptides from the cells requires harsh chemicals, which may damage the product's nutritional value. Finally, understanding novel bioactive peptides from microalgae is still limited and undiscovered. Nowadays, the isolation of these microalgae bioactive peptides is in high demand [16]. Although many challenges remain before microalgae can become a viable option for human consumption, researchers believe that this technology holds promise for the future of agriculture.

Extraction and Purification of Microalgae Bioactive Peptide

Microalgae bioactive peptides have a chain length of 2–20 amino acids with mass values less than 10-KDa and behave similar to hormones released from the parent substance, which have positive qualities [17]. Chemical residues have become more critical because of their positive effects on human health and biological activity. Microalgae-derived biologically active peptides are less well-known as functional components [15, 18, 19]. Depending on the microalgae and target protein properties based on amino acid sequencing, the method of extraction and purification techniques will vary (Fig. **1**). Bioactive peptides are produced using three distinct strategies: chemical solvent extraction, enzymatic protein breakdown, and microbial fermentation. Several technologies support more efficient bio-peptide extraction, including ultrasound or microwave-assisted extraction [17, 20]. However, effective extraction of a bioactive peptide is not easy; predicted chemical residues are lost. In addition, the new technology is challenging to implement on a large scale and industrial scale. So, in the biopharmaceutical and food product industries, enzymatic hydrolysis is the most widely used procedure [21, 22]. Enzymatic hydrolysis is the non-thermal extraction method that uses enzymes and “green technologies” to improve extraction efficiency and reduce the impact on the environment. Following the enzymatic extraction process, the peptide fractions will be extracted and isolated based on many extraction methods, including membrane ultra-filtration with pore sizes ranging from 3, 5, 10, and 30 KDa, as well as chromatography techniques such as size exclusion, ion-exchange, and affinity [23, 24]. LC-MS and LC-MS/MS spectrometry investigate the structural characteristics and mass determination of microalgae peptides.

The subcritical water extraction process is also another technique to assist extraction. The originality of this subcritical water extraction (SWE) or pressurized liquid extraction (PHE) technology is that it is a simple step process primarily employed in the food business to produce various bioactive peptides that boost human health function. SWE is a simple, eco-friendly, and high-energy

CHAPTER 8

Bioremedial Approach to the Mitigation of Environmental Pollution

S. K. Jasmine Shahina[1,*] and **Summera Rafiq**[1]

[1] *Department of Microbiology, Justice Basheer Ahmed Sayeed College for Women, Chennai-18, India*

Abstract: Anthropogenic events have caused environment all around the world to deteriorate, rendering them unsuited for the existence of indigenous biological species. Over the last few decades, environmental contamination seems to have been a prominent subject of concern, affecting the wellbeing of people. The environments have been gravely damaged by excessive industrialization, inappropriate farming techniques, and unregulated release of contaminants into soil and aquatic bodies. As a result, there has been poor utilization of natural resources, increase in deforestation, a decline of flora and fauna, drinking water scarcity, and significant economic losses which are challenging. The need to develop innovative, eco-friendly, low-cost, and much more effective environmental remediation technologies emerged as a result of environmental pollution. Microbes are well recognised for their propensity to degrade and absorb a broad range of organic chemicals and are now utilized to clean up environmental pollution through the process of 'bioremediation'. The bioremediation process involves a variety of microorganisms that help in degradation, eradication, immobilization, or detoxification of different chemical pollutants from the environment. Bioremediation methods are widely used and are still increasing at an enormous speed nowadays. Entrepreneurship can be developed by commercializing bioremediation in saving the environment.

Keywords: Biopile, Bioslurping, Biosparging, Bioventing, Entrepreneurship, Environmental pollution, Nano bioremediation, Polychlorinated biphenyls, Soil vapour extraction, Sustainability, Windrows.

INTRODUCTION

Pollution is caused when harmful substances are introduced into the environment causing disruption in the ecosystem. Pollution can be in the form of any substance (solid, liquid, or gas), or it might be in the form of energy (similar as radioactivity, heat, sound, or light). Adulterants are either foreign substances/ influences or nat-

* **Corresponding author S. K. Jasmine Shahina:** Department of Microbiology, Justice Basheer Ahmed Sayeed College for Women, Chennai-18, India; Tel: +919381981919; E-mail: jasmine.shahina@gmail.com

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urally being adulterants that contribute to pollution. Although natural measures can induce pollution, the term pollution generally refers to defilement that has an anthropogenic source - that is, a source that was created by mortal action [1, 2]. Mortal conditioning contaminates the water we drink, the air we breathe, and the soil in which vegetation grows, all of which have an adverse impact on the ecosystem. Although the artificial revolution was a huge success in terms of technology, society, and the provision of a wide range of services, it also resulted in the release of substantial amounts of adulterants into the air that are dangerous to human health. Without a hesitancy, global environmental declination is seen as a multifaceted transnational public health issue. This big issue is linked to social, profitable, and legislative enterprises, as well as life behaviors. Understandably, urbanization and industrialization are reaching saturation levels and leading to uncertainty over the world's population in recent times.

The number of man- made composites is growing by the day, and several of them are refractory and xenobiotic in nature. According to estimates, 10 million tonnes of dangerous chemicals are released into the surroundings around the world. Soil and water systems have come defiled as a result of the addition of dangerous poisonous composites including polycyclic aromatic hydrocarbons (PAH) and polychlorinated biphenyls (PCBs). These pollutants are carcinogenic and persistently, wreaking the ecosystems, jeopardizing environmental health and affecting all life forms. Residual poisoning caused by the heavy metals has another negative impact on anthropogenic activity.

Heavy metal contamination in the environment is mostly caused by industrial activities such as refineries, metal processing units, waste incineration, fossil fuel combustion, nuclear power plants, lead-based paints, plastics, electronic wastes, agrochemicals, pharmaceutical chemicals, car exhausts, and leather industries. Heavy metals impair the quality of soil and water, making them unsustainable and of little or no value, as well as having a severe impact on ecosystem biological health.

Although Green Revolution in the 1950s and 1960s increased food productivity, it also resulted in severe environmental toxification due to the indiscriminate application of synthetic fertilizers and pesticides. The tenacious nature of pesticides, in particular, has resulted in their long-term buildup in soil, water, and food chains. Pesticide output surged from 0.2 million tonnes in 1950 to 5 million tonnes in 2000, according to a report by the Food and Agriculture Organization (FAO), resulting in the degradation of high-yielding soil, the death of non-targeted bacteria, birds, and animals, and ultimately devastating to human health. Pesticides are thought to be responsible for a quarter of a million premature deaths and more than 3 million hospitalizations each year, according to the World Health

Organization (WHO). Oil spills in the seas and on terra firma have also wrecked ruination on the respective ecosystems, putting natural systems' lives and quality in peril. Over the last five years, it is estimated that 40,000 tonnes of oil have been spilled in marine ecosystems due to offshore mining, accidents, and damaged tankers, among other things. The insoluble oil strata prevent oxygen and sunlight from accessing the water body, resulting in the mortality of ocean flora and fauna, species extinction, and a reduction in microbial population. On land, spilled oil forms a layer, reducing oxygen levels and releasing poisonous components, rendering the system desolate.

