



### Postgraduate Diploma

### Pharma Biotech Equipment Management for Nursing

» Modality: online

» Duration: 6 months

» Certificate: TECH Technological University

» Dedication: 16h/week

» Schedule: at your own pace

» Exams: online

Website: www.techtitute.com/in/nursing/postgraduate-diploma/postgraduate-diploma-pharma-biotech-equipment-management-nursing

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### tech 06 | Introduction

In a complex context such as the pharmaceutical and biotechnology industry, equipment management plays a key role in ensuring compliance with regulations and quality standards, as well as in maximizing productivity and reducing the risks associated with product research and development. In this case, Pharma Biotech's working groups are made up of professionals with diverse profiles, such as scientists, researchers, engineers, physicians and regulatory specialists, among others.

Effective management of these groups also involves establishing clear roles and responsibilities, fostering open and fluid communication, strategic planning, setting clear objectives and encouraging close collaboration among team members. In addition, it also involves properly allocating resources and applying sound project control practices.

In this sense, it is important that the nurse with the desire to lead these working groups has the most advanced skills and knowledge to lead and coordinate multidisciplinary teams in the pharmaceutical and biotechnology industry. With this in mind, TECH has developed this Postgraduate Diploma, which will allow these professionals to perfect their skills in this field. In this way, you will identify cuttingedge coaching strategies to boost employee motivation or techniques to manage conflicts that may arise in the workplace.

The program is presented in a 100% online format, which allows professionals to carry out their daily activities and learning without being subject to a pre-established schedule. In addition, the program incorporates the Relearning learning methodology, which will enable the nurses to strengthen their understanding of knowledge in the long term.

This **Postgraduate Diploma in Pharma Biotech Equipment Management 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



Delve into the different coaching models and discover how to apply them in the management of nursing teams in the pharmaceutical industry"



You will learn the tools to understand the current situation of your team and overcome problems in search of common objectives thanks to this Postgraduate Diploma offered by TECH"

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.

Its multimedia content, developed with the latest educational technology, will enable the professional to learn in a situated and contextual way, i.e., a simulated environment that will provide immersive training programmed to train 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.

You will apply the Grow model to your work practice and visualize what role each member of your team should play.

In just 12 months, you will learn the best techniques for effective leadership of Pharma Biotech teams.







### tech 10 | Objectives



### **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**

#### Module 1. Comprehensive Coaching in Pharma Biotech

- Know the capabilities and ethics of the Coach
- Understand the essence of coaching and its focus on learning
- Know the contributions of North American, Humanistic-European and Ontological Coaching
- Evaluate the client's current situation, breakdowns and objectives
- Use tools such as the "Wheel of Professional Life" to know the current situation
- Define individual and team goals, vision and objectives
- Explore models such as GROW, SMART methodology and Merlin Method
- Use examples such as the Mandala to visualize the ideal situation of the team
- Understand mental models and their importance in healthy teams
- · Observe, distinguish and analyze beliefs, judgments, facts and opinions

### Module 2. The Medical Department

- 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

### Module 3. Team Leadership in Pharma

- 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
- Delve into the development of leadership skills necessary to efficiently manage teams
- Know the organization and time management strategies to optimize team productivity
- Learn how to plan and set clear and measurable objectives for the team, and effectively evaluate their performance
- Delve into team management skills, including motivation, effective communication and conflict resolution

- Develop decision-making skills based on the evaluation of options and consideration of different factors
- Learn negotiation strategies and techniques to manage conflicts within the team
- Understand the importance of personal and professional development of team members, and its impact on the overall success of the project
- Apply the knowledge acquired to work towards the achievement of a common objective through the development of a specific project



You'll have at your fingertips interactive summaries and a range of multimedia resources to help you communicate effectively, engage with your team, motivate and make good decisions"





### tech 14 | Course Management

### 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**

#### Mr. Cobo Sainz, Manuel

- Key Account Manager at Bayer
- KAM Champions in Bayer
- Degree in Business Administration and Management from Cesine University Center attached to the University of Wales
- ECOI's Coaching Expert Course
- Executive MBA from Cesine
- Master's Degree in Marketing and Sales Management from ESIC

#### 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

#### Mr. Junco Burgos, Eduardo

- Therapeutic Area Director at AMGEN
- Service Manager for GRUPO CLECE (TALHER)
- Product Specialist in Celgene
- Product Specialist in Amgen
- Key Account Manager in Shionogi
- Agricultural Engineer graduated from the Polytechnic University of Madrid





