Postgraduate Certificate
Medical Affairs

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Postgraduate Certificate
Medical Affairs

- Modality: **online**
- Duration: **12 weeks**
- Certificate: **TECH Technological University**
- Dedication: **16h/week**
- Schedule: **at your own pace**
- Exams: **online**

Website: **www.techtitute.com/us/medicine/postgraduate-certificate/medical-affairs**

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01

Introduction

In recent years, the pharmaceutical industry has placed great value on the Medical Affairs department, which is responsible for informing and educating healthcare professionals and patients about pharmaceutical products.. This is why companies in the sector are increasingly calling for physicians with advanced and up-to-date knowledge of clinical and scientific information to facilitate correct decision making. An ideal and job-rich scenario, which nevertheless requires experts who are up to date with the advances that have taken place on the operation of companies in the sector, the 4.0 transformation or advances in clinical trials. All this will be possible thanks to this 100% degree created by TECH, which offers innovative and quality content, developed by a teaching team made up of specialists who have first-hand knowledge of the industry.

A 100% online Postgraduate Certificate that will bring you up to date in just 12 weeks on Medical Affairs and its transcendence in the pharmaceutical sector"

In today's world of information overload, knowing how to inform and educate is essential. This is why the pharmaceutical industry places special emphasis on the ability to analyze and measure the impact of the decisions made by the professionals who make up its medical affairs departments. This profile is also in charge of looking after the patient and knowing whether the company's treatments are working or not.

Therefore, at a time when the sector has self-imposed digital transformation as the axis of progression, innovation and sustainability, it is necessary to have medical professionals with in-depth knowledge of the current functions of Medical Affairs, as well as the roles of the Medical Scientific Liaison or the Medical Advisor. Given this reality, TECH has designed this Postgraduate Certificate, which offers the specialist the most recent and innovative content in this field. For this purpose, it has assembled an excellent team of pharmaceutical professionals and researchers in the industry, whose experience in the sector, either in management positions or as project managers, is reflected in the agenda of this program. As a result, this program offers the latest news on the medical and product plan, the weight of communication and evidence-based study designs and Compliance.

A university program that offers medical professionals a global and future vision of the transformation of the role of *Medical Affairs* in the pharmaceutical industry, the changes that are taking place in research with drugs for human use, clinical trials and their evolution. A theoretical as well as practical approach, where the specialist will also be able to delve into the most recent methodologies used in these clinical studies, ranging from design, planning, trial stages, data management and monitoring.

In order to achieve this updating of knowledge in a dynamic and attractive way, this academic institution has developed multimedia didactic resources that students can access 24 hours a day, from any electronic device with an Internet connection.

This is a fantastic opportunity for professionals to pursue a flexible university degree that is compatible with their work and/or personal responsibilities. Moreover, due to the Relearningused by TECH in all its programs, you will be able to advance through the syllabus in an agile way, reducing the long hours of study. The medical specialist is faced with a flexible university degree that can be taken comfortably at any time of the day, without attendance or fixed class schedules. An ideal academic option for those seeking to combine their professional responsibilities with a top-quality Postgraduate Certificate.

This **Postgraduate Certificate in Medical Affairs** 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 experts in medicine and the pharmaceutical industry
- 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 are looking at an intensive university program that will take you further into the tools used in the RWE"

TECH provides you with an academic option without classroom attendance and without the pressure of having to attend classes with fixed schedules"

Access 24 hours a day to the most up to date academic agenda on Medical Affairs.

Learn about the latest developments in clinical trials and the need for regulation in this Postgraduate Certificate.

The program's teaching staff includes professionals from the sector 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 allow the professional a situated and contextual learning, that is, a simulated environment that will provide an immersive education programmed to prepare 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 student will be assisted by an innovative interactive video system created by renowned and experienced experts.