NEED FOR AN ALTERNATIVE METHOD

To get the most out of natural resources, we need additional resources, productive fields, and clean water bodies as the human population grows. To do so, we must clean up the mess by removing harmful pollutants from ecosystems, reclaiming waste and marginal areas, saline soils, rejuvenating freshwater bodies, and cleaning up the oceans. Various traditional approaches, such as physical, chemical, and thermal procedures, have been employed to clean and restore ecosystems over time. However, these procedures have a number of significant downsides, including the creation of toxic intermediates, transportation of polluted soil/water for treatment, high treatment costs, and ineffective restoration of native flora and fauna. Biodegradation and bioremediation approaches utilizing biological systems such as bacteria, their products, and plants, on the other hand, are long-term and cost-effective ways to reduce pollution and render pollutants harmless through natural biological processes. In bioremediation, biological processes are used to change toxic pollutants into less harmful or fully non-hazardous forms in order to restore contaminated soil/water. Biosequestration, biodegradation, phytohydraulics, biological extraction and volatilization are examples of technical components of bioremediation that involve bacteria or plants immobilizing or transforming the complex moieties of the pollutants being remedied on land and water. Groundwater, lagoons, sludge, water streams, agricultural areas, oil spills, and petroleum and hydrocarbon-contaminated places have all been effectively cleaned up using these biological systems.

Despite many advancements in the detection and analysis of harmful chemical disposal, a large spectrum of toxins remain unreported, raising environmental concerns [3]. From the point of contamination, environmental pollutants might be mobile or stationary. Human activities also have a crucial impact on the accumulation of new toxins like mercury. To overcome these issues, biotechnology has been employed to improve the chances of efficient heavy metal recovery and detection in the ecosystem [4]. In addition, the fields of molecular biology and nanotechnology have aided in a better understanding of the function

CHAPTER 9

Industrial Biotechnology - Scope and Risks in Establishing an Enterprise

Antony V. Samrot[1,*], **M. Sathiyasree**[2] and **P. Prakash**[2]

[1] *School of Bioscience, Faculty of Medicine, Bioscience and Nursing, MAHSA University-42610, Jenjarom Selangor, Malaysia*

[2] *Department of Biotechnology, School of Bio and Chemical Engineering, Sathyabama Institute of Science and Technology, Chennai, Tamil Nadu, 600119, India*

Abstract: The use of enzymes, microorganisms, and plants to create energy, and industrial chemicals for consumers is industrial biotechnology. This sector utilizes natural processes to maximise and improve biochemical pathways that can be used in the manufacturing process. The integration of biotechnology into industrial processes is changing not only how we produce goods but also bringing us new goods that were unthinkable just a few years ago and has created a lot of room for innovation and entrepreneurship. The commercial aspects of industrial biotechnology as well as the possible fundamental strategies associated with working biotech entrepreneurs and professionals in addition to its scope and risk involved in it are discussed here.

Keywords: Entrepreneurship, Industrial biotechnology, Risks.

INTRODUCTION

The word biotechnology comes from the Greek word “bios” meaning life, “technos” meaning technology and “logos” referring to language, proof. Biotechnology refers to the technological use of living things for different purposes, such as food, enzymes, medicines, and recycling of wastewater [1]. Biotechnology has various branches and is differentiated based on colours by Kafarski [2]. They are: industrial as white biotechnology, agricultural as green biotechnology, marine as blue biotechnology, pharmaceutical as red biotechnology, desert as brown biotechnology, patents/inventions as purple biotechnology and insect as yellow biotechnology. The white biotechnological process involves the industrial scale production of chemicals, materials and energy using living organisms, such as yeast, fungi, bacteria, plants, and enzymes

* **Corresponding author Antony V. Samrot:** School of Bioscience, Faculty of Medicine, Bioscience and Nursing, MAHSA University, 42610, Jenjarom, Selangor, Malaysia; E-mail: antonysamrot@gmail.com

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[3]. It also involves the application of biotechnological technologies for the production of food and beverages.

The application of biotechnology to industrial production is highly promising in the long run, but many must still pass a viability test to become financially viable [1]. People are increasingly seeking biobased products globally in recent years [4]. According to a new survey, 78% of customers believe corporations need to increase environmental outcomes, and 11% more consumers have adjusted their core product purchases based on environmental claims since 2019 [4]. The major components of industrial biotechnology include biocatalysis *i.e.*, enzymes catalyzing chemical reactions and fermentation using microorganisms to produce specific products. These are combined with breakthroughs in molecular genetics, directed evolutions, enzyme engineering, and metabolic engineering of microbes and cells for the production of various biobased products [5]. The products of this sector are bioethanol, biosurfactants, biohydrogen, organic acids, biocolorants, terephthalic acid, biodiesel, biofuels, biogas, biopolymers, biopesticides, industrial enzymes, antibiotics, biodegradable plastics and biopolyster [5 - 7]. Between the year 2015 and 2020, biotechnology was projected to grow by 1.3 percent annually. In the next five years, research and development (R&D) will increase in the biotechnology industry around the globe, and the industry is predicted to grow steadily [6]. In this review, the scope and risks in establishing an enterprise in the field of industrial biotechnology have been discussed briefly.

BIO-ENTREPRENEURSHIP

Entrepreneurship is the process of investing in an idea and taking the initiative to bring it to market while bearing the majority of the risks. The role of each entrepreneur is to reform or revolutionize the pattern of production by improvising or adapting a technological development to produce commodities in new ways, opening up new sources of materials and new outlets for products [8, 9]. The processes involved in the development of entrepreneurship are planning of ideas and innovation, triggering the event, implementation of the ideas, and growth (Fig. **1**). Planning of idea and innovation includes recognising opportunities in the market, development of a novel product, and its price determination. Triggering is the process of identification of the funding source and risk assessment. Implementation of the ideas is the event of launching the new enterprise, business strategy, and managing the company. Growth involves maturation, profit maximisation, reward harvesting, and expanding the venture to incorporate new opportunities [10, 11].

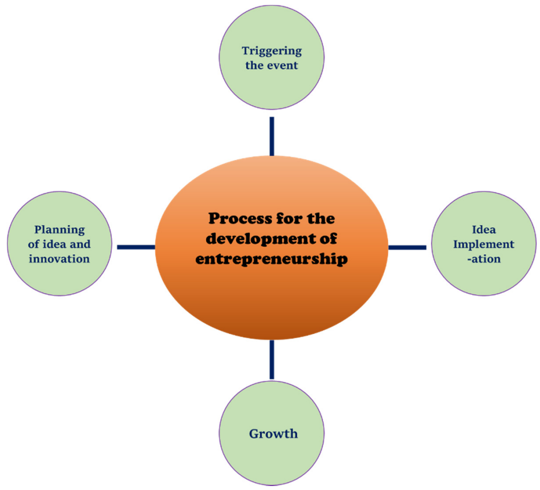

Fig. (1). Process for the development of entrepreneurship.

The term "Bioentrepreneurship" is a relatively new branch of biology that combines biotechnology and entrepreneurship. It now refers to the utilisation of any biological notion that may be used to benefit humanity while also making a profit through the establishment of a business. It is a broad term that encompasses all of the steps involved in establishing a biotechnology-related product manufacturing business. This involves setting up a business to produce and market biotechnological products [12, 13]. A good management team, appropriate funding and innovation initiatives are considered to be the "pillars" of bioentrepreneurship [14, 15]. According to a research report by Worldwide Market Insights Inc., the global biotechnology business made total revenues of $200 billion in 2009, and the economic impact will total $729 billion by 2025. It has captured the interest of both policy makers and academics [16].

Types of Entrepreneurships

The four main types of entrepreneurships include: survival, lifestyle, managed growth and aggressive growth entrepreneurship [17].