### tech 18 | Structure and Content

### Module 1. Comprehensive Coaching in Pharma Biotech

- 1.1. Basis of Coaching in Pharma Biotech
  - 1.1.1. Coach's Capabilities and Ethics
  - 1.1.2. The Essence of Coaching
  - 1.1.3. Learning to Learn
  - 1.1.4. Recommended Film: The Pacific Warrior
- 1.2. The Coaching Process Schools and Models
  - 1.2.1. North American Coaching Contributions
  - 1.2.2. Humanistic-European Coaching Contributions
  - 1.2.3. Ontological Coaching Contributions
  - 1.2.4. Conclusions
- 1.3. The Coachee-Client
  - 1.3.1. Present Breakdown Objectives
  - 1.3.2. How to Know The Situation of Each Person in a Professional Team and in This Way Be Able to Overcome Problems in Order to Achieve The Objectives
  - 1.3.3. Know The Current Situation through The Tool "THE WAY OF PROFESSIONAL LIFE"
  - 1.3.4. Conclusions
- 1.4. Ideal Situation
  - 1.4.1. Where I Am Going
  - 1.4.2. Identify Goal, Vision and Clarification of Objectives Both as an Individual Professional and as a Team Coordinator
  - 1.4.3. Grow Model
  - 1.4.4. Example: Where You Want to Have Each Member of Your Team through a Mandala
- 1.5. The Technique Our Mind
  - 1.5.1. Mental Models
  - 1.5.2. Observe, Distinguish
  - 1.5.3. Beliefs, Judgments
  - 1.5.4. Facts and Opinions

- 1.6. The Technique Language
  - 1.6.1. Basic Postulates of the Ontology of Language according to Rafael Echevarría
  - 1.6.2. Listening, Silence and Speech Competence
  - 1.6.3. Recommended Books
  - 1.6.4. Rafael Echevarría Language Ontology
  - 1.6.5 Leonardo Wolk The Art of Blowing Embers
- .7. The Technique Emotion
  - 1.7.1. Management and Emotional Intelligence
  - 1.7.2. Legitimizing Emotion in order to Manage It from the Linguistic Dimensions
  - 1.7.3. Emotional
  - 1.7.4. Conclusions
- 1.8. Technique-Corporeality
  - 1.8.1. Who Am I from my Body?
    - 182 Posture and Movement
    - 1.8.3. Trends that Support or Block Conversations with the Body
    - 1.8.4. Conclusions
- .9. Powerful Questions How to Use The Questions to Help Each Member of Your Team Find Their Best Version of Themselves
  - 1.9.1. To Determine The Profile of Our Customer and to Design a Plan of Action
  - 1.9.2. Coaching Questions to Reconnect You
  - 1.9.3. Coaching Questions to Change Perspective
  - 1.9.4. Coaching Questions for Awareness
  - 1.9.5. Coaching Questions to Create Action
  - 1.9.6. Coaching Questions for Goal Setting
  - 1.9.7. Coaching Questions for Designing a Plan of Action
  - 1.9.8. Coaching Questions for Clients to Find Their Own Solutions
- 1.10. The Action
  - 1.10.1. Action Plan Phases
  - 1.10.2. Accompany
  - 1.10.3. Monitoring
  - 1.10.4. Commitment
  - 1.10.5. How to Elaborate a Plan of Action with Each Delegate of Your Team

### Module 2. The Medical Department

- 2.1. The Medical Department
  - 2.1.1. General Structure of The Medical Department in Different Companies
  - 2.1.2. Objective and Functions of The Department
  - 2.1.3. Roles in The Medical Department
  - 2.1.4. How They Relate to Other Departments: Marketing, Access, Sales, etc.
  - 2.1.5. Career Opportunities in The Medical Department in The Pharmaceutical Industry
- 2.2. Monitoring
  - 2.2.1. Fundamentals of Clinical Development
  - 2.2.2. Legislation on Clinical Trials
  - 2.2.3. Types of Clinical Trials
  - 2.2.4. Clinical Trial Phases
    - 2.2.4.1. Phase I Clinical Studies
    - 2.2.4.2. Phase II Clinical Studies
    - 2.2.4.3. Phase III Clinical Studies
    - 2 2 4 4 Phase IV Clinical Studies
- 2.3. Clinical Trial Methodology
  - 2.3.1. Clinical Trial Design
  - 2.3.2. Stages in the Development of Clinical Trial
  - 2.3.3. Clinical Trial Feasibility
  - 2.3.4. Identification and Selection of Centers and Researchers
  - 2.3.5. Recruitment Materials and Strategies
  - 2.3.6 Contracts with Research Centers
  - 2.3.7. Protocol
  - 2.3.8. Patient Information Sheet and Informed Consent
- 2.4. Trial Monitoring: Follow-Up and Control
  - 2.4.1. Monitoring Visit
    - 2.4.1.1. Pre-Study Visit
    - 2.4.1.2. Initiation Visit
    - 2.4.1.3. Monitoring Visit
    - 2.4.1.4. Closing Visit
  - 2.4.2. Remote Monitoring
  - 2.4.3. Monitoring Visit Reports
  - 2.4.4. Data Management Obtaining Results

