

# Postgraduate Diploma Market Access in Pharma Biotech





## Postgraduate Diploma Market Access in Pharma Biotech

- » Modality: online
- » Duration: 6 months
- » Certificate: TECH Technological University
- » Dedication: 16h/week
- » Schedule: at your own pace
- » Exams: online

Website: [www.techtute.com/pk/medicine/postgraduate-diploma/postgraduate-diploma-market-access-pharma-biotech](http://www.techtute.com/pk/medicine/postgraduate-diploma/postgraduate-diploma-market-access-pharma-biotech)

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# 01

# Introduction

The protocol for introducing a new drug to the market is lengthy and requires close collaboration with various health authorities in order to comply with the procedures in force in this field. Therefore, all those doctors who wish to be part of this industry must have cutting-edge skills to deal with the Public Administration and comply with the requirements for the development and marketing of drugs. For this reason, TECH has created this qualification, which allows the student to identify the updated processes and market access strategies for Pharma Biotech products. All this, enjoying an innovative 100% online methodology that will optimize the specialist's update without forcing them to move from their home.





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*With this Postgraduate Diploma, you will learn the leading strategies for accessing the market of new drugs in the pharmaceutical industry”*

The Access Market department plays a crucial role in the biopharmaceutical industry, being responsible for managing the entire development and commercialization process of a new product. In this line, the professionals who practice in this area are responsible for ensuring compliance with the requirements of public administrations to incorporate innovative drugs into the market. In this way, the specialist who wishes to be part of this sector is obliged to keep up to date with the procedures required to make these drugs available to the client.

For this reason, TECH has created this degree, through which the student will delve into the most avant-garde intricacies of the Access Market in Pharma Biotech. Throughout this academic period, students will delve into the recent processes of authorization and registration of new drugs or learn about the structure of organizations focused on evaluating these drugs. In addition, you will identify cutting-edge strategies to ensure optimal integration of a biopharmaceutical product in the market.

This academic proposal is presented in a 100% online format, which enables students to complete their studies from any device with an internet connection, adapting to their own personal and professional needs. Likewise, you will enjoy teaching through the Relearning method, which allows you to understand complex concepts more efficiently in less time.

This **Postgraduate Diploma in Market Access in Pharma Biotech** contains the most complete and up-to-date scientific program on the market. The most important features include:

- ♦ The development of practical cases presented by experts in Pharma Biotech
- ♦ The graphic, schematic, and practical content with which they are created, provide scientific and practical information on the disciplines that are essential for professional practice
- ♦ Practical exercises where self-assessment can be used to improve learning
- ♦ Its special emphasis on innovative methodologies
- ♦ Theoretical lessons, questions to the expert, debate forums on controversial topics, and individual reflection assignments
- ♦ Content that is accessible from any fixed or portable device with an Internet connection



*Learn about the importance of the Access Market department for the development of biopharmaceutical products"*

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*You will delve into the key functions of the market access department and become the most up-to-date expert in the pharmaceutical and biotech environment"*

The program's teaching staff includes professionals from the sector who contribute their work experience to this program, in addition to renowned specialists from leading societies and prestigious universities.

Its multimedia content, developed with the latest educational technology, will provide the professional with situated and contextual learning, i.e., a simulated environment that will provide an immersive education programmed to learn in real situations.

The design of this program focuses on Problem-Based Learning, by means of which the professional must try to solve the different professional practice situations that are presented throughout the academic course. For this purpose, the student will be assisted by an innovative interactive video system created by renowned experts.