Survival Entrepreneurship

These businesses may or may not be formally registered, and most work on a cash or barter basis with no premises, little assets, and no banking connections. The firm typically has limited capacity to reinvest once its costs are met as it is there to serve human financial needs [17]. "Survivalist enterprises" are businesses run by individuals unable to access a conventional wage job or certain sectors of the economy. In general, the incomes from these firms typically fall short of even a

CHAPTER 10

Generating Successful Start-up & Research Opportunities in Industrial Biotechnology

Chidhambara Priya Dharshini K.[1] and **S. Umamaheswari**[1,*]

[1] *Department of Biotechnology, Manonmaniam Sundaranar University, Tirunelveli-627 012, Tamil Nadu, India*

Abstract: Industrial Biotechnology is concerned with the sustainable production of materials from renewable sources. It is one of the widely recognized fields of biotechnology as it is associated with a decreased utilization of energy sources and reduced emission of greenhouse gases and its popularity in terms of economic value in recent years. With such concerns, the current chapter provides an insight into the opportunities for building start-ups and research scope in the field of Industrial Biotechnology and focuses on the various opportunities for initiating a start-up related to the field of Industrial Biotechnology. Moreover, it highlights the attractive approaches for setting up and developing the start-ups and government schemes associated with them. The scope of research and various research opportunities for students and scholars are highlighted in the field of Industrial Biotechnology. Since entrepreneurship based on innovation has immense potential in any field, the chapter highlights the essential entrepreneurial skills and various innovations happening in this era of Industrial Revolution.

Keywords: Entrepreneurship, Industrial biotechnology, Research.

INTRODUCTION

Industrial Biotechnology is a broad field of biotechnology that deals with the application of modern biotechnology for the sustainable production of microbial or chemical products, materials, and other fuels with high-end values for human use and other applications. A number of companies related to industrial biotechnology have been developed over the recent years owing to the state of the art of various disciplines especially the scientific disciplines falling under industrial biotechnology which broadly include genomics, proteomics, biochemistry, microbiology, bioinformatics and system biology [1]. The realm of the biological science sector is changing rapidly, which creates a favourable path for generating small start-ups especially in the field of Industrial Biotechnology.

* **Corresponding author S. Umamaheswari:** Department of Biotechnology, Manonmaniam Sundaranar University, Tirunelveli-627 012, Tamil Nadu, India; Tel: +9442040205; E-mail: umamsu@gmail.com

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Developing a start-up in general creates a number of opportunities like discovering a scientifically important product, claiming intellectual property, marketing the product with good margin values, and finally competitive intelligence. Even though a number of advantages and opportunities are associated with building a start-up, it is also risky and highly challenging at the same time. Neither a clever research idea alone will be found sufficient and worthy for developing a start-up nor the need of the hour that needs to be addressed by the background question for initiating a start-up [2]. It is a thorough understanding of the question to be addressed, ending up with an apt solution in the form of a new product with clear research findings and proof of concept that is more needed for building a start-up [3]. With concern to Industrial Biotechnology ventures, the scientific concept needs to be very strong and there needs to be a potential investor along with funds from any of the funding agencies, team members with expertise in different fields like accounting and marketing and advisors who may be in the cadre of a Senior Professor with expertise in the theoretical knowledge of the field concerned. In this case, if all the above-mentioned prerequisites are met, the task of launching a new research and development-based enterprise will be quite easier [4]. Since this chapter deals with the start-up related to Industrial Biotechnology, scientific and technological ideas are highlighted. In this chapter, you may get answers to the queries like what a start-up means, types of start-ups, where one may receive funds for initiating a start-up, and what are all funding agencies available in our country to support such start-ups and most importantly the research concerned with the Industrial Biotechnology field is also elaborately discussed.

START-UP

A start-up is a fairly new entrepreneurial venture or company that aims to meet a marketplace by developing or offering an innovative product, process, or service. The start-up usually gets initiated with high costs, limited revenue, and founders who wish to generate new products which seem to be in demand to earn capital from a variety of sources like venture capitalists, crowd funding and loans from banks. Raising capital and developing a strong business model is the important criteria for successful initiation of small start-up [2].

There are a number of factors that are needed to be specially considered for initiating a start-up and proceeding the operation to be followed simultaneously.

Innovation

In order to reinvigorate a business and promote new value and growth, innovation is the act of introducing something novel to it, such as a new product, market approach, process, *etc*. A business needs to have a differentiator competition in order to gain a competitive advantage in the market. The innovation may be present in their products or in the business model associated with the company. An innovation plays an essential role in the success of a start-up, so all entrepreneurs should mandatorily take up this aspect seriously before the initiation of a start-up.

Age

A start-up is a new company which is still in the early stages of brand management, sales, and hiring employees. Too often the allocation of this concept to business has been on the market for less than 3 years, however, this is not true. That is, one company can have 7 years of working experience and can be still considered as a start-up. It depends not only on the age but on a specific set of features like the collaborations made, products that find a good margins in the market, and most importantly the profit earned.

Location

The location of the start-up depends on the product the company is targeting to produce or manufacture and the services the start-up is going to provide for the customers. Choosing the right location for building start-up is an important criterion needed to be considered before initiating the start-up. For example, if one is going to perform Spirulina farming, an adequate amount of land area with tanks located in the outer region of a city or town is the best suitable criteria as finding more land inside a city is too much costly and one can avoid fellow human interventions apart from the working labourers. A physical storefront may be necessary for a technology start-up selling virtual reality hardware to allow their clients to demonstrate the intricate aspects of the product in person.

Growth

Start-up founders generally were not looking to keep a small and limited team over a longer period of time since they want to dramatically impact and disrupt the current market on their start-up business ideas. The main goal of any start-up is to grow and expand rapidly, sometimes taking drastic measures in order to do so. This is one of the points that distinguish a start-up from a small business. Henceforth, many startups were found within the tech industry since technology-based ones have a wide reach, easily scalable and receives funds fast.

Risk

Once a start-up has demonstrated strong innovation, there always exist several possible uncertainties about its long-term success. For this reason, they are

CHAPTER 11

Biopharmaceuticals: Present and Prospects

Subramani Parasuraman[1,*], **Krishnamoorthy Venkateskumar**[2,*], **Thanapakiam Ganeson**[2] and **Kamini Vijeepallam**[3]

[1] *Department of Pharmacology, Faculty of Pharmacy, AIMST University, Bedong, Malaysia*

[2] *Department of Pharmaceutical Technology, Faculty of Pharmacy, AIMST University, Bedong, Malaysia*

[3] *Department of Basic Health Science, Faculty of Pharmacy, AIMST University, Bedong, Malaysia*

Abstract: Biopharmaceuticals include vaccines, bioengineering drugs, blood products, genetic engineering drugs, microecological preparations, and recombinant therapeutic proteins. They are intended for the prevention, diagnosis, and treatment of human diseases. Biopharmaceuticals are delivered using different drug delivery methods which include nanoparticles, microparticles, jet injections, depot injections, and pumps. It can be administered orally or in injectable form. In recent years, most of the biopharmaceuticals including monoclonal antibodies are available as liquid formulations. The emergence and re-emergence of infectious diseases require the development of newer diagnostic tools and pharmacotherapeutic approaches. The traditional approach may take a long time to get a new lead, whereas the biotechnological applications may give highly specific antibodies which can minimize the time of the drug discovery process and these molecules may have high specificity. In the last few decades, many biopharmaceuticals have been approved for various indications including cancer treatment. Many countries consider the biopharmaceutical sector to be one of the most important industries for national growth. Biopharmaceuticals have wider applications and it is gaining much more attention clinically than conventional pharmaceuticals. The purpose of the chapter is to highlight the importance of biopharmaceuticals and their prospects.