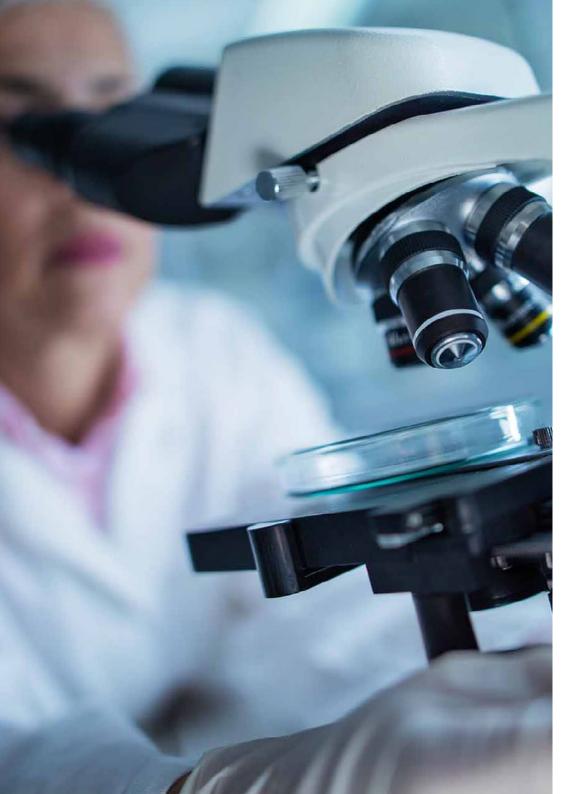
- 2.5. Real Clinical Practice Studies RWE
  - 2.5.1. RWE Studies: Design, Analysis, Minimization of Bias
  - 2.5.2. Types of RWE Studies
  - 2.5.3. Integration in The Medical Plan
  - 2.5.4. Collection and Communication of Results
  - 2.5.5. Current Challenges in The Use of Evidence and Knowledge of RWE
  - 2.5.6. How RWE Can Support Decision Making throughout The Product Life Cycle
  - 2.5.7. Initiated Studies/Trials and Research Collaborations Investigator
- 2.6. The Medical Affairs Department
  - 2.6.1. What Is The Medical Affairs Department?
    - 2.6.1.1. Objective and Functions of The Department
    - 2.6.1.2. General Structure of The Department in Different Companies
    - 2.6.1.3. Interactions Between Medical Affairs And Other Departments (Clinical Operations & Commercial Departments)
    - 2.6.1.4. The Relationship of Medical Issues in Terms of Product Life Cycle
  - 2.6.2. Creation of State-of-The-Art Data Generation Programs
  - 2.6.3. Medical's Co-Leadership Role
  - 2.6.4. Affairs in Multifunctional Pharmaceutical Organizations
- 2.7. Roles in The Medical Affairs Department
  - 2.7.1. Medical Advisor's Role
  - 2.7.2. Medical Advisor Functions
  - 2.7.3. HCP Participation Tactics
    - 2.7.3.1. Advisory Board and Promotional Programs
    - 2.7.3.2. Scientific Publications
    - 2.7.3.3. Scientific Congress Planning
  - 2.7.4. Development of a Medical Communications Plan
  - 2.7.5. Medical Product Strategy Design
  - 2.7.6. Management of Medical Projects and Studies Based on Real Clinical Practice Data (RWE)
  - 2.7.7 Medical Science Liaison Role
    - 2.7.7.1. MSL functions: medical communication and interlocutors.
    - 2.7.7.2. Implementation of Medical Projects and Territorial Management
    - 2.7.7.3. Initiated Studies/Trials and Research Collaborations Investigator
    - 2.7.7.4. Scientific Communication and Collection of Insights