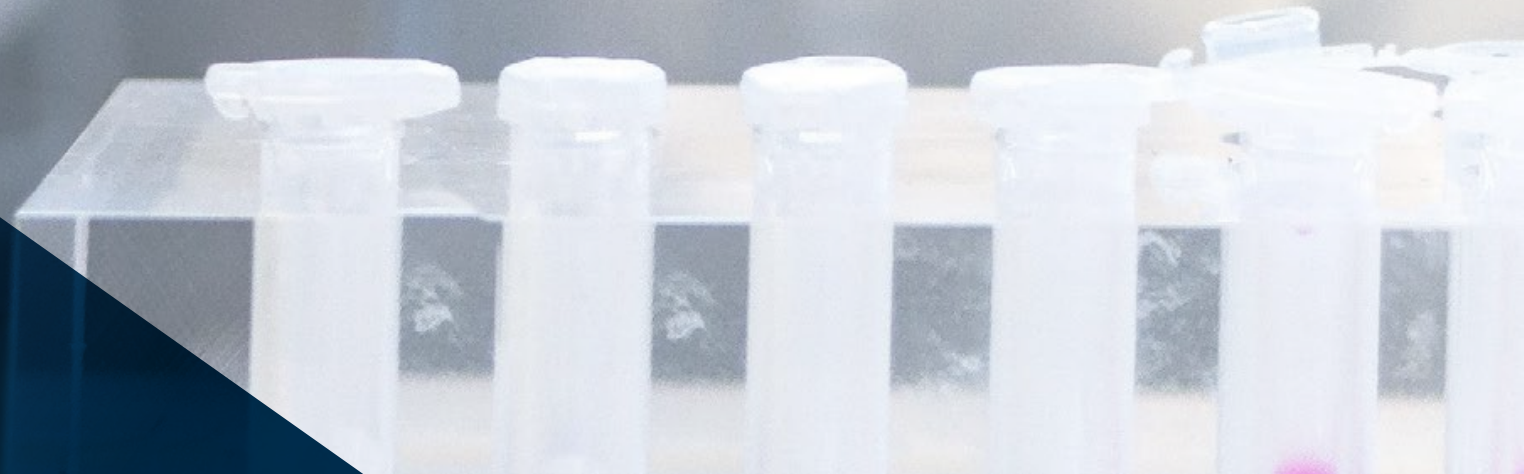
*TECH's Relearning method allows you to delve deeper into the key aspects of the syllabus at your own pace of study to consolidate your knowledge.*

*Update yourself 100% online without giving up your professional and personal life.*



# 02 Objectives

The purpose of this degree is to provide the physician with the most up-to-date knowledge on the introduction of a new biopharmaceutical product to the market. In this way, they will be prepared to assume fundamental responsibilities in critical areas such as research, development and project management. In addition, they will do so while enjoying the most innovative didactic content in the teaching environment.





