



# Postgraduate Diploma

Medical Affairs

» Modality: online

» Duration: 6 months

» Certificate: TECH Global University

» Credits: 18 ECTS

» Schedule: at your own pace

» Exams: online

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

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# 01 Introduction

In recent years, the pharmaceutical industry has undergone an extraordinary change resulting from the new industrial revolution 4.0. In this absolutely disruptive scenario, the sector has renewed objectives and interests. This transformation involves different departments, including medical affairs, which has experienced a considerable increase in recent decades. That is why, in view of this panorama of innovation and specialization, TECH has designed this 100% online program, which offers professionals the most notorious advances in the functions of Medical Affairs, as well as the progress in their functions and structures of large pharmaceutical companies. For this purpose, this institution has created quality multimedia content, prepared by specialists with an excellent professional track record.



# tech 06 | Introduction

The pharmaceutical industry is continually evolving, transforming its role in the field of human drug research. Likewise, the incorporation of new technologies and the need for increasingly qualified professionals with broad capabilities has led to a considerable growth of the Medical Affairs department in the most important companies in the sector.

In this scenario, Medical Affairs must nowadays master the key concepts of clinical trials, design methodologies, planning, milestones, data management and monitoring in the pharmaceutical sector. Therefore, in response to the growing need for companies to have specialists with up-to-date knowledge, TECH has designed this university degree in a 100% online academic format.

A program that undoubtedly stands out for its management and teaching team, whose knowledge of Medical Affairs is reflected in the syllabus. and whose knowledge about the figure of Medical Affairs is reflected in the syllabus that has been that has been prepared ad hoc for this Postgraduate Diploma. In this way, the specialist will have at his disposal video summaries of each topic, videos in detail, diagrams, essential readings, which will provide an innovative theoretical approach. In addition, the case studies provided by the faculty will bring the graduates closer to real situations, whose methods and strategies they will be able to apply in their daily practice.

This university program is an excellent opportunity for the medical professionals to keep up to date with the latest advances in this department through an education that can be taken comfortably, whenever and wherever they wish. You only requires an electronic device with internet connection to access to the contents hosted in the virtual campus. Freedom and flexibility, which also make it easier to combine the most demanding responsibilities with a quality academic option.

This **Postgraduate Diploma in Medical Affairs** contains the most complete and up-todate 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 work
- Content that is accessible from any fixed or portable device with an Internet connection



A Postgraduate Diploma that will provide you with the most effective keys to currently perform the functions of Medical Affairs"



A library of multimedia resources that is available 24 hours a day. Access it whenever you want, from any electronic device with an internet connection"

This program will introduce you to the latest developments in human drug research, its types and ethical foundations.

Delve into medical product strategy design and drug research at your convenience.

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.

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.

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







# tech 10 | Objectives



# **General Objectives**

- Assimilate the scientific-technical knowledge that will allow to perform the functions in the Medical Affairs department
- Know in depth the relationship between the MSL and the *Medical Advisor* with the rest of the departments
- Analyze and learn about different structures of Medical Affairs departments
- Train the professional, through the necessary skills, to improve problem solving and develop essential professional competencies
- Learn in depth about new projects of value for the pharmaceutical industry, such as *Lean* methodology and digital transformation
- Show the vision of hospital pharmacy as a collaborative research agent
- Gain in-depth knowledge of the latest research support tools
- Develop actions and initiatives that improve health outcomes, in collaboration with physicians, industry personnel and health departments
- Develop skills in scientific communication to train and inform other departments and improve the relationship with the physician and patient
- Train the professional in critical reading of articles and in evidence management
- Design effective leadership strategies in work teams and with other departments
- Train the professional in conflict resolution in the workplace
- Implement emotional intelligence in the pharmaceutical industry sector
- Interpret the priorities of the pharmaceutical company and establish cooperation with health institutions, understanding the strategic competencies of the medical department, within the ethical framework
- Manage scientific databases for carrying out reviews and bibliographic searches of scientific studies
- Use medical information as a strategy for keeping the medical team up to date
- Train the practitioner to communicate medical information to the patient and the health professional