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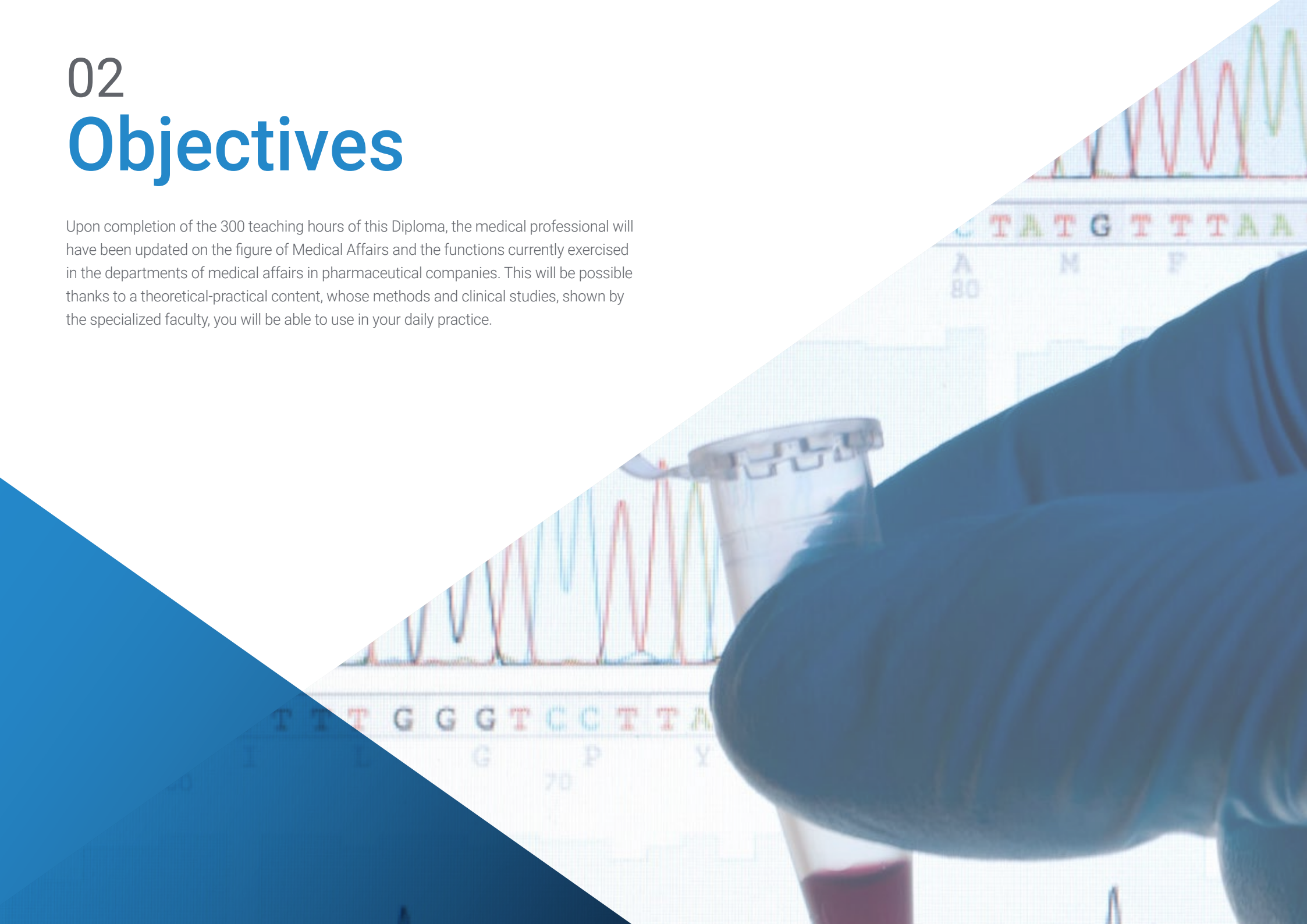
Objectives

Upon completion of the 300 teaching hours of this Diploma, the medical professional will have been updated on the figure of Medical Affairs and the functions currently exercised in the departments of medical affairs in pharmaceutical companies. This will be possible thanks to a theoretical-practical content, whose methods and clinical studies, shown by the specialized faculty, you will be able to use in your daily practice.