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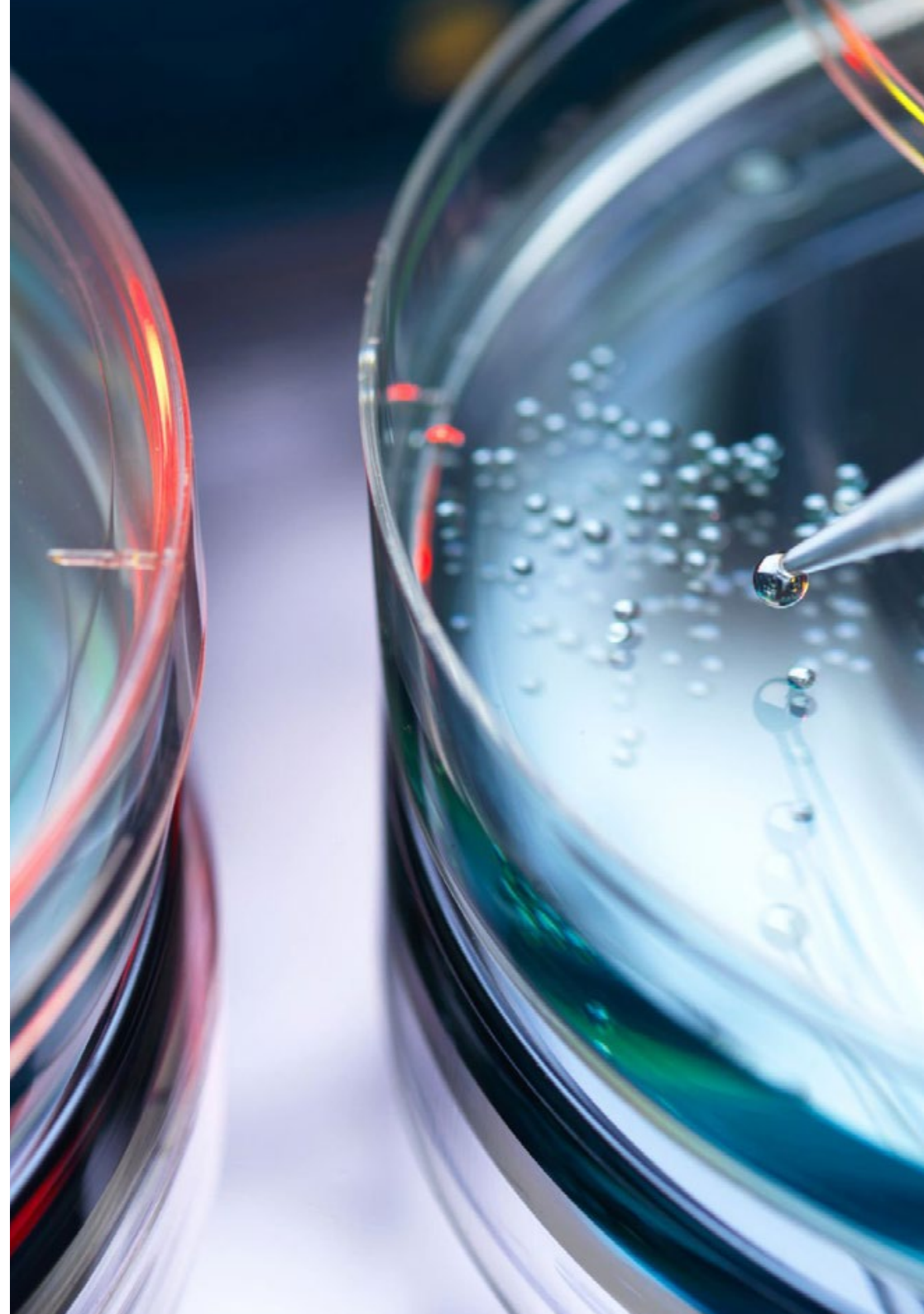
*You will have specialized readings and a whole series of multimedia resources at your fingertips, that will bring you up to date on new drug evaluations”*



## General Objectives

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- ♦ Acquire knowledge about the history of strategic management
- ♦ Categorize the different definitions over time
- ♦ Evaluate financial efficiency
- ♦ Optimize working capital management
- ♦ Understand the different types of healthcare systems, such as public, private/ private insurance, and managed health care
- ♦ Assess unmet patient needs and chronicity management
- ♦ Understanding what Market Access is and how the need for this function arises in the pharmaceutical industry
- ♦ Know about the structure, organization and functions of the National Health System
- ♦ Delve into the steps to be followed to plan the market access of a new drug
- ♦ Review the points to be analyzed in a phase prior to the development of the access plan to know the environment and competitors
- ♦ Know about the capabilities and ethics of the Coach
- ♦ Understand the essence of Coaching and its approach to learning
- ♦ Acquire basic knowledge about the fundamental concepts of leadership and its application in the pharmaceutical industry
- ♦ Understand and categorize leadership theories, exploring the leadership process and the different existing styles and models
- ♦ Achieve an effective tool to achieve results
- ♦ Define unique and differentiated value propositions





## Specific Objectives

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### Module 1. Market access (1). Organization and Processes