# **Specific Objectives**

### Module 1. Medical affairs department

- Describe the characteristics of the structure and functions of a Medical Affairs department
- Investigate models of the relationship between the medical affairs department and the rest of the departments of the pharmaceutical industry
- Recognize the different roles within the Medical Affairs department
- Simulate a medical plan and a product plan
- Define the integral communication plan
- Design RWE studies
- Recognize the importance of Compliance in the medical affairs department

# Module 2. What is the reason for a *Medical Affairs*? department? Its reason for being

- Understand the new role of the pharmaceutical industry since the emergence and development of *Medical Affairs* departments
- Investigate 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
- 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, its ethical foundations
- Know the future of clinical trial research, the new approach to clinical trials

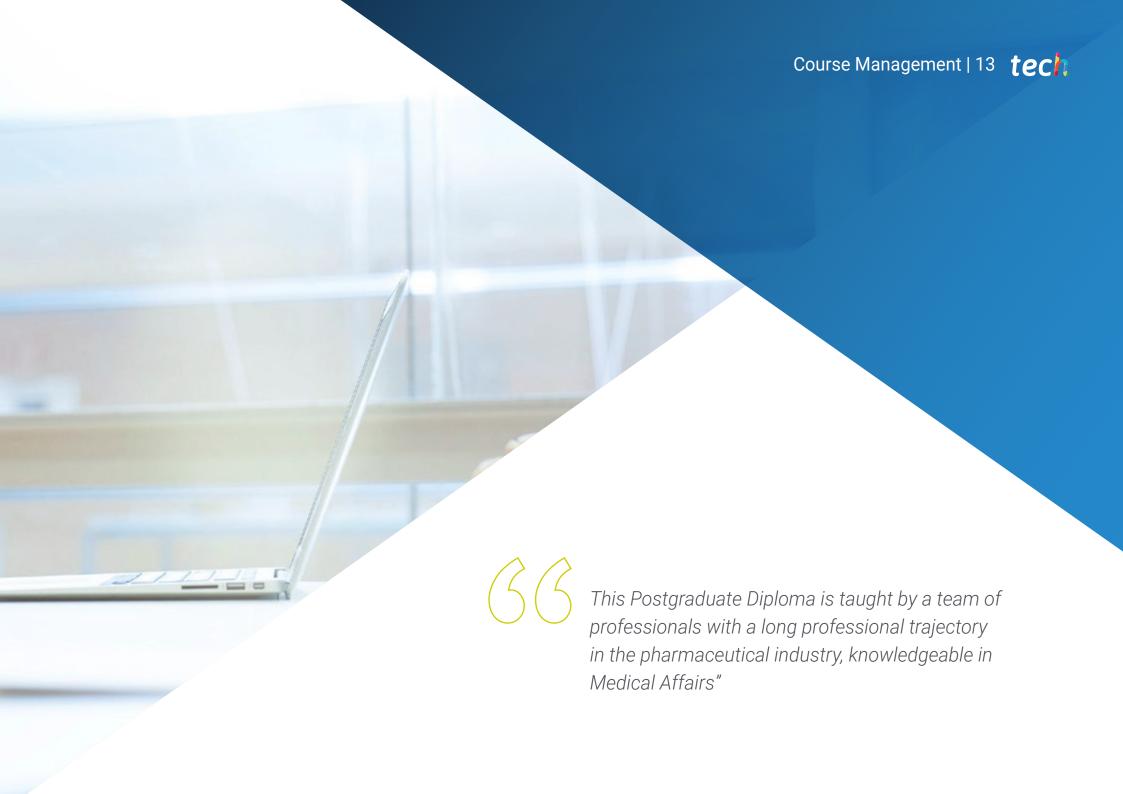
### Module 3. Professional competencies to work in Medical Affairs