They will be able to integrate the different methodologies exposed in the clinical cases provided in this online program"

General Objectives

- Recognize the importance of Compliancein the medical affairs department
- Define the comprehensive communication plan
- Research the future expectations of the medical affairs department as a co-creator in research, relationships with institutions, physicians and patients
- Recognize the various commitments of the pharmaceutical industry to patients and to the sustainability of the system without undermining quality
- Know the future of clinical trial research, the new approach to clinical trials
- Recognize the different roles within the Medical Affairs department

This program will enhance your communication skills through the development of a comprehensive communication plan"

Specific Objectives

- Describe the characteristics of the structure and functions of a Medical Affairs department
- Research models of the relationship between the medical affairs department and the rest of the departments of the pharmaceutical industry
- Simulate a medical plan and a product plan
- Design RWE studies
- Understand the new role of the pharmaceutical industry since the emergence and development of Medical Affairs departments
- Simulate scientific communication and professional development, with the design of the career plan
- Describe clinical trials, their types, phases and the objective of each phase
- Define human drug research, its types and ethical foundations

03

Course Management

Professionals who pursue this university program can count on a management and faculty made up of a team of top-level professionals in the pharmaceutical industry. Their experience in this sector, as well as their knowledge in Medical Affairs, is evident in this teaching. Furthermore, throughout the 12 weeks of this program, the specialist will be able to resolve any doubts that may arise regarding the syllabus with this teaching staff.

You have a teaching team made up of professionals from the pharmaceutical industry who know how it works"

Management

Dr. Cuchí Alfaro, Miguel Ignacio

- Medical Director of Hospital Universitario Puerta de Hierro Majadahonda in Spain
- Medical Coordinator of Hospital Audits in the Madrid Service
- Deputy Manager of the Ramón y Cajal University Hospital of Madrid
- Deputy Medical Director of the Ramón y Cajal University Hospital of Madrid
- Degree in Medicine

Professors

Ms. Susanna, Gabriela

- Medical Advisor. Novartis
- MBA Pharma & Biotech, Esame Pharmaceutical Business School, Madrid
- Master's Degree in Virology Universidad Complutense, Madrid
- Degree in Veterinary Medicine from the Complutense University Madrid

Ms. Ferreira de Campos, Karine

- Medical Affairs at Merks
- Master's Degree in Clinical Research and Pharmaceutical Medicine from Universidad Europea
- Degree in Pharmacy from the Federal University of Minas Gerais

Mr. Ayuso Sacido, Ángel

- Director of the UFV-FV Brain Tumor Laboratory,
- Production Specialist at Merck
- Degree in Biological Sciences in the Autonomous University of Madrid

04

Structure and Content

The multimedia pills, videos and clinical cases, as well as the complementary readings integrate the didactic resources of this Diploma, to which the professional will have access at any time of the day. Pedagogical tools that will make it much easier to update your knowledge of medical affairs departments and their important role in the pharmaceutical industry. Likewise, the *Relearning* system will favor the reduction of memorization and study hours so frequent in other teaching methods.

You will be able to obtain a theoretical-practical vision of Medical Affairs and the future expectations of this professional profilel"

Module 1. Medical Affairs department

1.1. What is the medical affairs department?
- 1.1.1. History of the Medical Affairs department and its evolution in pharmaceutical companies
- 1.1.2. Objective and functions of the department
- 1.1.3. General department structure in different companies

1.2. Medical affairs department in pharmaceutical companies and Biotechs
- 1.2.1. Relationship of medical affairs with commercial departments
- 1.2.2. Relationship of medical issues with the Market AccessDepartment
- 1.2.3. Relationship of medical issues with the Regulatory Department
- 1.2.4. Relationship of medical issues with the Research and Clinical Trials Department
- 1.2.5. The relationship of medical issues in terms of product life cycle

1.3. Product Life Cycle medical
- 1.3.1. Medical affairs according to product life cycle
- 1.3.2. Launching strategies

1.4. Medical and product plan
- 1.4.1. Definition of medical plan and product plan
- 1.4.2. Product plan structure: strategic and action plan
- 1.4.3. Medical Affairs and Medical Societies: support for healthcare professionals through societies

1.5. Roles in the Medical Affairs Department: the Medical Advisor
- 1.5.1. Medical Advisor functions: design of medical product strategy
- 1.5.2. Management of medical projects and Phase IV studies
- 1.5.3. Medical project finance

