

# Postgraduate Certificate

Medical Department at Pharma  
Biotech for Nursing



## Postgraduate Certificate Medical Department at Pharma Biotech for Nursing

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

Website: [www.techtitute.com/in/nursing/postgraduate-certificate/medical-department-pharma-biotech-nursing](http://www.techtitute.com/in/nursing/postgraduate-certificate/medical-department-pharma-biotech-nursing)

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# 01

# Introduction

To guarantee the safety, efficacy and excellence of the products designed by pharmaceutical companies, it is essential to have a specialized area in the field. In this way, the solid experience and up-to-date knowledge of its members supports drug development and its supervision. It is therefore essential for nurses working in this field to keep up-to-date so that they do not fall behind with developments in the field. For this reason, TECH has designed this program, which will allow students to delve into cutting-edge clinical trial methodologies and techniques for communicating novel scientific findings. In addition, you will enjoy a 100% online modality that will allow you to combine your daily responsibilities with your studies.



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*Identify, throughout this program, revolutionary techniques with which to undertake the design of clinical trials aimed at the development of pharmacological products”*



One of the main responsibilities of the Medical Department is to ensure compliance with health and regulatory standards in all Pharma Biotech products and services developed. To this end, they participate in the conduct of clinical studies, prepare information on clinical efficacy and safety, and communicate the latest healthcare advances to professionals. In this way, healthcare professionals working in this field must keep up-to-date in order to position themselves at the forefront of research and contribute to the improvement of pharmacology.

In view of this situation, TECH has designed this Postgraduate Certificate, which allows the nurse to get up-to-date with respect to the operation of the Medical Department in Pharma Biotech. Through this program, you will delve into the protocols for the elaboration of a scientific communication plan or the current particularities of the various phases of clinical trials. You will also learn about the sophisticated procedures for periodic drug safety reporting.

In addition, this Postgraduate Certificate is taught in a 100% online format, providing the student with a unique learning experience through didactic resources that can be enjoyed at any time and place. In addition, this methodology is combined with Relearning, which allows the nurse to reduce study hours and understand the concepts more effectively.

This **Postgraduate Certificate in Medical Department at Pharma Biotech for Nursing** contains the most complete and up-to-date scientific program on the market. The most important features include:

- ◆ The development of case studies presented by Pharma Biotech specialists
- ◆ The graphic, schematic, and practical contents with which they are created, provide scientific and practical information on the disciplines that are essential for professional practice
- ◆ Practical exercises where the self-assessment process can be carried out 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 incorporate in your daily practice the most up-to-date knowledge about clinical trials and the different phases and legislations that govern them"*

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*Thanks to TECH, you will implement clinical trial methodology and acquire skills for the design, recruitment and follow-up of clinical trials"*

*You will explore into Real Clinical Practice Studies (RWE) and discover how they support decision making in the drug product lifecycle.*

*With this Postgraduate Certificate, you will delve into the latest advances in Medical Affairs departments.*

The program's teaching staff includes professionals from the field who contribute their work experience to this educational 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 educational year. For this purpose, the students will be assisted by an innovative interactive video system created by renowned and experienced experts.



# 02 Objectives

The purpose of this program is to provide the nurse with the most up-to-date essential knowledge and resources to perform in clinical settings. This will enable you to use your healthcare skills to contribute to the company's success in the medical and pharmaceutical field. In this way, you can ensure regulatory compliance, efficient project management and optimal communication with healthcare professionals.





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*In just 6 weeks, you will gain a deep and up-to-date insight into the workings of the Medical Department at Pharma Biotech"*



## General Objectives

- ◆ Acquire knowledge about the history of strategic Management
- ◆ Categorize the different definitions over time
- ◆ Assess financial efficiency
- ◆ Optimize working capital management
- ◆ Understand the different types of health care systems, such as public, private/private insurance, and private 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 the structure, organization and functions of the National Health System
- ◆ Delve into the steps involved in planning the market access of a new drug
- ◆ Review the points to be analyzed prior to the development of the access plan to understand the environment and competitors
- ◆ Know the capabilities and ethics of the Coach
- ◆ Understand the essence of coaching and its focus on learning
- ◆ Acquire basic knowledge of the fundamental concepts of leadership and their 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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- Understand the role and purpose of the medical department
- Analyze the general Structure of the medical department and the team that integrates it
- Explore the main activities of the medical department
- Collaborate with other areas of the company
- Explore current challenges and trends
- Understanding the purpose of clinical trials
- Analyze the types of clinical trials
- Explore in the phases of clinical trials
- Define the objective of each phase
- Plan and design clinical trials
- Know the ethical and regulatory aspects of clinical trials
- Delve deeper into sample selection and sample size
- 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
- Know the purpose of monitoring in clinical trials
- Define the responsibilities and functions of the clinical trial monitor



*Study through cutting-edge didactic formats such as the explanatory video or the interactive summary and achieve your professional objectives with ease"*

03

# Course Management

This program is distinguished by a team of highly qualified teachers who will impart innovative knowledge. The faculty is composed of recognized experts in the fields of pharmaceuticals, medicine and business, and have extensive professional experience. In this way, students will have the guarantee of acquiring excellent knowledge directly from outstanding specialists in the Biotech industry.