- ◆ Understand what Market Access is and how the need for this function arises in the pharmaceutical industry
- ◆ Know about the structure, organization and functions of the National Health System
- ◆ Describe the marketing authorization process of a new drug and identify the Spanish and European health authorities involved in the process
- ◆ Analyze the national and international health technology assessment agencies
- ◆ Identify the agencies that evaluate new drugs, decision makers and influencers
- ◆ Describe the price and reimbursement application process
- ◆ Differentiate the access processes for hospital drugs and those dispensed in street pharmacies
- ◆ Familiarize with traditional and innovative financing schemes
- ◆ Know about the processes of public purchase of medicines in the Spanish healthcare system
- ◆ Know about the professional profiles assigned to the access department
- ◆ Analyze the interaction of Market Access professionals with other departments of the pharmaceutical industry
- ◆ Review the latest trends in drug evaluation (Multicriteria Analysis) and drug purchasing

## Module 2. Market access (2). Tools and Strategy

- ♦ Delve into the steps to be followed to plan the market access of a new drug
- ♦ Review the points to be analyzed in a phase prior to the development of the access plan to know the environment and competitors
- ♦ Meet and segment Co-Workers
- ♦ Develop market access strategy and plans, specifying the timeline and roles involved
- ♦ Know how to manage the approach to health authorities for both hospital drugs and street pharmacy drugs
- ♦ Know about the requirements for applying for drug financing: official and supplementary documents
- ♦ Become familiar with the documents and tools that support the value of the drug and that will be essential in the negotiation of price and reimbursement with the health authorities, and in the subsequent regional and local access
- ♦ Study in depth the elements included in a drug value dossier
- ♦ Identify the clinical value of a drug, the value perceived by the patient, and the economic aspect
- ♦ Become familiar with the key concepts of pharmaco-economics
- ♦ Delve into the economic analysis of a drug, differentiating between partial and complete economic evaluations





### Module 3. Digital Health Management: Technological Innovation in the Health Sector

- ♦ Understand the different types of healthcare systems, such as public, private/private/insurance, and managed health care
- ♦ Assess unmet patient needs and chronicity management
- ♦ Analyze the role of cost, effectiveness and safety as determining factors in health care
- ♦ Understand the professional-patient relationship and the rights and duties of both.
- ♦ Analyze the challenges of care pressure and cost management based on ethical principles
- ♦ Define the skills and attitudes needed to be an effective professional manager
- ♦ Explore leadership and the management of emotional climate and work conflicts
- ♦ Utilize timekeeping as a tool for efficient management
- ♦ Analyze health spending and outcomes, as well as processes of improvement, innovation and transformation
- ♦ Evaluate the use of indicators, benchmarking, clinical guidelines, EDO, claims and pharmacovigilance in healthcare quality

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*Complete your update through formats such as videos or interactive summaries”*

03

# Course Management

The program has a renowned faculty that will provide content with a cutting-edge academic approach. This will ensure that students acquire knowledge from recognized experts, who accumulate vast experience in the fields of medicine, pharmacy and business. In this way, physicians can be fully confident in obtaining a high quality degree that will give them the updates required in their daily practice.



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*Get up to date on Access Market  
in Pharma Biotech with great  
specialists in this area"*

## Management



### D. Cardenal Otero, César

- ♦ Pharmabiomedical Executive at Amgen
- ♦ Author of the book "Personal Brand Communication through Social Networks by Professionals in the Health Sector"
- ♦ Degree in Marketing from Prifysgol Cymru University in Wales
- ♦ Distinction degree in the course Inspiring Leadership through Emotional Intelligence from Case Western Reserve University
- ♦ Postgraduate Degree in Management and Health of the Pharmaceutical Industry from the European University
- ♦ Master's Degree in SME Administration from the Polytechnic School of Management
- ♦ Specialization in Social Media Marketing from Northwestern University
- ♦ Postgraduate Diploma in: International Trade and Transport by the University of Cantabria

## Professors

### Ms. Restovic, Gabriela

- ♦ Public health technology evaluator for the Innovation Department of Hospital Clinic de Barcelona
- ♦ Associate Director of Market Access at Novocure
- ♦ Economist at the Catholic University of Chile
- ♦ Master's Degree in Applied Economics at the Univeritat Pompeu Fabra in Barcelona
- ♦ Senior Management Program in Healthcare Government Affairs at EADA, Barcelona Business School
- ♦ Associate professor of academic programs in the service of his specialization

