

Postgraduate Certificate

Medical Department in Pharma Biotech





Postgraduate Certificate Medical Department in Pharma Biotech

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

Website: www.techtute.com/us/medicine/postgraduate-certificate/medical-department-pharma-biotech

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01

Introduction

To ensure product safety, efficacy and excellence in a clinical company, it is essential to have a department specialized in the field. In this way, the solid scientific expertise of its members supports drug development, product monitoring, effective communication and continuing medical education. For this reason, it is crucial for physicians to keep up to date on all aspects related to their environment. In this sense, TECH has developed a 100% online program, which offers students the opportunity to balance their daily responsibilities with their studies, as it is not restricted by pre-established schedules.



A close-up photograph of a medical device, possibly a syringe or a specialized needle, with a prominent red ring. The device is metallic and has a textured, knurled section. The background is blurred, showing other parts of the device. The image is partially obscured by a blue and white geometric overlay.

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You will broaden your knowledge about the structure and functions of the Medical Department in different companies of the pharmaceutical industry"

One of the main responsibilities of the medical areas is to ensure that all Pharma Biotech products and services comply with medical and regulatory standards. This involves reviewing and analyzing scientific literature, conducting clinical studies, and ensuring that product information and promotion is accurate and ethical.

In addition, this area is the key link between the company and the medical and scientific community. It works closely with specialists to obtain their perspective and expertise in product development and marketing. It also organizes and participates in congresses, symposia and scientific meetings, where Pharma Biotech's advances and research results are presented.

Another important function of these units is pharmacovigilance management, which involves monitoring the safety and efficacy of the company's products once they are on the market. This is responsible for collecting and evaluating reports of adverse events and unexpected reactions, as well as communicating this information to the appropriate regulatory authorities.

It is for this reason that TECH has developed this Diploma in the Medical Department in Pharma Biotech. It is presented in a 100% online format, which offers the health professional a unique learning experience. In this way, by means of didactic resources housed in a virtual library, the participant will have access at any time and place from a device with a network connection. In addition to this, this methodology is combined with Relearning, which will allow the student to spend fewer hours of study and understand concepts with greater performance.

This **Postgraduate Certificate in Medical Department 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



You will delve into the key roles within the Medical Department and how they relate to other areas such as Marketing, Access and Sales"

“*You will explore all the career opportunities that the Medical Department has to offer in the Pharmaceutical Industry*”

Thanks to TECH, you will immerse yourself in the world of clinical trials and delve into the foundations, legislation and phases that compose them.

You will take an in-depth look at Real Clinical Practice (RWE) studies and their relevance in the design, analysis and communication of results for the Biotech industry.

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

The 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 immersive education programmed to learn in real situations.

This program is designed around Problem-Based Learning, whereby the professional must try to solve the different professional practice situations that arise during the academic year. For this purpose, the students will be assisted by an innovative interactive video system created by renowned and experienced experts.



02

Objectives

The objective of this degree is to provide the healthcare expert with the fundamental knowledge and resources to work in clinical settings. This will enable them to use their clinical skills to contribute to the success of the company in the medical and pharmaceutical field. In this way, you will be able to ensure regulatory compliance, effective project management, marketing strategy design and optimal communication with healthcare professionals.



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With this Postgraduate Certificate, you will discover how clinical trial monitoring is carried out, both face-to-face and remotely, and how to manage data to obtain results”



General Objectives

- ♦ 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
- ♦ 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
- ♦ 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 about the environment and competitors
- ♦ Knowing 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