- Acquire the necessary knowledge to speak in public effectively
- Manage emotions in conflict situations
- Describe the most relevant characteristics of the negotiation process
- Know the importance of personal branding and what it brings to the table
- Research models of adaptation to change
- Recognize problems, understand them, know their causes in order to solve them
- Simulate the management of a team
- Know the importance of time management and use time management tools
- Describe and learn about the labor market insertion process Know the tools to define to define the professional goal



This university program will enhance your professional skills as a Medical Affairs and team manager"





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## 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 Complutense University, 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

### Mr. González Francisco, Alfredo

- Senior Account Manager at SOAINT, IT Consulting Company
- Senior Business Strategy and Innovation Consultant at CEGOS, a Consulting, Learning and Competence Development company
- Business Director at Woork Smart Business Solutions
- Senior Account Manager in the public sector







# tech 18 | Structure and Content

### Module 1. The medical affairs department

- 1.1. What is the medical affairs department?
  - 1.1.1. History of the *Medical Affairs* y 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 and *Biotechs* companies
  - 1.2.1. Relationship of medical affairs with commercial departments
  - 1.2.2. Relationship of medical issues with the Market Access Department
  - 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. Medical issues based on product life cycle
  - 1.3.1. The medical strategy based on the product life cycle
  - 1.3.2. Launching strategies
- 1.4. Medical plan and product plan
  - 1.4.1. Definition of medical and product plan
  - 1.4.2. Product plan structure: strategic and action plan
  - 1.4.3. *Medical Affairs and Medical Societies*: support for health care professionals through the companies
- 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 organization 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 congresses
  - 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
  - .9.4. Collection and Measuring of Results
- 1.10. Compliance in the medical affairs department
  - 1.10.1. Promotion definition
  - 1.10.2. On Label/Off Label Definition
  - 1.10.3. Differences between commercial department and medical affairs
  - 1.10.4. Integrity at Work

## Module 2. What is the reason for a Medical Affairs department? Its 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 as 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

# Structure and Content | 19 tech

- 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: to 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 information
  - 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. Know whether the strategic decisions we have made are having the desired impact the desired 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 within 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 medicinal products 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: promoter, investigator, monitor, the patient
- 2.7. Clinical Trials Phases I
  - 2.7.1. Phase 0 Clinical Studies
  - 2.7.2. Phase I Clinical Studies: Is the treatment safe?
- 2.8. Clinical Trials Phases II.
  - 2.8.1. Phase II Clinical Studies: Is the treatment effective?
  - 2.8.2. Clinical Trials Phases III 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 Obtaining results
  - 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 needed?
  - 2.10.4. Patient Monitoring
  - 2.10.5. The cooperative environment for evidence generation

### Module 3. Professional competencies to work in Medical Affairs

- 3.1. Effective public speaking
  - 3.1.1. Ensuring the success of your presentation: overcoming stage fright. Rely on oneself to occupy all the space. Harmonize (voice, gestures, posture, gaze)
  - 3.1.2. Clearly present your ideas: organize your thinking. Define your objectives to maintain a direction. Structure your message
  - 3.1.3. Establishing an authentic dialog: understanding the keys to communication.

    Use and take advantage of the group's resources. Encourage and control public participation. How to get ideas across?
  - 3.1.4. Make the public your ally: keep them interested with or without media. Learn how to react during exchanges with improvisation. Know how to close
- 3.2. Manage emotions in conflict situations
  - 3.2.1. Understanding emotions: the role of the brain. Identifying Emotions
  - 3.2.2. Develop emotional balance: manage incoherent emotional reactions. Develop Self-confidence
  - 3.2.3. Using emotions to build trust
  - 3.2.4. Resolve conflict situations
  - 3.2.5. Develop Control skills

# tech 20 | Structure and Content

#### 3.3. Leadership

- 3.3.1. Strategic planning: tools to build the vision focused on achieving the objectives. Planning as a Success Warranties
- 3.3.2. Decision-making: decision-making process with a clear methodology to avoid unnecessary subjectivity. Balance between reason and emotion
- 3.3.3. Achievement orientation: work by objectives. Tools for defining objectives and their follow-up. Introduction to OKRs
- 3.3.4. Continuous improvement: continuous learning. The Deming Cycle