### Ms. Caloto González, M.<sup>a</sup> Teresa

- ♦ Market Access Consultant
- ♦ Subdirector General of Epidemiology of the Ministry of Health
- ♦ Doctorate in Biological Sciences from the Complutense University of Madrid
- ♦ University Expert in Probability and Statistics in Medicine
- ♦ University Expert in Advanced Methods in Applied Statistics
- ♦ Master in Health and Environment, Autonomous University of Madrid
- ♦ Master's Degree in Public Health from the Autonomous University of Madrid
- ♦ Master in Pharmacoeconomics and Health Economics, Pompeu Fabra University, Barcelona





**Ms. Armesto Alonso, Susana**

- ♦ Medical Service, Marqués de Valdecilla University Hospital
- ♦ President of the Astur-Cantabrian-Castellano-Leonese Society of Dermatology
- ♦ Co-author of the book Economic Evaluation of Hospital Hyperbaric Medicine
- ♦ Degree in Medicine and Surgery from the University of Salamanca
- ♦ Doctor of Dermatology, University of Oviedo
- ♦ Master's Degree in Health Management
- ♦ Member of: AEDV Board of Directors



*A unique, key, and decisive educational experience to boost your professional development"*

# 04

## Structure and Content

The content that is part of this Postgraduate Diploma in Access Market in Pharma Biotech covers relevant topics in this field, delving into the updated phases to achieve a successful entry of a new drug in the market. Furthermore, the Relearning method of this degree will allow students to acquire the key concepts of the syllabus at their own pace of study and using less time than with other academic methodologies.



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*Choose the multimedia didactic formats that best suit your study needs and optimize your updating”*

## Module 1. Market access (1). Organization and Processes

- 1.1. Market Access in the pharmaceutical industry
  - 1.1.1. What do we mean by Market Access?
  - 1.1.2. Why is a Market Access department necessary?
  - 1.1.3. Functions of the Market Access department
  - 1.1.4. Conclusions
  - 1.1.5. National Health System (NHS). Organization, Structure and Functions
  - 1.1.6. Health care expenses and drug expenses
  - 1.1.7. Regional Health Service
  - 1.1.8. Organization, Structure and Functions
- 1.2. Authorization and registration of new drugs
  - 1.2.1. Health Authorities
  - 1.2.2. European Medicines Agency (EMA)
  - 1.2.3. Ministry of Health
  - 1.2.4. New drug marketing authorization process: centralized, decentralized and mutual recognition processes.
- 1.3. Evaluation of new drugs at national level
  - 1.3.1. Health Technology Assessment Agencies.
  - 1.3.2. Relations
  - 1.3.3. Europe
  - 1.3.4. Therapeutic Positioning Reports(TPR)
  - 1.3.5. Decision makers and influencers
- 1.4. Other new drug evaluations
  - 1.4.1. GENESIS group evaluations
  - 1.4.2. Regional evaluations
  - 1.4.3. Evaluations in hospital pharmacies: Pharmacy and Therapeutics Committees.
  - 1.4.4. Other evaluations
- 1.5. From drug approval to availability to the patient
  - 1.5.1. New drug pricing and reimbursement application process
  - 1.5.2. Marketing and financing conditions
  - 1.5.3. Procedure for access to medicines at hospital level
  - 1.5.4. Access procedure for drugs dispensed in street pharmacies.
  - 1.5.5. Access to generic and biosimilar drugs.
- 1.6. Drug Financing
  - 1.6.1. Traditional versus new financing schemes
  - 1.6.2. Innovative agreements
  - 1.6.3. Risk-sharing agreements (RSAs)
  - 1.6.4. Types of ARC
  - 1.6.5. Criteria for ARC selection
- 1.7. Medication Purchasing Process
  - 1.7.1. Public contracting
  - 1.7.2. Centralized Purchasing of Medicines and Medical Devices
  - 1.7.3. Framework agreements
  - 1.7.4. Conclusions
- 1.8. Market Access Department (1). Professional Profiles
  - 1.8.1. Evolution of the Market Access professional profile
  - 1.9.2. Professional profiles in Market Access
  - 1.8.3. Market Access Manager
  - 1.8.4. Pharmaco-economics
  - 1.8.5. Pricing
  - 1.8.6. Key Account Manager
- 1.9. Market Access Department (2). Interaction with other departments of the pharmaceutical industry.
  - 1.9.1. Marketing and Sales
  - 1.9.2. Medical Department
  - 1.9.3. Institutional Relations
  - 1.9.4. Regulatory
  - 1.9.5. Communication