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*TECH has selected the best specialists in Pharma Biotech to provide you with the most cutting-edge knowledge in this field"*



## 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
- ♦ Distinguished grade in the Inspiring Leadership through Emotional Intelligence course at Case Western Reserve University
- ♦ Postgraduate Degree in Management and Health of the Pharmaceutical Industry of 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, University of Cantabria, Spain
- ♦ Postgraduate Certificate in Business Administration from the University of Cantabria

## Professors

### Ms. Rodríguez Fernández, Silvia

- ♦ Project Manager Scientific Communications at Boehringer Ingelheim Medical Unit
- ♦ Senior Scientific Advisor for R&D at Ahead Therapeutics
- ♦ Medical Advisor at Ahead Therapeutics
- ♦ Product Manager in Amgen's Inflammation Marketing team
- ♦ D. in Advanced Immunology from the Autonomous University of Barcelona
- ♦ MBA from the Pharmaceutical and Biotechnology Industry
- ♦ Master's Degree in Advanced Immunology from the Autonomous University of Barcelona
- ♦ Degree in Biomedical Sciences from the Autonomous University of Barcelona



# 04

## Structure and Content

TECH presents this program with up-to-date content that will analyze the functioning and responsibilities of the Medical Department in the pharmaceutical industry. In addition, it will focus on this discipline within the organizational context, emphasizing its informative role with respect to treatment advances and the importance of having scientific and communication skills. All this, through a variety of multimedia formats, which will be accessible from any location simply by using a device connected to the Internet.





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*Inquire into the collection of scientific information relevant to the Medical Affairs Department through this program"*

## 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. Objective 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 in The Medical Department in The Pharmaceutical Industry
- 1.2. Monitoring
  - 1.2.1. Fundamentals of Clinical Development
  - 1.2.2. Legislation on Clinical Trials
  - 1.2.3. Types of Clinical Trials
  - 1.2.4. Clinical Trial Phases
    - 1.2.4.1. Phase I Clinical Trials
    - 1.2.4.2. Phase II Clinical Trials
    - 1.2.4.3. Phase III Clinical Trials
    - 1.2.4.4. Phase IV Clinical Trials
- 1.3. Clinical Trial Methodology
  - 1.3.1. Clinical Trial Design
  - 1.3.2. Stages in the Development of Clinical Trial
  - 1.3.3. Clinical Trial Feasibility
  - 1.3.4. Identification and Selection of Centers and Researchers
  - 1.3.5. Recruitment Materials and Strategies
  - 1.3.6. Contracts with Research Centers
  - 1.3.7. Protocol
  - 1.3.8. Patient Information Sheet and Informed Consent
- 1.4. Trial Monitoring: Follow-Up and Control
  - 1.4.1. Monitoring Visit
    - 1.4.1.1. Pre-Study Visit
    - 1.4.1.2. Start-up 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 Studies
  - 1.5.3. Integration in The Medical Plan
  - 1.5.4. Collection 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. Initiated Studies/Trials and Research Collaborations Investigator
- 1.6. The Medical Affairs Department
  - 1.6.1. What Is The Medical Affairs Department?
    - 1.6.1.1. Objective 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 Multifunctional Pharmaceutical Organizations
- 1.7. Roles in The Medical Affairs Department
  - 1.7.1. Medical Advisor Role
  - 1.7.2. Medical Advisor Functions
  - 1.7.3. HCP Participation Tactics
    - 1.7.3.1. Advisory Board and Promotional Programs
    - 1.7.3.2. Scientific Publications
    - 1.7.3.3. Scientific Congress Planning
  - 1.7.4. Development of a Medical Communications Plan
  - 1.7.5. Medical Product Strategy Design
  - 1.7.6. Management of Medical Projects and Studies Based on Real Clinical Practice Data (RWE)
  - 1.7.7. Medical Science Liaison Role
    - 1.7.7.1. MSL Functions: Medical Communication and Partners
    - 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 Collection of Insights
- 1.8. Compliance In the Medical Affairs Department
  - 1.8.1. Compliance Concept in The Medical Department
    - 1.8.1.1. Promotion of Prescription Drugs
    - 1.8.1.2. Interrelation with Healthcare Professionals and Organizations
    - 1.8.1.3. Interrelation with Patient Organizations
  - 1.8.2. On Label/Off Label Definition
  - 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 Information
  - 1.9.1. Integral Communication Plan
  - 1.9.2. Media and Omnichannel Plan
  - 1.9.3. Integration of The Communication Plan in Medical Plan
  - 1.9.4. Biomedical Information Resources
    - 1.9.4.1. International Sources: Pubmed, Embase, WOS, etc
    - 1.9.4.2. Sources in Latin America: Indexes CSIC, Ibecs, LILACS, etc
    - 1.9.4.3. Sources for Locating Clinical Trials: WHO, ClinicalTrials, Cochrane CENTRAL, etc.
    - 1.9.4.4. Sources of Drug Information: Bot Plus Web, FDA, etc
    - 1.9.4.5. Other Resources: Official Organizations, Websites, Scientific Societies, Associations, Assessment Agencies, etc
- 1.10. Pharmacovigilance
  - 1.10.1. Pharmacovigilance in Clinical Trials
    - 1.10.1.1. Legal Framework and Definitions
    - 1.10.1.2. Adverse Event Management
  - 1.10.2. Notification of Adverse Events, Eudravigilance
  - 1.10.3. Periodic Security Reports
  - 1.10.4. Pharmacovigilance in Others Clinical Trials: Posauthorization 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.



