Florentina Matei · Daniela Zirra *Editors*

Introduction to Biotech Entrepreneurship: From Idea to Business

A European Perspective

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Editors
Florentina Matei
Faculty of Biotechnology
University of Agronomic Sciences
and Veterinary Medicine
Bucharest, Romania

Daniela Zirra
Department of Commerce, Economic
Integration and Business Administration
Romanian-American University
Bucharest, Romania

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Preface

We often ask why in some areas the entrepreneurial process is ampler and faster than in others, why business success is more famous or why entrepreneurial initiatives are more common. Please note that there is no simple answer for any of the matters outlined above. However, there are some factors that help us better understand why these differences exist, for example, the size of the profit that can be achieved and the time required to obtain a consistent profit, the frequency of emergence of opportunities and the pace of change in consumer needs and wishes, the degree of novelty of the products and services that are to be created, the degree of risk specific to the field, diversity and accessibility of funding sources, the legislative and institutional framework that exists in the chosen field and the level of availability of necessary resources.

Considering the importance of biotechnologies in the current context of global economic development, it is more than obvious that an effective entrepreneurial process in this area is vital. We must not forget that no matter how innovative, numerous or important are the discoveries and results of biotechnology research, if they are not capitalized on the market and do not reach the end beneficiaries, in this case consumers (regardless of whether we are talking about individuals or firms), all the effort will be in vain and all the resources used to achieve those performances can be considered as wasted.

In response to the biotech business environment, the biotech entrepreneurship study programs are booming in Europe, completed with the highly claimed need for industrial PhD in the domain of life sciences. These are viewed as very important tools in filling the gaps between Europe and Northern-American biotech business. This book addresses mainly the students and teachers involved in such educational programs, and actually, the idea for such a handbook arose during the setup of a new master's program in "Biotechnology and Entrepreneurship". Teachers and students will find in this book valuable teaching and/or learning material, adapted to the biotech business reality in Europe. Meanwhile, the provided information targets academic and industrial researchers in the field, as well as business professionals and potential investors.

Some other books have been written on the same topic, but the most cited are describing biotech business in the USA and Canada or biotech venture in Europe, with a focus on the suboptimal state of the European biotechnology industry especially in the UK, just before the global financial crunch of 2008.

Our handbook is supposed to provide an overview on the opportunities and drawbacks of biotech entrepreneurship in the European context, including a comparative analysis among different countries' perspectives and European regions (Eastern and Western Europe), as well as to identify possible gaps or even advances, comparing with other world economic regions. The book provides information on technical and economical solutions useful for the development of a biotech start-up, capable of generating value and employment, supported with clear examples from the European environment. They approach different fields of biotechnology, from plant and food biotechnology, to food industry and environmental areas, passing through human and animal health biotech opportunities, as well as bioinformatics as source of income. As a must, the book includes key elements of the biotech markets and financial/investment sources, taking also into account the huge importance of the innovation and intellectual property issues.

The readers will find valuable information on how to deal with a start-up in the biotech field, will be able to choose from a long list of potential profitable biotech start-ups and will be in a position to access a collection of successful stories of biotech start-ups developed in the European context. The potential investors and business consultants will be punctually informed on benefits and potentials risks in supporting biotech business.

Bucharest, Romania
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Florentina Matei
Daniela Zirra

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We would like to thank all the contributors to the biotech case studies presented in this work and to people accepting to provide written and video testimonials about their experience in biotech start-up.

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Last but not the least, we send our deep and sincere gratitude to our families for their continuous and unparalleled love, help and support.