Keywords: Antibodies, Biotherapeutics, Biopharmaceutical classification system, Living cells, Liquid formulations.

INTRODUCTION

Biopharmaceuticals (biological or biologic) are a pharmaceutical dosage form which is produced by biotechnology. This product consists of sugars, nucleic

* **Corresponding authors Subramani Parasuraman and Krishnamoorthy Venkateskumar:** Department of Pharmacology, Faculty of Pharmacy, AIMST University, Bedong, Malaysia; and Department of Pharmaceutical Technology, Faculty of Pharmacy, AIMST University, Bedong, Malaysia; Tel: +604 429 8000; Ext.: 1288; Fax: +604 429 8009; E-mails: parasuraman@aimst.edu.my and venkateskumar@aimst.edu.my

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acids, proteins, living cells, or tissues extracted or semisynthesized from biological sources like microorganisms, animals, or humans, and they include vaccines, bioengineering drugs, blood products, genetic engineering drugs, microecological preparations, and recombinant therapeutic proteins. The most important technology applied in biopharmaceutical formulation is genetic engineering technology which uses tissue culture and cloning techniques to cut, insert, link, and recombine deoxyribonucleic acid (DNA) fragments to gain useful biopharmaceutical products [1]. Human recombinant insulin was the first biopharmaceutical product approved for human therapeutic use in 1982 [2]. Biopharmaceuticals are intended for the prevention (vaccine), diagnosis (monoclonal antibodies), and treatment (antibodies) of human diseases. Biopharmaceuticals make up around one-third of the drugs currently in development.

BIOPHARMACEUTICAL FORMULATION

Biopharmaceuticals are diverse groups of products that include tissues, therapeutic proteins, vaccines, blood and blood components, allergenics, and gene therapy products. These are isolated from living things such as humans, animals, microorganisms, or plants and have a larger and more complex structure than tiny molecules synthesized chemically, which have a well-defined structure such as sugar, proteins, and nucleic acids [3]. Biotechnologically produced biological products, notably synthesized with heat, are prone to microbial contamination. In contrast to most traditional medications, it is therefore vital to use aseptic principles from the very beginning of the manufacturing process [4].

Biopharmaceuticals include cell therapy products and gene therapy products. Cell therapy products are biomedicines that contain cells or tissues that have undergone modifications to alter their biological properties. These tissues or cells can be utilized to diagnose, prevent, or treat illnesses [5]. Gene therapy products are therapeutic agents used to enhance a patient's genetic makeup by repairing, deleting, substituting, or replacing defective genes, or by making site-specific modifications for target therapy [6]. The process of improving, repairing, or replacing just a portion or the whole biological tissues, such as bone, cartilage, blood vessels, organs, skin, muscles, *etc*., using a combination of cell, engineering, and material technologies is known as tissue engineering. Creating new healthy tissues for medical applications also entails the usage of a tissue scaffold [7].

Biopharmaceuticals are classified based on the Biopharmaceutical classification system (BCS) which is based on the scientific framework describing the three rate-limiting phases in oral absorption *viz*., the release of drug from dosage forms, maintaining the dissolved state along the gastrointestinal tract and permeation of drug molecules through the gastrointestinal membrane into hepatic circulation [8]. Based on the BCS, the drugs can be classified into one of the following four categories [9]:

- Class I: High solubility, high permeability: generally, very well-absorbed compounds.
- Class II: Low solubility, high permeability: exhibits dissolution rate-limited absorption.
- Class III: High solubility, low permeability: exhibits permeability-limited absorption.
- Class IV: Low solubility, low permeability: very poor oral bioavailability.

The BCS has gained acceptance across the industry, academic institutions, and public authorities. For Class I, II, and III drugs, BCS offers biowaivers with some limitations. This exemption applies to both the pre-and post-approval stages. If the necessary information assures the similarity of the submitted pharmaceutical product and the appropriate comparator product, BCS-based biowaivers are applicable for immediate-release solid oral dosage formulations containing one or more of the active pharmaceutical ingredients (APIs) identified by the World Health Organization (WHO) prequalification of medicines programme to be eligible [10]. By utilizing the BCS, manufacturers can lower the cost of authorizing scale-up and postapproval modifications to selected oral formulations without sacrificing public safety concerns.

TYPES OF BIOPHARMACEUTICAL FORMULATION

Biopharmaceuticals are complex medicines produced from living cells/ tissues or organisms. They vary in their complex structure due to the presence of polymeric chains and this complex structure may limit its exploration [11]. The properties of APIs in biopharmaceuticals significantly depend on the manufacturing method. Biopharmaceuticals are potentially immunogenic and a small difference in their structure may significantly affect its immunogenicity. They are also called by a specific term such as “Advanced therapy medicinal products (ATMPs)” as coined by the European Medicines Agency (EMA). The following are the types of biopharmaceutical formulations;

Innovator Biologic

An innovator biologic is the original version of a biopharmaceutical product developed by pharmaceutical companies. It is approved based on a full complement of safety and efficacy data of developed products and it needs huge

CHAPTER 12

Octocorals in Turbid Waters – An Untapped Source of Potential Bioactive Molecules

R. Chandran[1,2,4,*], **K. Padmakumar**[2], **Ch. Satyanarayana**[3] and **R. Senthil Kumaran**[1]

[1] *Marine National Park, Forest Colony, Jamnagar-Gujarat-361 001, India*

[2] *Centre for Marine Biodiversity, University of Kerala, Kariavattom Campus, Thiruvanan thapuram-695581, India*

[3] *MBRC-Zoological Survey of India, 130, Santhome High Road, Chennai–600 028, India*

[4] *General Non-Chordata Section, Zoological Survey of India, FPS Building, Indian Museum Kolkata-700 016, India*

Abstract: Discovering new secondary metabolites is an especially urgent task due to the rapid spread of bacterial resistance and the emergence of multi-resistant pathogenic strains of infectious diseases. Octocorals (soft corals and gorgonians) are a highly diverse group of marine organisms, which are known to contain a rich variety of rare and unusual secondary metabolites. These substances show not only great significance in chemical ecology but also various biological activities. Despite the intense interest in the isolation of novel compounds from octocorals, little is known about within and between-habitat variability in the levels and types of compounds in these species. Marine organisms living in extreme environments evolve unique strategies by biosynthesizing more diverse compounds than their counterparts living in moderate environments. Coral reefs of the Gulf of Mannar in India have a more moderate environment (with a sedimentation rate of 12.31 $mg.cm^{-2}day^{-1}$); whereas the Gulf of Kachchh is a marginal reef experiencing arid climate and heavy sedimentation rate (upto119.60 $mg.cm^{-2}d^{-1}$). In a preliminary cytotoxicity assay, carried out to evaluate the bioactivity of selected soft corals from the Gulf of Mannar and the Gulf of Kachchh, the highest cytotoxicity was exhibited by Mannar soft corals, *Sinularia leptoclados* (LC_{50}=25.15µg/ml) followed by *Sarcophyton ehrenbergi* (LC_{50}=43.76µg/ml). Whereas soft corals collected from the Gulf of Kachchh exhibited higher cytotoxicity than the Mannar samples (*Si. leptoclados* (LC_{50}=19.24µg/ml) followed by *Si. polydactyla* (LC_{50}=24.50µg/ml). Extreme physico-chemical and biological conditions in the Kachchh are the drive for the production of variant molecules with specific adaptations. Hence, soft corals inhabited in extreme waters may yield more effective compounds

[*] **Corresponding author R. Chandran:** Marine National Park, Forest Colony, Jamnagar-Gujarat-361 001, India; and Centre for Marine Biodiversity, University of Kerala, Kariavattom Campus, Thiruvananthapuram-695581, India; and General Non-Chordata Section, Zoological Survey of India, FPS Building, Indian Museum Complex, Kolkata-700 016, India; Tel: +91 7818046452;
E-mail: chandranrethnaraj@gmail.com

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that may potentially be useful in drug development for existing and emerging human ailments.