- ◆ Understand the role and objective of the medical department
- ◆ Analyze the general structure of the medical department and its staff
- ◆ Explore the main activities of the medical department
- ◆ Collaborate with other areas of the company
- ◆ Explore current challenges and trends
- ◆ Understand the purpose of clinical trials
- ◆ Analyze the types of clinical trials
- ◆ Explore in the phases of clinical trials
- ◆ Define the focus of each phase
- ◆ Plan and design clinical trials
- ◆ Know the ethical and regulatory aspects of clinical trials
- ◆ Delve into sample and sample size selection
- ◆ Collect and analyze data
- ◆ Define roles and responsibilities of the different participants in clinical trials
- ◆ Explore randomization and types of blinding
- ◆ Analyze data and interpret results
- ◆ Design protocols
- ◆ Develop an Informed Consent and Patient Information Sheet
- ◆ Understand the purpose of monitoring in clinical trials
- ◆ Define the responsibilities and roles of the clinical trial monitor

03

Course Management

This program stands out for having a high quality faculty that will offer innovative learning. The professors are renowned experts in the fields of Pharmaceutical Industry, Medicine and Business, and have extensive work experience. In this way, students are guaranteed to receive excellent learning, acquiring knowledge from leading specialists in their respective areas.





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You will understand the role of the Medical Affairs Department and its co-leadership in multifunctional pharmaceutical organizations”

Management



Mr. 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. Pascual Alfonso, Eva

- ♦ Senior Medical Advisor at AMGEN
- ♦ Degree in Pharmacy from the Complutense University of Madrid
- ♦ Specialization in Methodology and Management of Clinical Trials and Drug Registration by the Spanish Association of Pharmaceutical Industry Pharmacists (AEFI)
- ♦ MBA in Management and Direction of the Pharmaceutical Industry from the University of Alcalá de Henares



04

Structure and Content

TECH presents this qualification with an up-to-date content that will address the functioning and responsibilities of the Medical Department in the pharmaceutical industry. It will also focus on this area under the organizational context, emphasizing its informative role on advances in treatments and the importance of having scientific and communicative skills. With this in mind, the program has been designed in a 100% online format. This provides students with multimedia resources such as specialized readings and interactive summaries that can be accessed anywhere with just an Internet-connected device.



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With the Relearning method, you will avoid spending long hours studying and will be able to focus on the most important concepts in an efficient way"

Module 1. The Medical Department

- 1.1. The Medical Department
 - 1.1.1. General structure of the medical department in different companies
 - 1.1.2. Purpose and functions of the department
 - 1.1.3. Roles in the medical department
 - 1.1.4. How they relate to other departments: Marketing, Access, Sales, etc
 - 1.1.5. Career opportunities for the medical department in the Pharmaceutical Industry
- 1.2. Monitoring
 - 1.2.1. Fundamentals of Clinical Development
 - 1.2.2. Legislation in clinical trials
 - 1.2.3. Types of Clinical Trials
 - 1.2.4. Clinical Trials Phases
 - 1.2.4.1. Phase I Clinical Studies
 - 1.2.4.2. Phase II Clinical Studies
 - 1.2.4.3. Phase III Clinical Studies
 - 1.2.4.4. Phase IV Clinical Studies
- 1.3. Clinical Trials Methodology
 - 1.3.1. Clinical Trial Design
 - 1.3.2. Stages in the Development of Clinical Trials
 - 1.3.3. Clinical Trials Viability
 - 1.3.4. Identification and Selection of Researcher Centers
 - 1.3.5. Recruitment Materials and Strategies
 - 1.3.6. Contracts with Research Centers
 - 1.3.7. Protocol
- 1.4. Trial Monitoring: Monitoring and Control
 - 1.4.1. Monitoring Visit
 - 1.4.1.1. Pre-Study Visit
 - 1.4.1.2. Initiation Visit
 - 1.4.1.3. Monitoring Visit
 - 1.4.1.4. Closing Visit
 - 1.4.2. Remote Monitoring
 - 1.4.3. Monitoring Visit Reports
 - 1.4.4. Data Management Obtaining results