Contents

The Potential of Biotechnology to Generate Prosperity

1

Florentina Israel-Roming and Mihaela Ghiduruş

Abstract

Biotechnology is considered now as a key knowledge-based business that generates products and processes for the growing global needs. Biotechnology offers modern solutions for almost every aspect of human life: economic, social, health and environment. It promotes sustainable economic growth, increasing productivity and diversity and lowering by-products and wastes generation. Modern diagnostic approaches, therapeutic solutions, vaccines and other pharmaceutical products are generated by biotechnology. These achievements are intended to increase the survival rate and to lower the resources and pain associated with a non-suitable treatment. Biotechnology also offers solutions for producing food enriched with specific nutrients, with significant contribution to a proper human health condition and even to malnutrition. Microbial processes are successfully used for improving the environmental quality by biodegradation and bioremediation. Economic prosperity is expected in rural areas or in developing countries based on agriculture, as well as in developed economies where biotechnology engenders "high-tech" solutions.

Keywords

Prosperity · Agricultural biotechnology · Biopesticides · Biofertilisers · Herbicide resistance · Industrial biotechnology · Biofuels · Environmental biotechnology · Health biotechnology

F. Israel-Roming (✉) · M. Ghiduruş
University of Agronomic Sciences and Veterinary Medicine of Bucharest, Bucureşti, Romania
e-mail: florentina.israel@biotehnologii.usamv.ro

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Doing Business in Biotech: European Paradigm Versus American Success

2

Daniela Zirra

Abstract

Entrepreneurship is the central element of growth and economic development. In the absence of it, however abundant and available the economic resources may be, progress cannot be achieved in any field of activity. The entrepreneurial process presents both common and specific elements, depending on the level of economic development, the pace of technical progress, the social and cultural elements, the applied development strategies and policies, the level of education, the conjectural aspects, etc. For this reason, a comparative analysis of successful factors in entrepreneurship can make a valuable contribution to identifying aspects that can decisively influence the stimulation and sustainable development of entrepreneurship. We refer here to national, regional, or microeconomic level effects and to the level of various fields of activity such as biotechnology. The American entrepreneurial process is characterized as the most advanced in the world, and this is intended to encourage other countries to make sustained efforts to reduce development gaps in entrepreneurship. As far as US entrepreneurship in biotech is concerned, there is an important difference between it and the degree of development of entrepreneurship at European level for several reasons. Thus, identifying the similarities and differences between the European and American perspectives on entrepreneurship in biotech can reveal several directions for action to increase the speed of development of this field in the future.

Keywords

Entrepreneurship · Entrepreneurial process · Biotechnology industry · European approach · American perspective · Comparative analyses · Reduce the gap

D. Zirra (✉)
Department of Commerce, Economic Integration and Business Administration, Romanian-American University, Bucharest, Romania

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Creating Products and Services in Plant Biotechnology

3

Monica Boscaiu, Miquel Estruch, Ana Fita, Mariola Plazas, Jaime Prohens, Adrián Rodríguez-Burruezo, Mercedes Verdeguer, and Oscar Vicente

Abstract

This chapter presents a brief description of the most relevant applications of plant biotechnology, with examples of specific techniques that can be used to provide commercial products and services to customers and represent, therefore, business opportunities to entrepreneurs. Start-up companies can base their activities on the development of *molecular markers*, their use in MAS (marker-assisted selection) for molecular breeding programmes or in genetic fingerprinting applications; on the use of *mutagenesis* for generation of mutant collections in species of interest, the development of novel mutant detection methods and the phenotypic or molecular analysis of the mutants; or on applications of in vitro *culture* techniques. These are all services that can be offered to small breeding companies and research laboratories that do not have in-house facilities to perform these activities. Small start-ups cannot afford to bring a novel *transgenic* crop variety to the market; they can, however, develop and characterise the initial transgenic lines with traits of interest and transfer them (for a price) to big transnational companies, which can undertake all further field tests and marketing procedures. It can also be profitable to use GM plants as *biofactories* for the production of high added-value recombinant proteins or other biomolecules for different industries. Other topics included in this chapter are the applications of *'omics' technologies* in plant biotechnology, the new business opportunities opened by the customers' increasing interest in the products of *organic agriculture* and the possible commercial exploitation of some of the thousands of compounds—*phytochemicals*—synthesised by plants.