Keywords: Adaptation, Chemical ecology, Extreme environment, Marginal reefs, Marine natural products, Octocoral, *Sarcophyton*, *Sinularia*, Soft coral, Turbid water.

INTRODUCTION

The marine environment is an exceptional reservoir of an ocean of biologically active natural products, with potential benefits for mankind. Several marine natural products have become the source of novel chemical leads for the ongoing global search of therapeutic agents for the treatment of multiple disease categories. Interestingly, the majority of marine natural products engaged in clinical or preclinical trials are secondary metabolites produced mostly by invertebrates, *i.e*., sponges, octocorals, bryozoans, mollusks and tunicates [1]. Most of these compounds are unique from those of terrestrial counterparts in chemical structures as well as peculiarities of biological actions [2]. Physico-chemical and biological conditions in the environment like hyper-normal temperature, salinity, sedimentation, and high irradiation; competition, threatened by overgrowth, poisoning, infection, or predation, are the intensive pressures which drive for the production of these varieties of molecules with exceptional structural features. Marine organisms use these complementary metabolites as their defensive chemical weapons for their safeguard. These marine molecules exhibit various types of biological activities [3], with compounds of high economic interest; having potential applications in the pharmaceutical and medical sectors. Some of these secondary metabolites have antibacterial, antifungal, antiviral, and anti-HIV properties [4]. Marine bioactive compounds also display varied applications, namely, as molecular tools, in cosmetics, as fine chemicals, as nutraceuticals, and in agrochemical industries [5]. In the present scenario of the world, which has become prone to pandemic diseases, discovering new secondary metabolites is a prerequisite for the development of novel pharmaceuticals, and this is an especially urgent task in case of antibiotics due to the rapid spreading of bacterial resistance and the emergence of multi-resistant pathogenic strains of infectious diseases [6].

OCTOCORALS – A PROLIFIC SOURCE OF NOVEL MOLECULES

The animal phylum Cnidaria or Coelenterata is a large, diverse, and ecologically important group of marine invertebrates that comprises over 11,000 extant species [7]. More than 3000 Marine Natural Products have been reported so far from this phylum alone, mostly in the last decade. However, further research has confirmed that Marine Natural Products produced by cnidarians are other than toxins and venoms [8]. Among the cnidarians, octocorals (soft corals and sea fans) have attracted considerable attention due to the wide range of bioactive secondary metabolites generated by these marine invertebrates. The interest began with the isolation of 'prostaglandins' from the octocoral *Plexaura homomalla* [9]. This was followed with the examination of the Alcyonacean octocorals in the early 1970s, chemists came to the conclusion that terpenoids predominate across the subclass Octocorallia [10]. Coll [11] reviewed the chemistry and chemical ecology of octocorals and made several contributions to the ecological causes of the structural chemical diversity. This has evinced sharp interest in chemical investigations by this group, resulting in the identification of several novel bioactive metabolites with potential biomedical applications, *i.e*., sesquiterpenes, diterpenoids, furanoditerpenes, capnellenes, polyhydroxylated sterols, *etc.,* [12, 13]; diterpenes belonging to cembranolides, [14, 15]; norcembranoids, [16 - 19] and amphilactane classes. Among the several diterpenes reported, cembranoids and their cyclized derivatives are the most abundant metabolites of soft corals and gorgonians [20 - 23]. Most of these metabolites of tropical and temperate waters octocorals are derived from the mevalonate pathway [24, 25].

EXTREME MARINE ENVIRONMENTS

Since marine bioprospecting began, there are about 22,000 different marine natural products that have been isolated so far [26]. However, only a very limited number have attained industrial application. Research of species from unexplored geographical sites can provide novel, rare marine bioactive compounds [25]. Hence, exploring these molecules from previously unexplored marine habitats has also started to draw the attention of researchers. Extreme environments, *i.e*., polar and hot regions, deep seas, hydrothermal vents and marine areas of high pressure or high salinity, experience conditions close to the limit of life. Although the species richness of these extreme environments is poor, organisms develop unique chemical ecological adaptations to thrive in such habitats. Organisms have obtained adaptability and varied strategies to cope with such extreme conditions, such as the production of secondary metabolites which in turn are bioactive molecules; potentially valuable for biotechnological applications and for pharmaceutical and many other commercial sectors.

Many chemicals isolated from organisms living in extreme environments may be of great interest in the detergent, textile, paper, and food industries. Marine natural products produced by organisms evolved under hostile conditions exhibit a wide structural diversity and biological activity. In fact, they exert more antimicrobial, anticancer, antioxidant, and anti-inflammatory activities than organisms living in unhostile environments. Further in-depth exploration of

CHAPTER 13

Biogenic Nanoparticles: A Functional Platform for Antiviral Activity – An Entrepreneurial Approach

Ranjit Singh A. J. A.[1,*], **P. Dhasararthan**[1], **Gokul Shankar Sabesan**[2] and **Bibin G. Anand**[3]

[1] *Department of Biotechnology, Prathyusha Engineering College, Chennai-602025, India*

[2] *Microbiology Department Preclinical Sciences, Faculty of Medicine, Manipal University College, Melaka, Malaysia*

[3] *Department of Physiology & Biophysics, Boston University, Boston, MA 02215, USA*

Abstract: Science-based businesses are taking a new dimension today. Biotechnological innovations and inventions are given much attention in transforming laboratory findings into business. Vaccine technology, since the pandemic 2019, has become a billion-dollar business. An integrated approach of nanotechnology and biotechnology as a single unit called Nano biotechnology opens a promising avenue for business opportunities in health care. After the SARS-CoV-2 threat emerged, intensive searches were accelerated to find remedial measures from different systems of medicine. In this search, nanoparticles of both organic and inorganic origin are prioritized, and research in nano -biotechnology gets immediate attention. Laboratory research is intensified to formulate and patent some products to fight against the coronavirus attack. Bio-inspired inorganic nanoparticles are reasonable in using nanoparticles as a workhorse for biomedical applications. The biosynthesized nanoparticles and quantum dots of gold, silver, cadmium, titanium, *etc*., have multiple biomedical applications. The biogenic nanometal products enhance immunity, fight against viruses, help in diagnosis, and play a role in preparing antiviral dressings, face masks, and drug carriers. This venture promotes promising business avenues.

Biopharma industries are interested in developing the nanotechnology-based therapeutic drug dexamethasone for SARS-CoV-2 drugs; nano-based vaccination to boost immune responses is also progressing. The global market for nanobiotechnology is expected to reach $68.4 billion by 2026. As nanobiotechnology-based business is becoming a promising area for start-ups and entrepreneurs, the stakeholders can utilize the opportunity as quoted “make hay while the sun shines”.

* **Corresponding author Ranjit Singh A. J. A.:** Department of Biotechnology, Prathyusha Engineering College, Chennai-602025, India; Tel: +919443451076; E-mail: ranjithsingh@prathyusha.edu.in

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Keywords: Antiviral, Biogenic nanoparticles, COVID, Entrepreneur, Green nanotechnology, Immunity booster, Nanomedicines, Nanobiotechnology, Science-based business, Start-ups.