- 1.5. Real Clinical Practice Studies. RWE
 - 1.5.1. RWE studies: design, analysis, minimization of bias
 - 1.5.2. Types of RWE Study
 - 1.5.3. Integration in the medical plan
 - 1.5.4. Inquiry and Communication of Results
 - 1.5.5. Current challenges in the use of evidence and knowledge of RWE
 - 1.5.6. How RWE can support decision making throughout the product life cycle
 - 1.5.7. Investigator Initiated Studies/Trials and Research Collaborations
- 1.6. The Medical Affairs Department
 - 1.6.1. What is the Medical Affairs Department?
 - 1.6.1.1. Purpose and functions of the department
 - 1.6.1.2. General structure of the department in different companies
 - 1.6.1.3. Interactions Between Medical Affairs And Other Departments (Clinical Operations & Commercial Departments)
 - 1.6.1.4. The relationship of medical issues in terms of product life cycle
 - 1.6.2. Creation of state-of-the-art data generation programs
 - 1.6.3. Medical's co-leadership role
 - 1.6.4. Affairs in cross-functional pharmaceutical organizations
- 1.7 Roles in the Medical Affairs Department
 - 1.7.1. Role of the Medical Advisor
 - 1.7.2. Functions of the Medical Advisor
 - 1.7.3. Participation tactics with HCP
 - 1.7.3.1. Advisory Board and promotion programs
 - 1.7.3.2. Scientific publications
 - 1.7.3.3. Planning of scientific congresses
 - 1.7.4. Elaboration of a medical Communication Plan
 - 1.7.5. Design of medical product strategy
 - 1.7.6. Management of medical projects and studies based on real clinical practice data (RWE)
 - 1.7.7. Role of the Medical Science Liaison
 - 1.7.7.1. MSL functions: medical communication and interlocutors
 - 1.7.7.2. Implementation of medical projects and territorial management
 - 1.7.7.3. Investigator Initiated Studies/Trials and Research Collaborations
 - 1.7.7.4. Scientific Communication and Insights Gathering
- 1.8. Compliance In the Medical Affairs Department
 - 1.8.1. Concept of compliance in the medical department
 - 1.8.1.1. Promotion of prescription drugs
 - 1.8.1.2. Interrelation with Health Professionals and Organizations
 - 1.8.1.3. Interrelation with Patient Organizations
 - 1.8.2. Definition of On Label/Off Label
 - 1.8.3. Differences between commercial department and medical affairs
 - 1.8.4. Code of Good Clinical Practice in medical promotion and information
- 1.9. Medical Reports
 - 1.9.1. Comprehensive Communication Plan
 - 1.9.2. Media and omnichannel plan
 - 1.9.3. Integration of the communication plan in the medical plan
 - 1.9.4. Information Resources in biomedicine
 - 1.9.4.1. International sources: Pubmed, Embase, WOS, etc
 - 1.9.4.2. Sources in Latin America: CSIC , Ibecs, LILACS, indexes etc
 - 1.9.4.3. Sources for locating clinical trials: WHO, ClinicalTrials, Cochrane CENTRAL, etc
 - 1.9.4.4. Drug Information Sources: Bot Plus Web, FDA, etc
 - 1.9.4.5. Other resources: official bodies, web pages, scientific societies, associations, evaluation agencies, etc
- 1.10. Pharmacovigilance
 - 1.10.1. Pharmacovigilance in Clinical Trials
 - 1.10.1.1. Adverse Event Management
 - 1.10.2. Notification of Adverse Events, Eudravigilance
 - 1.10.3. Periodic Security Reports
 - 1.10.4. Pharmacovigilance in Other Clinical Trials: Post-authorization Studies

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 Certificate in Medical Department in Pharma Biotech guarantees students, in addition to the most rigorous and up-to-date education, access to a Postgraduate Certificate 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 Certificate in Medical Department 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 Certificate** issued by **TECH Technological University** via tracked delivery*.

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

Title: **Postgraduate Certificate in Medical Department in Pharma Biotech**

Official N° of Hours: **150 h.**



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



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