Keywords

Molecular markers · Mutagenesis · In vitro culture · Transgenic plants · 'Omics' technologies · Organic agriculture · Phytochemistry

M. Boscaiu · M. Verdeguer
Mediterranean Agroforestry Institute (IAM, UPV), Universitat Politècnica de València, Valencia, Spain

M. Estruch
Viromii Innovation S.L., Valencia, Spain

A. Fita · M. Plazas · J. Prohens · A. Rodríguez-Burruezo
Institute for Conservation and Improvement of Valencian Agrodiversity (COMAV, UPV), Universitat Politècnica de València, Valencia, Spain

O. Vicente (✉)
Institute for Plant Molecular and Cell Biology (IBMCP, UPV-CSIC), Universitat Politècnica de València, Valencia, Spain
e-mail: ovicente@upvnet.upv.es

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Creating Products and Services in Environmental Biotechnology

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Calina Petruta Cornea, Catalina Voaides, Oana Alina Boiu Sicuia, Florentina Matei, and Narcisa Babeanu

Abstract

In the process of solving environmental protection problems biotechnology plays an essential role in providing alternative solutions to reducing pollution. The chapter approaches as a green alternative the phytoremediation of polluted environments, complete with microbial and vermiremediation as a clean-up alternative. Special attention is given to natural plant protection products, known as "biopesticides." Another aspect approached is the finding and development of new plants as a biomass source for energy production, which are objectives for start-ups, and have great business potential.

Keywords

Environmental biotechnology · Phytoremediation · Vermiremediation · Biopesticides · Energy crops · Start-up

All authors have made equal contributions.

C. P. Cornea (✉) · C. Voaides · O. A. Boiu Sicuia · F. Matei · N. Babeanu
Faculty of Biotechnologies, University of Agronomic Sciences and Veterinary Medicine of Bucharest, Bucharest, Romania

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5 Medicinal Biotechnology for Disease Modeling, Clinical Therapy, and Drug Discovery and Development

Robin Duelen, Marlies Corvelyn, Ilaria Tortorella, Leonardo Leonardi, Yoke Chin Chai, and Maurilio Sampaolesi

Abstract

Over the past decades, stem cell technology has revolutionalized medical biotechnology due to the unlimited self-renewal ability and differentiation capacity of stem cells to generate cells and tissues of the entire human body. Many efforts have focused on providing cutting-edge stem cell therapies in order to repair or replace damaged cells or tissues, hoping to ultimately cure devastating diseases. Undoubtedly, this novel technology guarantees a serial entrepreneur's confidence in the future prospects of stem cell-based products and services. Here, we describe the state of the art of several applications of adult stem cells, as well as of embryonic and induced pluripotent stem cells in biotechnology that represent entrepreneurial opportunities. Although the contribution of stem cells to medical research is enormous, several hurdles still have to be overcome, including ethical and regulatory issues, functional maturation of stem cell progenitors, stringent manufacturing guidelines, immune rejection, and tumorigenicity.

Nevertheless, key studies applying microfluidic technology, "organ-in-a-dish" and 3D bioprinting have been published, reporting the successful development of human pluripotent stem cell-based healthy and disease models for deciphering pathological mechanisms, drug discovery and toxicity screening, and regenerative medicine. Interestingly, because of the increasing amount of newly identified targets, assistance from computational chemistry and bioinformatics became indispensable to reduce the quantity of molecules that need to be tested in vitro or in vivo. In the past years, a boom in companies and start-ups all over the world occurred, focusing on bioinformatics and machine learning. Furthermore, biotechnological applications are highly applied in the veterinary medicine nowadays, and stem cell-based

R. Duelen · M. Corvelyn · I. Tortorella
Translational Cardiomyology Laboratory, Stem Cell Biology and Embryology Unit, Department of Development and Regeneration, KU Leuven, Leuven, Belgium

L. Leonardi
Department of Veterinary Medicine, University of Perugia, Perugia, Italy

Y. C. Chai
Translational Cardiomyology Laboratory, Stem Cell Biology and Embryology Unit, Department of Development and Regeneration, KU Leuven, Leuven, Belgium