INTRODUCTION

The commercialization of science is making a tremendous change in the business sector. “Science-based businesses” have induced a boundless technological revolution in biotech, nanotech, crop science, energy, *etc*. The extension of Watson and Crick's central dogma beyond protein to incorporate business using recombinant technology by Robert Swanson and Herbert Boyer in 1976 in their Genetech Company opened many avenues in biotech science-based businesses. Biotechnology and nanotechnology were fused to capitalize on the growing demand for nanobiotechnology. Nanobiotechnology, an integration of physical sciences, molecular engineering, biology, chemistry, and biotechnology, holds considerable promise for advances in pharmaceuticals and healthcare. The application of nanobiotechnology in the biopharma sector has created large-scale business avenues and market growth. The biotech-based industries registered magnificent growth during the pandemic, particularly in the biopharma sector. A report says that because of vaccine technology, the combined profit of the biotech firms Pfizer, BioNTech, and Moderna in the pandemic period was $65,000 per minute or $93.5 million a day (Oxfam News and Press Release Posted 16 Nov 2021). Recently, attention has been focused on developing nano-based vaccinations to boost humoral and cellular immune responses. The global market for nanobiotechnology is expected to grow from $38.5 billion in 2021 to $68.4 billion by 2026, at a compound annual growth rate (CAGR) of 12.2% from 2021 to 2026. The major driving force for the prosperity of the nanobiotechnology market at the global level is increasing healthcare awareness and emerging biomedical technologies. Young entrepreneurs can “Make hay while the sun shines” by getting into nanobiotechnological ventures.

THE ROLE OF BIOGENIC NANOPARTICLES IN THE HEALTHCARE SYSTEM

Several metals have been converted into nanosized particles from ancient times, and these particles have rich therapeutic applications [1]. For converting metals into nanosized particles, physical, chemical, and biological methods are used. Of the different approaches, using biological agents like bacteria, fungi, and plant materials for synthesis has several advantages over other methods [2]. Biogenic preparation of metal nanoparticles [BNPs] is eco-friendly, fast, safe, and cost-effective [3]. The presence of phytochemicals like flavonoids, amino acids, proteins, polysaccharides, enzymes, polyphenols, steroids, and reducing sugars facilitates the reduction, formation, and stabilization of nanoparticles. The biogenic nanoparticles demonstrate good antibacterial, antifungal, anticancer, and antioxidant activities and are helpful for medical diagnosis and drug delivery [4]. The biogenetic production of nanoparticles has several advantages [5]. The nanoparticles have unique characteristics, like small size, improved solubility, surface adaptability, and multifunctional nature. Hence, their role in developing practical and safer drugs, tissue-targeted specific treatments, personalized nano medicines, diagnosis, and disease prevention enhances their biomedical scope (Fig. **1**).

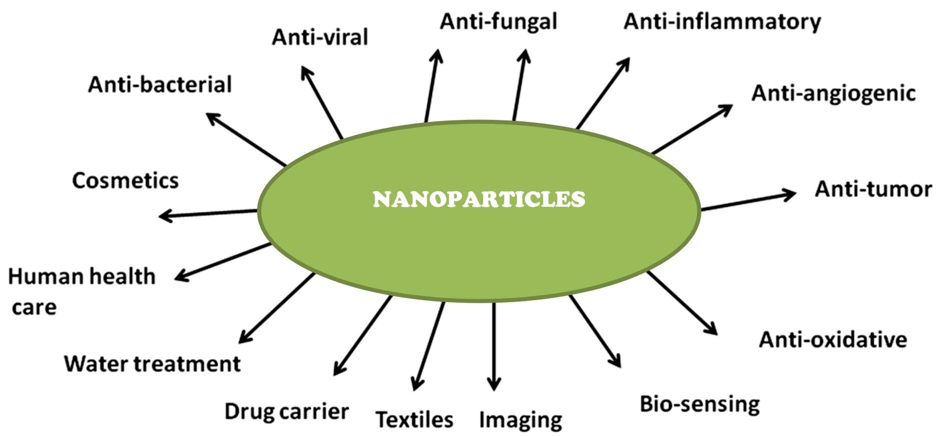

Fig. (1). Multiple roles of nanoparticles.

The antiviral role of nanoparticles came to the limelight after the COVID-19 pandemic. Nanotechnology is reported to prevent, diagnose, and treat COVID-19 and other viral infections [6]. The biogenic nanoparticle's role in COVID-19 virus management includes developing disinfectants, personal protective equipment, diagnostic systems, and nanocarrier systems for treatment and vaccine development [7]. The demand for NPs-based precise diagnostic tools to diagnose infection and evaluate immunity conditions also promotes business avenues. Drugs are needed other than vaccines for drug-resistant microbes and highly mutated viral particles. The biopharma industries have accelerated their science-based business by incorporating biogenic nanoparticles to develop new drugs, with enhanced tissue-target-specific drug delivery and activity, decreased toxicity, and sustained release [8]. In recent days, the development of nano-based vaccination to boost humoral and cellular immune responses is also focussed [9]. As nanoparticle-based vaccines to deliver SARS-CoV-2 antigens are given priority, more than 26 nanoparticle vaccine candidates are subjected to clinical

CHAPTER 14

Medical Biotechnology - Approaches to become an Entrepreneur in Medical Biotechnology

Antony V. Samrot[1,*], **Sanjay Preeth R.**[2] and **M. Bavanilatha**[2]

[1] *School of Bioscience, Faculty of Medicine, Bioscience and Nursing, MAHSA University-42610, Jenjarom Selangor, Malaysia*

[2] *Department of Biotechnology, School of Bio and Chemical Engineering, Sathyabama Institute of Science and Technology, Chennai, Tamil Nadu-600119, India*

Abstract: Medical biotechnology is one of its branches which involves the application of medicine and biotechnology resources. Entrepreneurship is said to be the development of a new business making profits where innovation and creditability are considered as the backbone for its expansion. In the field of medical biotechnology, the innovation of new medicines, methods for the identification and analysis of new diseases, discovery of new solutions for a complex problem by satisfying the specific needs, *etc*., are involved. In this chapter, various approaches and ideas for becoming an entrepreneur in the field of medical biotechnology are discussed briefly.

Keywords: Entrepreneurship, Medical Biotechnology, Opportunities.

INTRODUCTION

Biotechnology is a diverse science with tremendous societal implications, including the use of cells and cell-derived compounds for a variety of uses over many years. It is referred to as "technology of hope" since it has a wide range of applications that affect human health, the well-being of other life forms, and our environment with various diagnostics and therapies [1]. The various branches of biotechnology are i) Industrial - white biotechnology, ii) Medical - red biotechnology, iii) Agricultural - green biotechnology, iv) Marine - blue biotechnology, v) Environmental biotechnology, and vi) Food biotechnology [1, 2]. There is significant overlap between biomedical engineering or bioengineering and biotechnology, based on the applications [2]. Biotechnology is

* **Corresponding author Antony V. Samrot:** School of Bioscience, Faculty of Medicine, Bioscience and Nursing, MAHSA University-42610, Jenjarom Selangor, Malaysia; E-mail: antonysamrot@gmail.com

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used in a wide range of areas, including healthcare, food and beverage products, waste treatment, and agriculture [3]. An entrepreneurship in biotechnology includes the sum of all actions required to create a firm by combining scientific and commercial disciplines. It is the integration of two fields: science and business, which is the backbone of innovation in biotech industries [4]. Biotechnology entrepreneurship is characterized to be a combination of motivations, skills, and actions for identifying and exploiting opportunities resulting from the application of biological organisms and processes [3]. Some of the developments of biotechnology products are altering medicine and giving new and better ways for the detection, treatment, and prevention of diseases [5]. Medical biotechnology is one of the emerging fields in recent days. It includes diagnosis and therapies for diseases like cancer, mental disorders, cardiovascular problems, *etc*., various technologies like molecular biological techniques, discovery of vaccines, development of genetic medicine, *etc* [6 - 8]. In the medical biotechnology market, a product's value is typically realised by three customers: the patient, clinician, and the purchaser. Medical biotechnology products are effective based on the value proposition of the "payer," or the third party that covers some or all cost of these items ordered by the physician and the usage by the patients [9]. In this review, the scope, upcoming technologies, and challenges in starting entrepreneurship in the field of medical biotechnology have been discussed in detail.