**Module 2. Market access (2). Tools and Strategy**

- 2.1. Market access planning for a drug
  - 2.1.1. Analysis of the current scenario: management of the disease, competitors
  - 2.1.2. Region and account segmentation
  - 2.1.3. Scientific Societies
  - 2.1.4. Patient Associations
  - 2.1.5. Designing the Corporate Strategy:
  - 2.1.6. Strategy implementation chronology
- 2.2. Market access Management for a drug
  - 2.2.1. Access Management at Regional Level
  - 2.2.2. Access to the hospital drug market. Hospital pharmacy management and strategy
  - 2.2.3. Access to the street pharmacy drug market.
  - 2.2.4. Primary care pharmacist management and strategy
- 2.3. Clinical value of a drug
  - 2.3.1. Value based on clinical development
  - 2.3.2. Real Life Studies
  - 2.3.3. (RWD/RWE)
  - 2.3.4. Conclusions
- 2.4. Value perceived by the patient
  - 2.4.1. Patient Reported Outcomes, PRO)
  - 2.4.2. Quality of Life Related to Health(CVRS)
  - 2.4.3. Treatment Satisfaction
  - 2.4.4. Incorporation of patient preferences
- 2.5. Economic analysis. Types
  - 2.5.1. Types of Economic Analysis
  - 2.5.2. Parameters to be defined
  - 2.5.3. Partial economic assessments
  - 2.5.4. Costs and Burden of the the Disease
  - 2.5.5. Cost consequence
- 2.6. Studies of Economic Analysis
  - 2.6.1. Budget Impact Studies
  - 2.6.2. Market growth
  - 2.6.3. Associated risks
  - 2.6.4. Intellectual Property
- 2.7. Assessments of Economic Analysis
  - 2.7.1. Full economic assessments
  - 2.7.2. Cost-Effectiveness Analysis
  - 2.7.3. Cost-Utility Analysis
  - 2.7.4. Cost-Benefit Analysis
  - 2.7.5. Decision Rules
- 2.8. Drug value dossier
  - 2.8.1. Contents of the value dossier
  - 2.8.2. The clinical value of the drug
  - 2.8.3. The economic value of the drug
  - 2.8.4. Demonstrating the value of the drug to the health care system
  - 2.8.5. Adaptation of the dossier to the different Autonomous Communities.
- 2.9. Documents required for the price and reimbursement request
  - 2.9.1. Documentation Requirements
  - 2.9.2. Optional Documents
  - 2.9.3. Price documents
  - 2.9.4. Reimbursement documents
- 2.10. New Trends
  - 2.10.1. Value-based purchasing
  - 2.10.2. Multicriteria Analysis (MCA)
  - 2.10.3. Innovative Public Procurement
  - 2.10.4. Latest Trends