Department of Development and Regeneration, Stem Cell Institute Leuven, KU Leuven, Leuven, Belgium

M. Sampaolesi (✉)
Translational Cardiomyology Laboratory, Stem Cell Biology and Embryology Unit, Department of Development and Regeneration, KU Leuven, Leuven, Belgium

Human Anatomy Unit, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy
e-mail: maurilio.sampaolesi@kuleuven.be

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biotechnology is opening an exciting era in human therapeutics. In conclusion, scientists with strong entrepreneur mind-set are crucial to generate economic value in medicinal biotechnology. Thus, we need to educate next generation of scientists in entrepreneurship and work directly with institutions and funding agencies to guarantee a successful translational process in hiring and training our next generation of students.

Keywords

Stem cell biotechnology · Entrepreneurship · Regenerative medicine · Disease modeling · Computer-aided drug discovery and toxicity · Organ-in-a-dish · Veterinary medicine

Creating Products and Services in Industrial Biotechnology

6

Eleonora Calzoni, Alessio Cesaretti, and Carla Emiliani

Abstract

Biotechnologies represent a set of enabling technologies that find application in various industrial and economic sectors. There are more and more companies that, while operating in "traditional" fields, integrate biotechnological products and technologies into their production processes, in order to improve their quality and yield and reduce their environmental impact. Not surprisingly, no production process is less invasive for the environment than natural processes from which biotechnology originates.

Biocatalysis has now fully entered into all industrial sectors and is crucial for the development of sustainable chemistry. It is based on the use of bioprocesses mediated by microorganisms or enzymes capable of accelerating the speed of the reaction without the production of toxic substances and on the use of mild temperature conditions. Biocatalysis has therefore become a valuable tool, not only for its lower environmental impact, but also as it is increasingly becoming a cost-effective alternative to classical chemical processes. Biocatalysis is now used in a variety of fields, from the pharmaceutical and food sectors to the production of biofuels to the restoration and conservation of cultural heritage.

Bioeconomy is the challenge that Europe is taking on for the establishment of a new model of sustainable development, capable of generating value and employment. This new type of industry will therefore implement traditional processes with biotechnological processes with the aim being both to enhance its production yields and standards and to lower its impact on the environment.

Keywords

Bioeconomy · Biocatalysis · Bio-based products · Enzymes · Microorganisms

E. Calzoni · A. Cesaretti · C. Emiliani (✉)
Department of Chemistry, Biology and Biotechnology, University of Perugia, Perugia, Italy

Centro di Eccellenza su Materiali Innovativi Nanostrutturati (CEMIN), University of Perugia, Perugia, Italy
e-mail: carla.emiliani@unipg.it

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Creating Products and Services in Food Biotechnology

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Mona Elena Popa, Amalia Carmen Mitelut, Elisabeta Elena Popa, and Florentina Matei

Abstract

This chapter includes new material on applications of food biotechnology products in industry, e.g., in food fermentations, enzymes, probiotics, prebiotics, synbiotics, microbial food cultures, or improving food nutrition using bioactive compounds—functional and nutraceutical food through development of functional food products with good examples of this kind of food. At the same time, the chapter offers information regarding new trends on the market, biopreservation of food using bacteriocins, bacteriophages, and natural preservatives from plants. Considering the sustainability issues which are the latest trends in bioeconomy, the chapter also presents aspects regarding bio-valorization of food waste through biofuel and bioenergy production, biomaterials production, and food ingredients recovery.

Written by professors in food biotechnology, food microbiology, food conditioning and preservation, food safety, and food sustainability and very good researchers, the chapter includes up-to-date information which could be a useful tool for knowledge improvement in this field and a starting point for future entrepreneurs.