Biotechnology Entrepreneurship

Biotechnology is one of the fastest growing industries of the 21st century. Although the industry is still young, there are many biotech companies in the early stages of development. Therefore, biotechnology and entrepreneurship are inextricably linked, and a number of recent publications in the entrepreneurship literature have analyzed biotechnology at the regional, corporate, and individual levels [10]. In the field of biotechnology, entrepreneurship is the process of starting a company that combines technical and business expertise [4]. To fully comprehend the entrepreneurial process, it is important, at least in the beginning, to enter the black box [11]. In general, entrepreneurship is an endless cycle of drive, courage, and readiness that has a big impact on how the economy develops [12]. Biotechnology "start-ups" and entrepreneurs require a variety of skills in order to promote state-of-the-art research forward, whether they work together or on their own. A start-up company culture offers opportunities to contribute to a wide range of responsibilities: i) Research and development of proof-of-concept, ii) Competitive intelligence to timelines and business plans for the innovation of novel products. A start-up enterprise generally involves risks but truly involves unique experimental endeavours. These fields can give a demanding and fascinating job if the skills, abilities, knowledge, and attitude are well-suited to tolerate the eventual lack of stability [13]. The steps involved in the development of a start-up or enterprise are: planning ideas, sketching, business plan, start up, raising of funds, promotion, and growth of business and harvest (Fig. **1**).

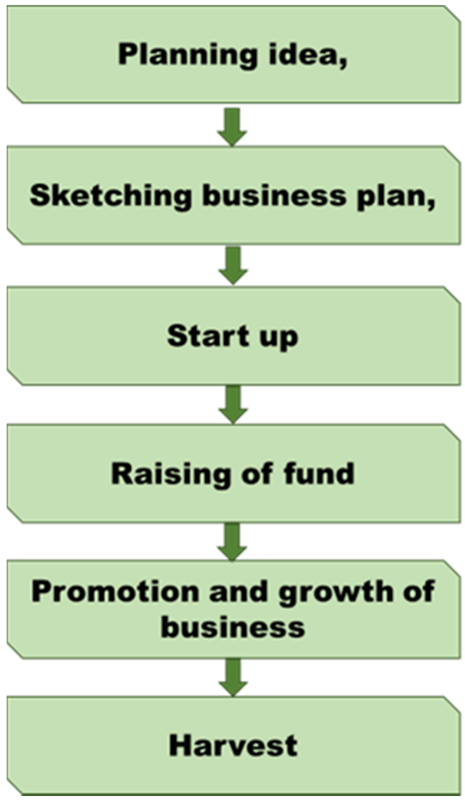

Fig. (1). Steps involved in the development of a start-up.

Planning Ideas and Business Plan

A business plan is the first step in the business planning process, and it plays a role in routinizing the first entrepreneurial activities of entrepreneurs [14]. Prior planning performance paradigms that stated planning would automatically boost performance have been debunked. The four activities listed above may be completed in any order. In the case of an entrepreneur, developing effective market plans for a new business can be difficult in terms of finance and time management. For instance, the company name, product, or service should all be important factors. In times of competing demands and a limited budget, business owners can discriminate their businesses by developing and implementing operational and strategic business plans [15]. Thus, entrepreneurs need to examine each of the four activities individually in any order to be able to get a better

CHAPTER 15

Promising Roadmap in the Development and Commercialization of Pharmaceutical Products for Early Career Researchers

Saranga Rajesh[1], Selva Sudha N.[1], Raksha Goswami[1], Kunal Kishore[1] and **Hannah R. Vasanthi[1,*]**

[1] *Natural Products Research Laboratory, Department of Biotechnology, Pondicherry University, Puducherry, 605014, India*

Abstract: Translational research by budding scientists in the pharmaceutical and biotechnological field demands the application of their knowledge to a bedside medical problem. Career opportunities in the pharmaceutical sector range from bench-side research which includes screening, discovery and development, and operational activities to manufacture, quality control, and marketing, including pharmacovigilance. The success of trials leading to commercialization is determined by the quality of research conducted in academia with the ultimate goal of moving the product ahead. Early career researchers should have a deep understanding of pharmaceutical products, particularly advanced drug delivery systems (DDS). Advanced DDS such as niosomes, liposomes, dendrimers, nanoparticles, and others are developed to increase drug distribution and bioavailability. DDS can accomplish localized or systemic drug distribution by careful selection of excipients. DDS could be used to deliver all types of therapeutic molecules, including biological macromolecules, to the site of action with more stability. However, one must be aware of several factors, including the physicochemical properties of the drug, formulation parameters, physiological considerations, intersubject variability, and the choice of an appropriate animal model for *in vivo* studies. In addition, the *in vitro* and *in-vivo* correlation (IVIVC) should be considered, as it confidently converts the bench trial to a market level for bedside applications. Accordingly, this review focuses on factors that influence drug delivery, approaches to drug delivery systems, excipient selection strategies, ways to translate the pilot scale to industrial scale, and the basic requirements of the pharmaceutical sector for product commercialization. Furthermore, this chapter will also discuss some of the possible funding avenues to nurture drug discovery and development to motivate early-career entrepreneurs.

* **Corresponding author Hannah R. Vasanthi:** Natural Products Research Laboratory, Department of Biotechnology, Pondicherry University, Puducherry, 605014, India; E-mails: hrvasanthi@gmail.com and hannah.dbt@pondiuni.ac.in

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Keywords: Active Pharmaceutical Ingredient (API), ADMET, Biosimilar, Bioavailability, BA/BE Studies, Clinical research, Drug delivery system, Excipients, Early career researchers (ECR), Innovation, Inter-subject Variability, *In vitro- In vivo* Correlation (IVIVC), Pharmaceuticals, Pharmacokinetics, Pharmacodynamics, Pre-clinical Research, Toxicity.

INTRODUCTION

Research has been the backbone of most commercialized products and services evident during emergencies such as the recent pandemic. Off-late, the fascination for research and translating the hypothesis is curtailed at the bench level, with validation and acceptance for commercialization. Nevertheless, many researchers face multifaceted problems in converting their ideas to a working prototype due to arid reasons such as ignorance of the standard procedures, difficulty in transferring the work from molecular level to a working formulation, and lack of awareness about policies and risks and procedures for commercialization. Understanding the potential application of the in-depth research work and its use for the beneficiary at a community level needs to be perceived for commercializing any product [1]. Developing a prototype for the beneficiary's needs is the most valued among the research outcomes and is in the queue for competing at the market level. Realizing these needs reveals the importance of biological and pharmacological aspects of any drug or formulation developed to combat certain diseases [2]. The primary understanding of the drug's action through *in vitro* and *in vivo* studies is the key to validating the research hypothesis. The awareness of the drug's action at both scales is one of the main reasons for the academic researcher's work to be at the desk level.