1.6. Roles in the medical affairs department: the MSL
- 1.6.1. MSL functions: medical communication and interlocutors
- 1.6.2. Implementation of medical projects and territorial management
- 1.6.3. MSL Skills
- 1.6.4. Time management and prioritization

1.7. Medical communication and Insights gathering
- 1.7.1. High-impact F2F communication
- 1.7.2. Tailoring communication to profile and *Insights*based communication
- 1.7.3. Management of medical requests and negotiation

1.8. Integral communication plan
- 1.8.1. Media and omni-channel plan
- 1.8.2. Communication at conferences
- 1.8.3. Integration of the communication plan in the medical plan

1.9. RWE and Phase IV studies
- 1.9.1. RWE and Phase IV study design
- 1.9.2. Medical plan integration
- 1.9.3. Investigator Initiated Studies/Trials and Research Collaborations
- 1.9.4. Collection and Measuring of Results

1.10. Compliance the medical affairs department
- 1.10.1. Promotion definition
- 1.10.2. Definition of On Label/Off Label
- 1.10.3. Differences between commercial department and medical affairs
- 1.10.4. Integrity at Work

Module 2. Why a Medical Affairs department? Your reason for being

2.1. Medical Affairs: the new role of the pharmaceutical industry
- 2.1.1. From how it was to how it is now
- 2.1.2. From Industries to Science
- 2.1.3. Beyond clinical trials: generating evidence

2.2. Expectations for the future of Medical Affairs departments
- 2.2.1. Relationship with public institutions, physicians and patients
- 2.2.2. "Win-Win" or "all-in-one" as the future
- 2.2.3. Coordination of Clinical Trials
- 2.2.4. Research Project Design
- 2.2.5. Patient as a source of success

2.3. Commitment of the pharmaceutical industry
- 2.3.1. In promoting the welfare of patients with ethical criteria of professionalism
- 2.3.2. In generating and maintaining confidence in the prescribing of medicines
- 2.3.3. Objective: contribute to the quality of care in a sustainable manner

2.4. Ability to measure the impact of what we do
- 2.4.1. Training and reporting
- 2.4.2. Correct analysis of scientific and non-scientific information
- 2.4.3. Evaluating whether or not a treatment works for our patients
- 2.4.4. Knowing whether the strategic decisions we have made are having the intended impact
- 2.4.5. Genuine concern for patients

2.5. Development of a health sciences professional in the pharmaceutical industry
- 2.5.1. Design of a Training Plan: what to study?
- 2.5.2. Self-training
- 2.5.3. Team profile: innovation, leadership, etc
- 2.5.4. Development plans in the role
- 2.5.5. Career Plans

2.6. Research with Drugs for Human Use
- 2.6.1. Definition, justification and objectives of research with drugs for human use for human use
- 2.6.2. Types of drug research studies
- 2.6.3. Ethical Foundations Standards of Good Clinical Practice
- 2.6.4. Agents involved in clinical research: sponsor, investigator, monitor, patient

2.7. Clinical Trials Phases I
- 2.7.1. Clinical Studies in Phase 0
- 2.7.2. Phase I Clinical Studies: How safe is the treatment?

2.8. Clinical Trials Phases II
- 2.8.1. Phase II Clinical Studies: How effective is the treatment?
- 2.8.2. Phase III Clinical Studies: Is the new treatment under study better than the conventional treatment?
- 2.8.3. Phase IV Clinical Studies: What else do I need to know?

2.9. Clinical Trials Methodology
- 2.9.1. Clinical Trial Design
- 2.9.2. Clinical Trial Planning
- 2.9.3. Stages in the Development of Clinical Trials
- 2.9.4. Monitoring: follow-up and control. The Importance of Quality
- 2.9.5. Data Management Results obtained
- 2.9.6. Risk-based Monitoring
- 2.9.7. Decentralized Studies

2.10. The future of clinical trial research
- 2.10.1. Clinical Trials Evolution
- 2.10.2. From clinical evidence to regulatory need
- 2.10.3. From clinical trial data to price approval: what more data is needed?
- 2.10.4. Patient Monitoring
- 2.10.5. The cooperative environment for evidence generation