### Module 3. Digital Health Management: Technological Innovation in the Health Sector

- 3.1. Hospital information systems
  - 3.1.1. Implementation
  - 3.1.2. Management of Hospital information systems
  - 3.1.3. Electronic Medical Records
  - 3.1.4. Information Systems Interoperability
- 3.2. Telemedicine and digital health
  - 3.2.1. Remote medical consultations
  - 3.2.2. Tele-monitoring platforms
  - 3.2.3. Patient Monitoring
  - 3.2.4. Mobile health and wellness applications
- 3.3. Big data and data analysis in healthcare
  - 3.3.1. Management and Analysis of Large Volumes of Data in health
  - 3.3.2. Use of predictive analysis for Decision-Making
  - 3.3.3. Privacy
  - 3.3.4. Health data security
- 3.4. Artificial intelligence and machine learning in healthcare
  - 3.4.1. Artificial intelligence applications in medical diagnostics
  - 3.4.2. Machine learning algorithms for pattern detection
  - 3.4.3. Chatbots
  - 3.4.4. Virtual assistants in medical care
- 3.5. The Internet of Things (IoT) in health
  - 3.5.1. Connected medical devices and remote monitoring
  - 3.5.2. Intelligent hospital infrastructures
  - 3.5.3. IoT applications in inventory management
  - 3.5.4. Supplies
- 3.6. Cybersecurity in healthcare
  - 3.6.1. Health data protection and regulatory compliance
  - 3.6.2. Prevention of cyber attacks
  - 3.6.3. Ransomware
  - 3.6.4. Security audits and incident management



- 3.7. Virtual Reality (RV) and Augmented Reality(RA) in Medicine
  - 3.7.1. Medical training using VR simulators
  - 3.7.2. AR applications in assisted surgery
  - 3.7.3. Surgical guides
  - 3.7.4. VR therapy and rehabilitation
- 3.8. Robotics in medicine
  - 3.8.1. Use of surgical robots in medical procedures
  - 3.8.2. Automation of tasks in hospitals and laboratories
  - 3.8.3. Prosthesis
  - 3.8.4. Robotic assistance in rehabilitation
- 3.9. Medical Images Analysis
  - 3.9.1. Medical image processing and computational analysis
  - 3.9.2. Computer-aided image diagnosis
  - 3.9.3. Real-time medical imaging
  - 3.9.4. 3D
- 3.10. Blockchain in healthcare
  - 3.10.1. Security and traceability of health data with blockchain
  - 3.10.2. Exchange of medical information between institutions
  - 3.10.3. Management of Informed Consent
  - 3.10.4. Privacy



*Don't miss the opportunity to take this course and make a difference in the pharmaceutical and biotechnology industry"*



05

# Methodology

This academic program offers students a different way of learning. Our methodology uses a cyclical learning approach: **Relearning**.

This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.







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*Discover Relearning, a system that abandons conventional linear learning, to take you through cyclical teaching systems: a way of learning that has proven to be extremely effective, especially in subjects that require memorization"*

## At TECH we use the Case Method

What should a professional do in a given situation? Throughout the program, students will face multiple simulated clinical cases, based on real patients, in which they will have to do research, establish hypotheses, and ultimately resolve the situation. There is an abundance of scientific evidence on the effectiveness of the method. Specialists learn better, faster, and more sustainably over time.

*With TECH you will experience a way of learning that is shaking the foundations of traditional universities around the world.*



According to Dr. Gérvas, the clinical case is the annotated presentation of a patient, or group of patients, which becomes a "case", an example or model that illustrates some peculiar clinical component, either because of its teaching power or because of its uniqueness or rarity. It is essential that the case is based on current professional life, trying to recreate the real conditions in the physician's professional practice.

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*Did you know that this method was developed in 1912, at Harvard, for law students? The case method consisted of presenting students with real-life, complex situations for them to make decisions and justify their decisions on how to solve them. In 1924, Harvard adopted it as a standard teaching method”*

The effectiveness of the method is justified by four fundamental achievements:

1. Students who follow this method not only achieve the assimilation of concepts, but also a development of their mental capacity, through exercises that evaluate real situations and the application of knowledge.
2. Learning is solidly translated into practical skills that allow the student to better integrate into the real world.
3. Ideas and concepts are understood more efficiently, given that the example situations are based on real-life.
4. Students like to feel that the effort they put into their studies is worthwhile. This then translates into a greater interest in learning and more time dedicated to working on the course.