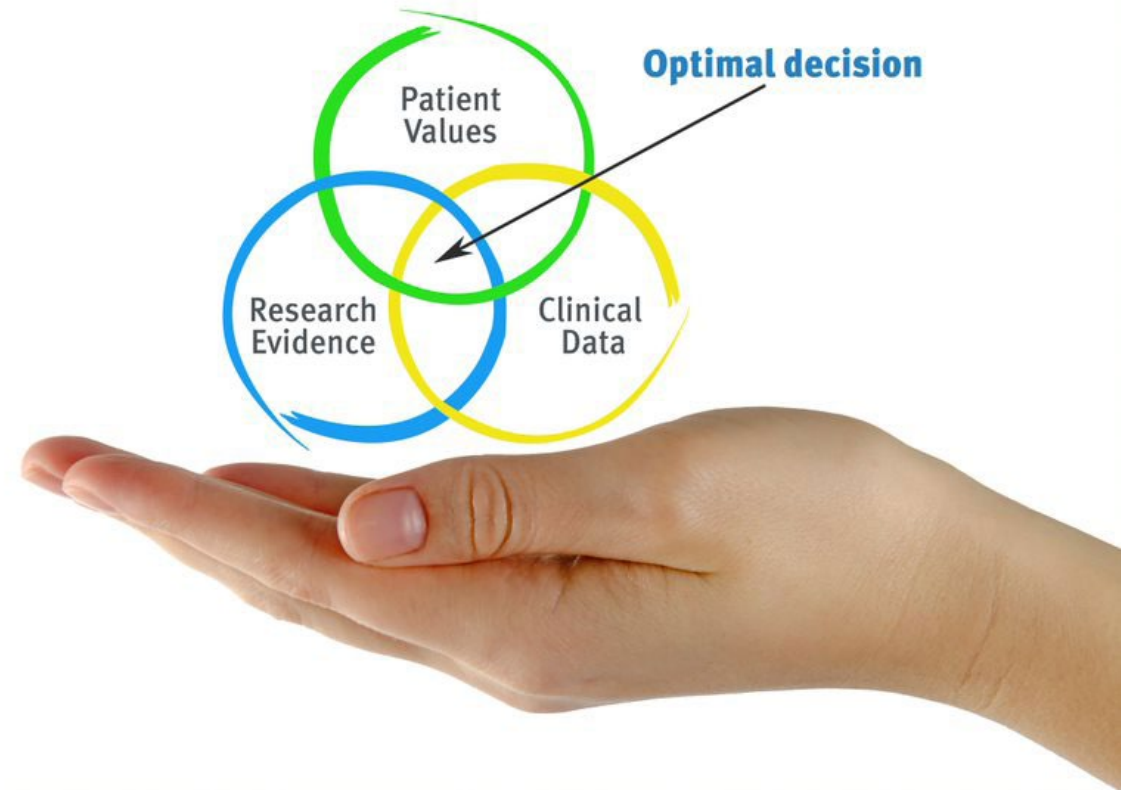
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*Discover Relearning, a system that abandons conventional linear learning, to take you through cyclical teaching systems: a way of learning that has proven to be extremely effective, especially in subjects that require memorization"*

## At TECH Nursing School we use the Case Method

In a given situation, what should a professional do? 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. Nurses learn better, faster, and more sustainably over time.

*With TECH, nurses can experience a learning methodology that is shaking the foundations of traditional universities around the world.*



According to Dr. Gervas, 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, in an attempt to recreate the real conditions in professional nursing 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. Nurses who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. The learning process has a clear focus on practical skills that allow the nursing professional to better integrate knowledge acquisition into the hospital setting or primary care.
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 case studies with a 100% online learning system based on repetition combining a minimum of 8 different elements in each lesson, which is a real revolution compared to the simple study and analysis of cases.



*The nurse will learn through real cases and by solving 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 we have trained more than 175,000 nurses with unprecedented success in all specialities regardless of practical workload. 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 really 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.



### Nursing Techniques and Procedures on Video

We introduce you to the latest techniques, to the latest educational advances, 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 them as many times as you want.



### 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 suggesting that observing third-party experts can be useful.  
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 at Pharma Biotech for Nursing 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 at Pharma Biotech for Nursing** contains the most complete and up-to-date scientific 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 Certificate 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 at Pharma Biotech for Nursing**

Official N° of Hours: **150 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.

future  
health confidence people  
education information tutors  
guarantee accreditation teaching  
institutions technology learning  
community commitment  
personalized service innovation  
knowledge present  
development language  
classroom



**Postgraduate Certificate**  
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for Nursing

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