A 100% online program that will immerse you in the latest trends in human medicines research"

05

Methodology

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

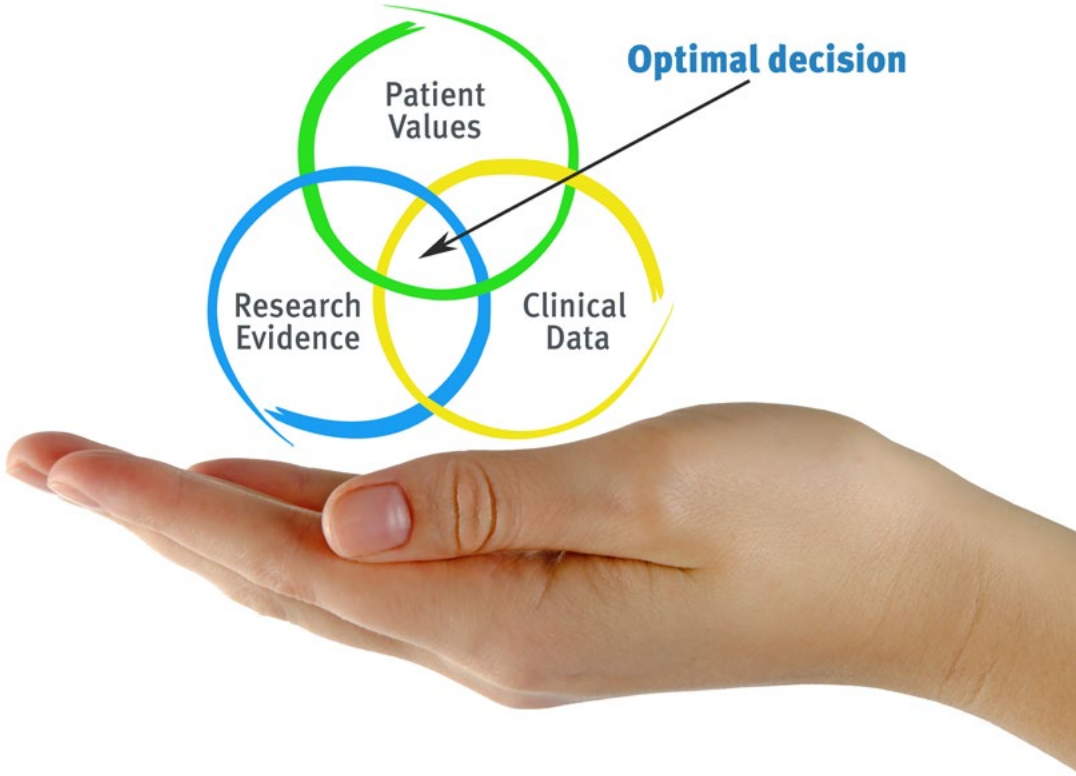
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.

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.

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:

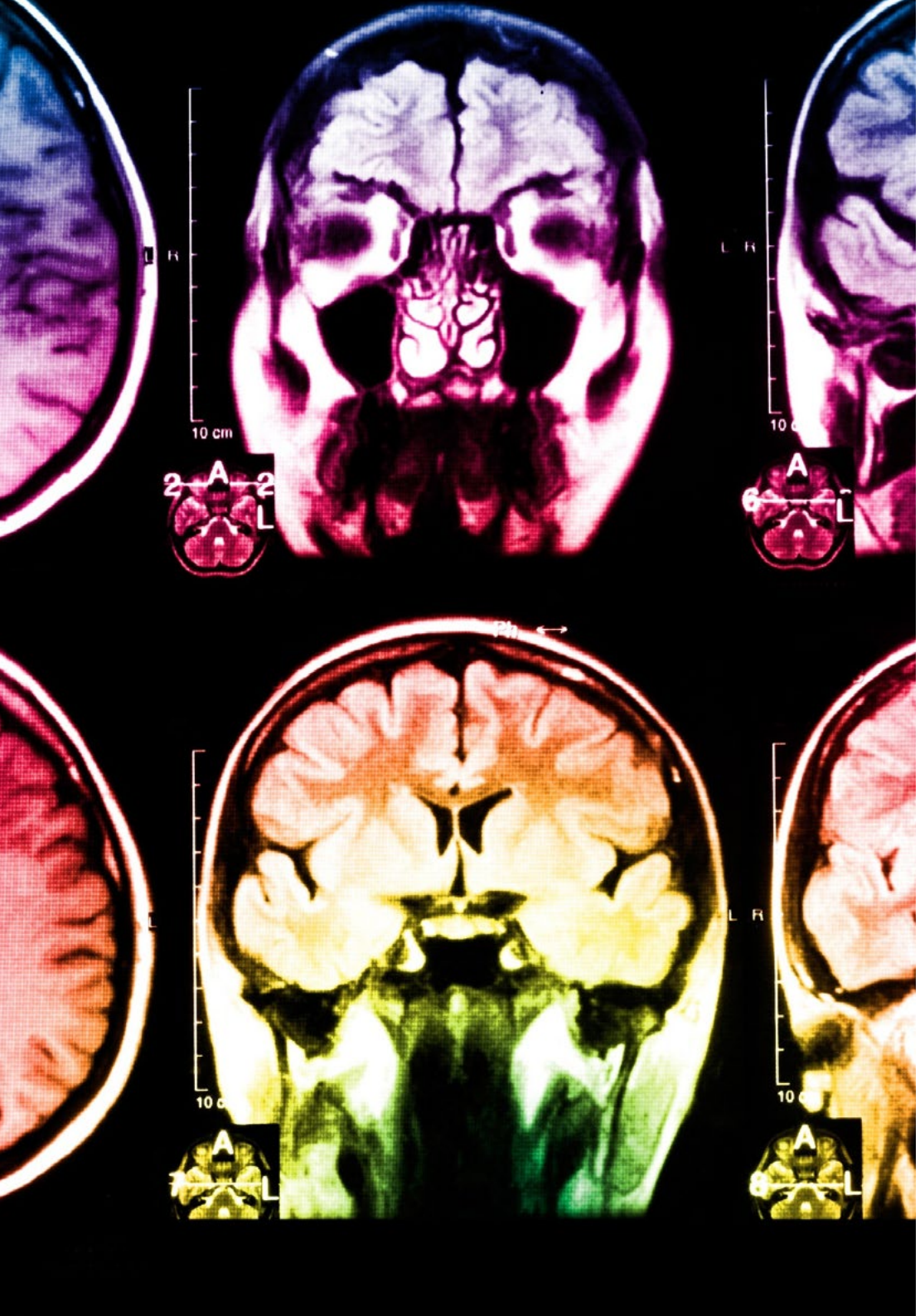
1. Students who follow this method not only achieve the assimilation of concepts, but also a development of their mental capacity, through exercises that evaluate real situations and the application of knowledge.
2. Learning is solidly translated into practical skills that allow the student to better 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.