## Relearning Methodology

At TECH we enhance the case method with the best 100% online teaching methodology available: Relearning.

This university is the first in the world to combine the study of clinical cases with a 100% online learning system based on repetition, combining a minimum of 8 different elements in each lesson, a real revolution with respect to the mere study and analysis of cases.

*Professionals will learn through real cases and by resolving complex situations in simulated learning environments. These simulations are developed using state-of-the-art software to facilitate immersive learning.*



At the forefront of world teaching, the Relearning method has managed to improve the overall satisfaction levels of professionals who complete their studies, with respect to the quality indicators of the best online university (Columbia University).

With this methodology, more than 250,000 physicians have been trained with unprecedented success in all clinical specialties regardless of surgical load. Our pedagogical methodology is developed in a highly competitive environment, with a university student body with a strong socioeconomic profile and an average age of 43.5 years old.

*Relearning will allow you to learn with less effort and better performance, involving you more in your specialization, developing a critical mindset, defending arguments, and contrasting opinions: a direct equation to success.*

In our program, learning is not a linear process, but rather a spiral (learn, unlearn, forget, and re-learn). Therefore, we combine each of these elements concentrically.

The overall score obtained by TECH's learning system is 8.01, according to the highest international standards.



This program offers the best educational material, prepared with professionals in mind:



#### Study Material

All teaching material is produced by the specialists who teach the course, specifically for the course, so that the teaching content is highly specific and precise.

These contents are then applied to the audiovisual format, to create the TECH online working method. All this, with the latest techniques that offer high quality pieces in each and every one of the materials that are made available to the student.



#### Surgical Techniques and Procedures on Video

TECH introduces students to the latest techniques, the latest educational advances and to the forefront of current medical techniques. All of this in direct contact with students and explained in detail so as to aid their assimilation and understanding. And best of all, you can watch the videos as many times as you like.



#### Interactive Summaries

The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

This exclusive educational system for presenting multimedia content was awarded by Microsoft as a "European Success Story".



#### Additional Reading

Recent articles, consensus documents and international guidelines, among others. In TECH's virtual library, students will have access to everything they need to complete their course.





#### Expert-Led Case Studies and Case Analysis

Effective learning ought to be contextual. Therefore, TECH presents real cases in which the expert will guide students, focusing on and solving the different situations: a clear and direct way to achieve the highest degree of understanding.



#### Testing & Retesting

We periodically evaluate and re-evaluate students' knowledge throughout the program, through assessment and self-assessment activities and exercises, so that they can see how they are achieving their goals.



#### Classes

There is scientific evidence on the usefulness of learning by observing experts. The system known as Learning from an Expert strengthens knowledge and memory, and generates confidence in future difficult decisions.



#### Quick Action Guides

TECH offers the most relevant contents of the course in the form of worksheets or quick action guides. A synthetic, practical, and effective way to help students progress in their learning.



# 06 Certificate

The Postgraduate Diploma in Access Market in Pharma Biotech guarantees students, in addition to the most rigorous and up-to-date education, access to a Postgraduate Diploma issued by TECH Technological University.





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*Successfully complete this program and receive your university qualification without having to travel or fill out laborious paperwork”*

This **Postgraduate Diploma in Market Access in Pharma Biotech** contains the most complete and up-to-date scientific program on the market.

After the student has passed the assessments, they will receive their corresponding **Postgraduate Diploma** issued by **TECH Technological University** via tracked delivery\*.

The certificate issued by **TECH Technological University** will reflect the qualification obtained in the Postgraduate Diploma, and meets the requirements commonly demanded by labor exchanges, competitive examinations, and professional career evaluation committees.

Title: **Postgraduate Diploma in Market Access in Pharma Biotech**

Official N° of Hours: **450 h.**



\*Apostille Convention. In the event that the student wishes to have their paper certificate issued with an apostille, TECH EDUCATION will make the necessary arrangements to obtain it, at an additional cost.



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# Postgraduate Diploma

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