### tech 20 | Structure and Content

2.8.	Compliance In the Medical Affairs Department	
	2.8.1.	Compliance Concept in The Medical Department
		2.8.1.1. Prescription Drug Promotion
		2.8.1.2. Interrelation with Healthcare Professionals and Organizations
		2.8.1.3. Interrelation with Patient Organizations
	2.8.2.	On Label/Off Label Definition
	2.8.3.	Differences between Commercial Department and Medical Affairs
	2.8.4.	Code of Good Clinical Practice in Medical Promotion and Information
2.9.	Medical Information	
	2.9.1.	Integral Communication Plan
	2.9.2.	Media and Omnichannel Plan
	2.9.3.	Integration of The Communication Plan in Medical Plan
	2.9.4.	Biomedical Information Resources
		2.9.4.1. International Sources: <i>Pubmed, Embase,</i> WOS, etc.
		2.9.4.2. Sources in Latin America: Indexes CSIC, Ibecs, LILACS, etc.
		2.9.4.3. Sources for Locating Clinical Trials: WHO, Clinical Trials, Cochrane CENTRAL, etc.
		2.9.4.4. Sources of Drug Information: Bot Plus Web, FDA, etc.
		2.9.4.5. Other Resources: Official Organizations, Websites, Scientific Societies, Associations, Assessment Agencies, etc.
2.10.	Pharmacovigilance	
	2.10.1.	Pharmacovigilance in Clinical Trials
		2.10.1.1. Legal Framework and Definitions
		2.10.1.2. Adverse Event Management
	2.10.2.	Notification of Adverse Events, Eudravigilance
	2.10.3.	Periodic Security Reports
	2.10.4.	Pharmacovigilance in Others Clinical Trials: Posauthorization Studies

### Module 3. Team Leadership in Pharma

- 3.1. Leadership
  - 3.1.1. Leadership Introduction
  - 3.1.2. Power and Influence
  - 3.1.3. What Is Leadership?
  - 3.1.4. Conclusions
- 3.2. Leadership Theory
  - 3.2.1. Leadership Process
  - 3.2.2. Leadership Styles
  - 3.2.3. Leadership Models
  - 3.2.4. Evolution
- 3.3. Leadership Skills
  - 3.3.1. Communication
  - 3.3.2. Commitment
  - 3.3.3. Motivation
  - 3.3.4. Decision Making
- 3.4. Group Management
  - 3.4.1. Organisation
  - 3.4.2. Time Management
  - 3.4.3. Planning and Objectives
  - 3.4.4. Equipment Assessment
- 3.5. Team Management Skills
  - 3.5.1. Goals
  - 3.5.2. Objectives
  - 3.5.3. Time Management
  - 3.5.4. Problem Management
- 3.6. Decision Making
  - 3.6.1. Process
  - 3.6.2. Team Decision-Making
  - 3.6.3. Strategic Decisions
  - 3.6.4. Ethical Decisions



### Structure and Content | 21 tech

- 3.7. Communication, Part of Success
  - 3.7.1. External Communication
  - 3.7.2. Internal Communication
  - 3.7.3. Crisis Communication
  - 3.7.4. Intercultural Communication
- 3.8. Negotiation and Conflict Management
  - 3.8.1. Communication Strategies
  - 3.8.2. Skills
  - 3.8.3. Conflict Management
  - 3.8.4. Team Negotiation
- 3.9. People Development
  - 3.9.1. Equipment
  - 3.9.2. Motivation
  - 3.9.3. Visibility
  - 3.9.4. Conclusions
- 3.10. Common Objective, Project Development
  - 3.10.1. Common Objective, Which Is
  - 3.10.2. Multidisciplinary Teams
  - 3.10.3. Building Alliances
  - 3.10.4. Most Used Strategies