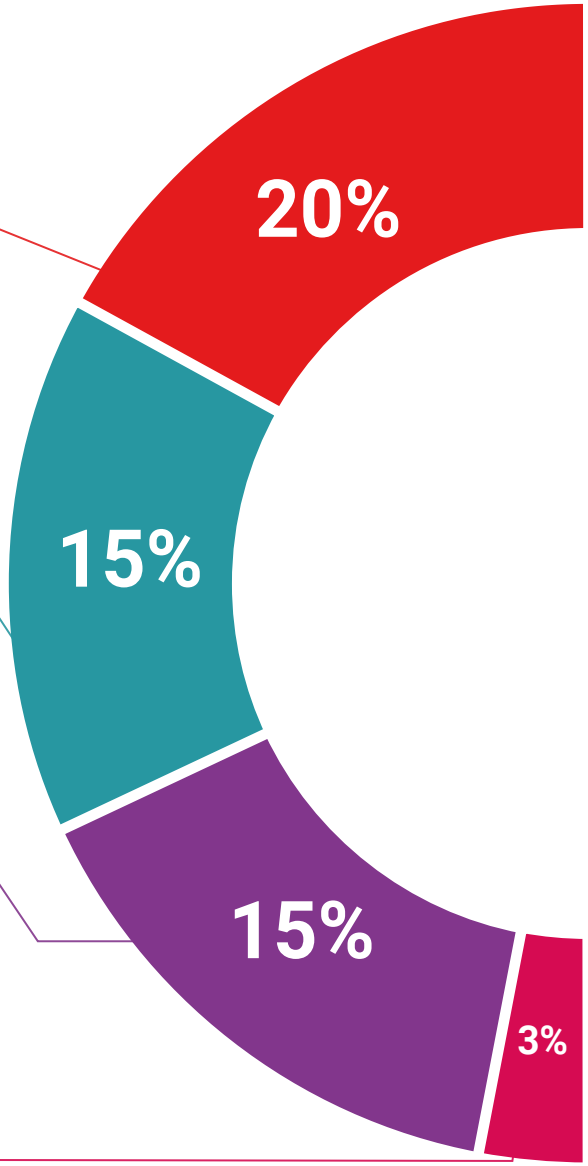
Interactive Summaries

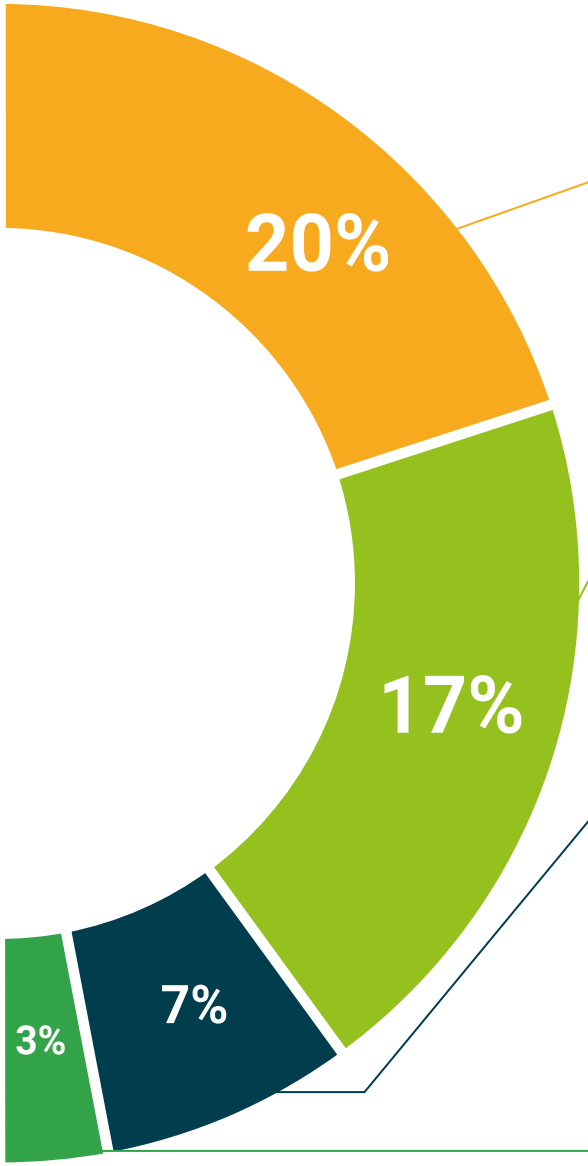
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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 Affairs guarantees students, in addition to the most rigorous and up-to-date education, access to a Postgraduate Certificate issued by TECH Technological University.

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

This **Postgraduate Certificate in Medical Affairs** 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 Affairs**
Official Nº of Hours: **300 h.**


tech technological university

Awards the following

DIPLOMA

to

Mr./Ms. _____, with identification number _____.

For having passed and accredited the following program

POSTGRADUATE CERTIFICATE

in

Medical Affairs

This is a qualification awarded by this University, equivalent to 300 hours, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

TECH is a Private Institution of Higher Education recognized by the Ministry of Public Education as of June 28, 2018.

June 17, 2020

Tere Guevara Navarro
Dean

This qualification must always be accompanied by the university degree issued by the competent authority to practice professionally in each country. Unique TECH Code: AFWORD23S techtitute.com/certificates

*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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