Keywords

Food biotechnology · Fermentations · Enzymes · Starter cultures · Functional food · Bio-preservatives · Bio-valorization · Food waste

M. E. Popa (✉) · A. C. Mitelut · E. E. Popa · F. Matei
Faculty of Biotechnologies, University of Agronomic Sciences and Veterinary Medicine of Bucharest, Bucharest, Romania

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Creating Products and Services in Bioinformatics

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Radu Cristian Toma, Laura Dorina Dinu, and Camelia Filofteia Diguta

Abstract

In this chapter, bioinformatics is defined, emphasizing the interdisciplinary aspects. There is detailed information regarding the bioinformatics fields such as database design and data mining, sequencing, gene and protein expression, structural bioinformatics, phylogenetic tree construction, biological networks, and their practical application. In addition, tools provided by bioinformatics are described (open-sources and web-based services in bioinformatics, educational programs, and training platforms in bioinformatics). The chapter analyze the path of a bioinformatics student toward entrepreneurship in the US context versus the European context.

Keywords

Bioinformatics · Databases · Health sciences · Precision medicine · Translational bioinformatics · Pharmacoinformatics · Microbiomics · Oncology · Biomedical computing

R. C. Toma (✉) · L. D. Dinu · C. F. Diguta
Faculty of Biotechnologies, University of Agronomic Sciences and Veterinary Medicine of Bucharest, Bucharest, Romania
e-mail: Radu.Toma@biotehnologii.usamv.ro; laura.dinu@biotehnologii.usamv.ro

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Start-Up and Management Features in Biotech Business

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Daniela Zirra, George Căruțașu, Gabriel Eugen Garais, Gabriela-Lucica Mărgărit, and Alexandra Perju-Mitran

Abstract

The start-up of new businesses is strongly influenced by the features of the economic environment, the diversity of business opportunities, the variety and availability of funding sources, and finally the available resources and economic and institutional infrastructure. As in any field, starting a business in biotech involves several steps. From this point of view, we mention that there are no significant differences in this area compared to other fields of activity. We do, however, have to say that the entrepreneurial process in biotech presents several specific elements that every investor must consider. Thus, the innovative feature of any biotechnology approach is crucial to the development of a successful business. At the same time, if the managerial process is the one applied to all types of business, in biotech it must consider the types of strategies that can be applied, the technological level, or the types of partnerships that can be established. Therefore, a further clarification of the elements of the entrepreneurial process in biotech is always useful and necessary.

Keywords

Biotech business · Biotechnology entrepreneurship · Business start-up · Managerial strategies · Innovation process · Business development · High-tech industry

D. Zirra (✉)
Department of Commerce, Economic Integration and Business Administration, Romanian-American University, Bucharest, Romania

G. Căruțașu · G. E. Garais
Faculty of Computer Science for Business Management, Romanian-American University, Bucharest, Romania

G.-L. Mărgărit
Faculty of Biotechnologies, University of Agronomic Sciences and Veterinary Medicine of Bucharest, Bucharest, Romania

A. Perju-Mitran
Faculty of Management-Marketing, Romanian-American University, Bucharest, Romania

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Financing and Investment in Biotechnology

10

Cristian Paun

Abstract

Capital is the most important production factor. In the absence of the capital, the other production factors remain unused. Capital accumulation is the key element for any business initiation and development. The limited access to finance is the common problem of any start-up or SME. However, innovative sectors (such as biotech) have more financing options in the early stages (such as venture capital, business angels, investment funds, mezzanine financings). This chapter is discussing the main challenges for initiating a business in the biotech sector from this perspective of attracting more capital that can be provided by classical 3Fs (known as "family, friends and other fools"). The chapter is presenting also the alternatives for later stages when the business became mature and is able to attract more long-term capital from capital markets (such as initial public offering—IPO, leasing, supplier credit facility, or buyer credit facility). The financing of innovative sectors is also considered as a priority for many governments of developed and emerging countries. This chapter is introducing some of the specific public financing schemes and state-aid mechanisms that are available now for innovative sectors such as the biotech sector.