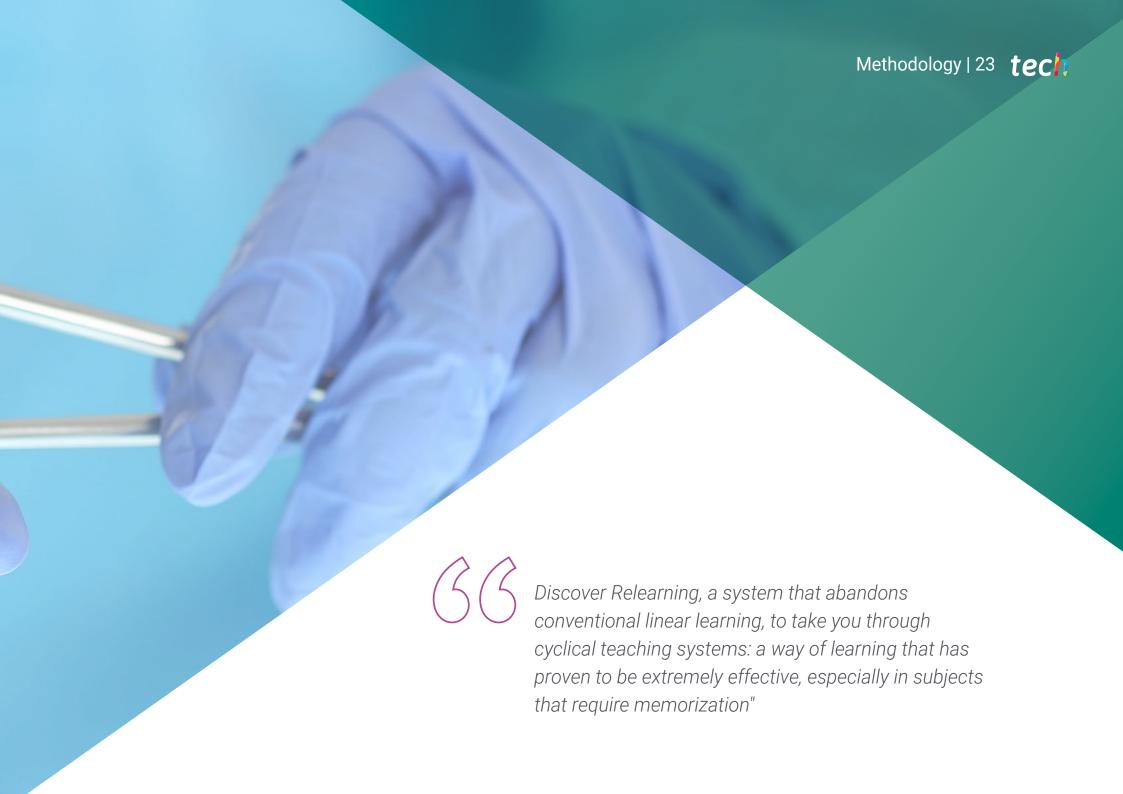


You will learn the basics of Pharma Biotech team leadership with this Postgraduate Diploma offered only by TECH"



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.

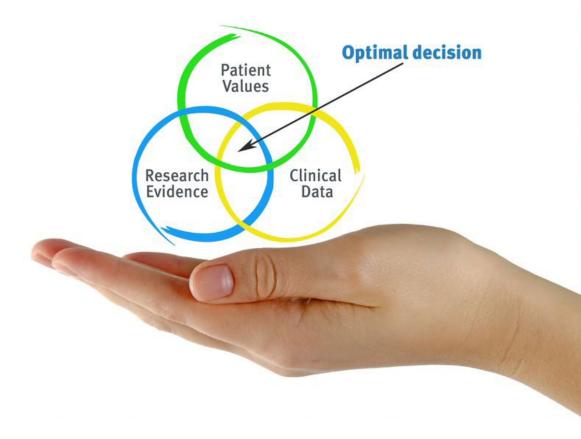


### tech 24 | Methodology

### 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. 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, in an attempt to recreate the real conditions in professional nursing practice.



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:

- 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.



### Methodology | 27 tech

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**

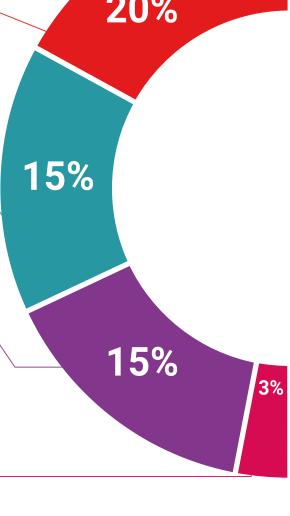
We introduce you to the latest techniques, to the latest educational advances, to the forefront of current medical techniques. All of this in direct contact with students and explained in detail so as to aid their assimilation and understanding. And best of all, you can watch them as many times as you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



### **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

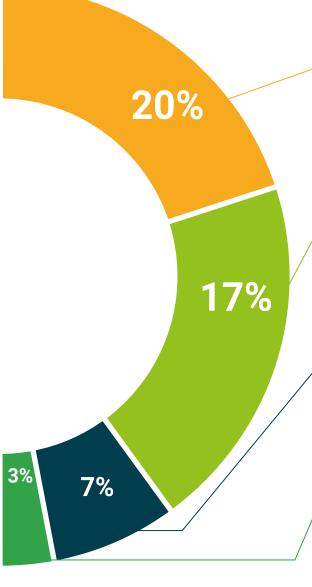
There is scientific evidence suggesting that observing third-party experts can be useful.

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.









### tech 32 | Certificate

This **Postgraduate Diploma in Pharma Biotech Equipment Management 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 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 Pharma Biotech Equipment Management for Nursing Official N° of Hours: **450 h.** 



<sup>\*</sup>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.

health confidence people
education information tutors
guarantee accreditation teaching
institutions technology learning



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