Pharmacological interventions are of paramount importance in treating a patient concerning disease management. Small molecule chemicals generated using chemical synthesis make up the majority of medications in the market today [3]. However, with advancements in technology and knowledge of the disease process and its intricacies, innovations with large molecules such as enzymes, hormones, antibodies, and vaccines are gaining momentum. Drug discovery and development is a wholesome process of identifying a new drug and bringing it to the market. Discovery may involve screening chemical libraries, identifying and characterizing the active ingredient from natural products, or designing and synthesizing a drug molecule by understanding the target. The development includes studies with microorganisms and animals, clinical trials, and, ultimately, regulatory approval [4]. Therefore, drug discovery and development is a time-consuming, lengthy process that involves massive investment, as shown in Fig. (**1**). Embracing the recent advances in drug development such as novel dosage forms, drug delivery systems, and alternatives by early career researchers would help develop innovative products for translational purposes. This chapter will outline the drug molecules used as Active Pharmaceutical Ingredients (API) in different dosage forms, the intricacies of novel drug delivery systems, and a roadmap for the commercialization of pharmaceutical products.

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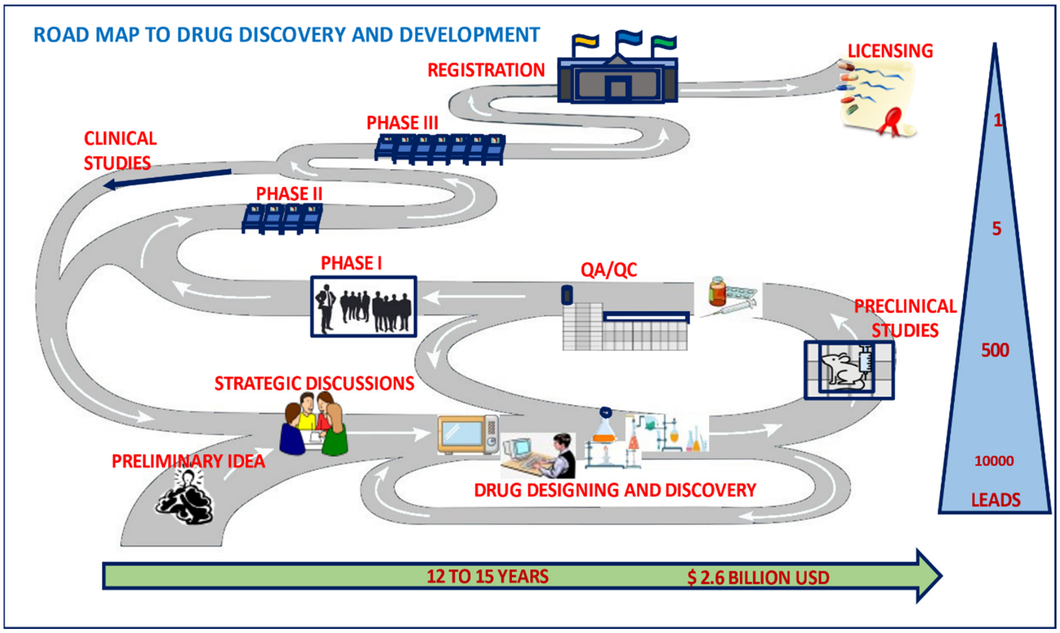

Fig. (1). Roadmap to Drug Discovery, Development and Commercialisation.

CATEGORIES OF MOLECULES IN DRUG DISCOVERY AND DEVELOPMENT

With a skyrocketing rise in disease burden and the search for pharmaceutical agents to combat these diseases, two classes of molecules are being analyzed and utilized in drug discovery and development: small and large molecules. As the name implies, small and large molecules differ in size. Large molecules known as biologics are often larger than 1kDa, and small molecules are typically between 0.1 and 1kDa in size. This distinction is not only due to its size but also aids in classifying the synthesis mode of the molecules, their nature, mechanism of action, pharmacokinetics, and their suitability in preparing various medicaments. Small molecules account for more than 90% of currently available medications, but large molecules are rapidly gaining importance and popularity in medical treatments. Both classes of drugs necessitate extensive and costly development steps to reach the clinic; nevertheless, the translational routes for both drug classes are distinct.

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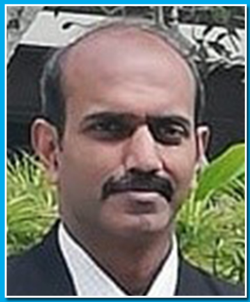
Sagarika Devi

Dr. Sagarika Devi received her Ph.D. in Microbiology from University of Madras, Chennai, India in 2014. With more than 8 years of experience in research and outreach skills, she is currently associated with Guru Nanak College, Velachery at Chennai as Assistant Professor of Biotechnology and Coordinator – Guru Nanak Centre for Research. She has worked as a Microbiologist in packaged drinking water, beverage, dairy and beer. She promotes natural dyes from plants and microbes for sustainable livelihood in India and abroad. She was awarded with DST Women Scientist (A) in 2019 and worked at ICMR-National Institute for Research in Tuberculosis, Chennai. She has received the Novozymes & Henning Holck Larsen Fellowship in 2016 and German Academic Exchange Service (DAAD) Fellowship in 2014. Other academic credentials include research contributions in publications, book chapters, conference proceedings, newsletters, articles and invited talks in national and international seminars. Her research interests include microbial biotechnology, secondary metabolites, metabolite profiling, bioassays and microbial dyes for textile application.



Gokul Shankar Sabesan

Prof. Gokul Shankar Sabesan is a doctorate in the field of microbiology armed with an extensive career of two decades in research and a distinctive expertise of more than 18 years as faculty in microbiology for the postgraduate and undergraduate students in India and Malaysia. He received several awards that include the Young Scientist Award at the 3rd International Conference on Medicinal Plants and Herbal Products organized by Faculty of Medicine & Institute of Indigenous Medicine, University of Columbo, Srilanka in 2011, and the Best Teacher in Microbiology Award in 2019 from Microbiologists Society of India. He has worked as food microbiologist in the hotel industry and as research scientist in Research and Development Centers of FMCG industries. He had been a consultant to various food industries including Britannia of India. He has published over 60 papers in national and international journals and has presented several research papers and guest talks in international conferences and seminars. He is currently the professor in Microbiology Department and deputy dean in the Faculty of Medicine, Manipal University College Malaysia, Malaysia.

Sultan Ahmed Ismail

Prof. Sultan Ahmed Ismail, M.Sc., M.Phil., Ph.D., D.Sc., with Diploma in Higher Education, is a soil biologist and soil biotechnologist. He is presently Member, State Planning Commission, Government of Tamil Nadu; and Member, Panel to frame the State Education Policy, Government of Tamil Nadu, India. He had been member of the Tamil Nadu Curriculum Framework Committee to oversee syllabus revision and implementation for Classes 1 to 12 of the Government of Tamil Nadu; and is Chairman of the Scientific Review Committee, Initiative for Research and Innovation in Science (IRIS) program of the Ministry of Science and Technology, Government of India. Teaching from 25th Nov 1974 he was the Head of the Department of Zoology and later the Department of Biotechnology, The New College, Chennai, India. He has published about 80 research and review papers in National and International Journals, guided 32 M.Phil, and 20 Ph.D, students.