Keywords

Capital · Financing · Investments · Financial markets · Financial institutions · Financial instruments · Cost of capital · Financial risks

C. Paun (✉)
The Bucharest University of Economic Studies, București, Romania
e-mail: cristian.paun@rei.ase.ro

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Key Elements of the Biotech Market

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Alexandra Perju-Mitran

Abstract

Addressing the uncontrollable factors influencing the European biotech market is critical to the commercial success of emerging biotech companies, as the accelerating pace of biotechnological research allows for the development and implementation of new products and services. Modern biotechnology demands rigorous oversight of macroenvironmental factors, as each of these uncontrollable macroenvironmental factors affect new ventures in biotech; change occurs when companies manage to favorably respond to the challenges imposed by each factor, constructing a different representation for the public, and thus shaping the development of biotechnology itself.

With biotechnology used in a wide variety of sectors, it is imperative to analyze market factors in several fields, with focus on one hand on specific European factors and on the other hand on global factors that either pose threats or opportunities for new ventures.

As in all cases, factors of the macroenvironment are beyond the influence capacities of individual companies and will always present themselves as either opportunities or threats. Given the specificity of biotechnology, there will always be needs that are not catered to.

Keywords

European biotech · External factors · Biotech start-up · Social factors · Economic factors · Political factors · Legal factors · Technological factors · Biotech marketing

A. Perju-Mitran (✉)
Faculty of Management-Marketing, Romanian-American University, Bucharest, Romania

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Intellectual Property and Transfer of Innovation in Biotechnology

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Cristina Popa, Narcisa Elena Babeanu, and Ovidiu Popa

Abstract

Intellectual property biotechnology, with special emphasis on biotech patents, is considered a strong tool in the development of biotechnological R&D and biotech industry. In the European patent system, more than 50% of the granted biotech patents cover pharmaceutical products, around 40% refer to industrial processes in biotechnology, and the rest are patents granted for application of biotechnology in agriculture and environmental protection.

The authors propose to reveal specific insights into patenting biotechnological inventions, according to the European Patent System, emphasizing what can be protected or not protected by patents in the area of biotechnology, considering the legislation in force in this field, and ethical and moral disputes on this subject.

The authors give special attention to aspects regarding the transfer of innovation in biotechnology, referring to its very specific problems and how intellectual property could interfere with facilitating this transfer of knowledge.

Keywords

Intellectual property · Biotech patents · Transfer of innovation

C. Popa (✉)
Rominvent SA, Bucharest, Romania

N. E. Babeanu · O. Popa
Faculty of Biotechnologies, USAMVB, Bucharest, Romania

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European Biotech Entrepreneur Profile: Case Studies

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Florentina Matei, Flavia Anghel, Mioara Varga, Mihaela Draghici, Cristina Coculescu, and Oscar Vicente

Abstract

To be entrepreneur it takes a certain type of personality, but there is also a range of skills needed for success. The authors have conducted a survey among European biotech entrepreneurs, trying to profile their skills, knowledge, and competencies adapted to different socioeconomical contexts; an analysis of potential differences between the Western and Eastern Europe sides has also been targeted. A high similarity in answers has been generally noticed, in relation to respondents' competences levels, as well as on the importance of common competences/skills/abilities for being an entrepreneur, like creativity and innovation, professionalism, communication, leadership, and teamwork. An important conclusion is that in biotech companies there is a high demand for higher education graduates and these graduates have to continuously improve their technical and managerial knowledge and skills following training courses. The societal and economic context in the targeted countries has different influence on biotech new ventures. Several European biotech entrepreneurs have provided testimonials on their own experience and useful recommendations for future graduates.

Keywords

Europe · Biotechnology · Entrepreneurship · Challenges · Testimonials

F. Matei (✉) · M. Varga · M. Draghici
Faculty of Biotechnologies, University of Agronomic Sciences and Veterinary Medicine of Bucharest, Bucharest, Romania
e-mail: florentina.matei@biotehnologii.usamv.ro

F. Anghel · C. Coculescu
Romanian-American University, București, Romania
e-mail: coculescu.cristina@profesor.rau.ro

O. Vicente
Institute for Plant Molecular and Cell Biology (IBMCP, UPV-CSIC), Universitat Politècnica de València, Valencia, Spain
e-mail: ovicente@upvnet.upv.es

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