#### 3.4. Influence and negotiation

- 3.4.1. Basic principles of negotiation: I actively promote collaboration to provide the best solution for my clients and colleagues
- 3.4.2. The Negotiation Process Objectives. Sides of the War of Negotiation
- 3.4.3. Negotiation Strategies How to approach the negotiation?
- 3.4.4. Communication and influence: convincing and making winning proposals

#### 3.5. Personal Brand

- 3.5.1. Understanding what personal branding is: Why is it important and what does it bring us?
- 3.5.2. Building and managing your personal brand: five universal goals for building your personal brand. How to establish a network of contacts?
- 3.5.3. Social networks: choose your social networks (Linkedin, Twitter, Facebook, Instagram)
- 3.5.4. Launching your personal brand: personal branding campaigns and how to measure success

### 3.6. Adaptation to Change

- 3.6.1. Accepting change: this is the phase of understanding the need for change, when people are stabilized and accept the new situation
- 3.6.2. Resistance to change: knowing how to identify the barriers and difficulties that position people against change is a way to find solutions that help to incorporate new ways of doing things
- 3.6.3. Process of Change. The hero's journey: understanding the process of change from denial to transformation of individuals
- 3.6.4. Change management in organizations: understanding Kotter-like models of change management in organizations





# Structure and Content | 21 tech

- 3.7. Problem Solving
  - 3.7.1. Understanding the problem: understanding the problem, identifying its causes and the challenges it presents
  - 3.7.2. Idea generation: processes of ideation and creativity to develop different solutions different solutions
  - 3.7.3. Analysis: idea analysis models
  - 3.7.4. Decision-making: tools for decision making
- 3.8. Team Management
  - 3.8.1. Functional teams: achievement-oriented teams. Lencioni Pyramid
  - 3.8.2. Team management tools: effective meetings, delegation, etc
  - 3.8.3. Motivation techniques: models for motivating the people who make up the teams. Intrinsic and Motivation Extrinsic Motivation
  - 3.8.4. Feedback: reinforce the employees' sense of responsibility in the development of the company's work
- 3.9. Professional efficiency. Time Management
  - 3.9.1. The time paradigm: understanding the relative importance of time
  - 3.9.2. Personal efficiency: be a strategist of your time and focus on what is really important to improve your productivity
  - 3.9.3. Time management tools and techniques: stress management, time management tools and methods
- 3.10. Job Placement
  - 3.10.1. Setting your career goal: tools to define your career goal
  - 3.10.2. CV preparation: identification of professional skills and competencies for CV preparation
  - 3.10.3. Job search: job search techniques. Networking, social networks, search engines and headhunter management
  - 3.10.4. The Interview How to face a job interview?



A 100% online academic option designed for professionals who wish to study a Postgraduate Diploma compatible with their personal responsibilities"





# tech 24 | Methodology

#### 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:

- 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.



# 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, 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.

# tech 28 | Methodology

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.









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This program will allow you to obtain your **Postgraduate Diploma in Medical Affairs** endorsed by **TECH Global University**, the world's largest online university.

**TECH Global University** is an official European University publicly recognized by the Government of Andorra (*official bulletin*). Andorra is part of the European Higher Education Area (EHEA) since 2003. The EHEA is an initiative promoted by the European Union that aims to organize the international training framework and harmonize the higher education systems of the member countries of this space. The project promotes common values, the implementation of collaborative tools and strengthening its quality assurance mechanisms to enhance collaboration and mobility among students, researchers and academics.

This **TECH Global University** title is a European program of continuing education and professional updating that guarantees the acquisition of competencies in its area of knowledge, providing a high curricular value to the student who completes the program.

Title: Postgraduate Diploma in Medical Affairs

Modality: online

Duration: 6 months

Accreditation: 18 ECTS



Mr./Ms. \_\_\_\_\_, with identification document \_\_\_\_\_ has successfully passed and obtained the title of:

#### Postgraduate Diploma in Medical Affairs

This is a program of 450 hours of duration equivalent to 18 ECTS, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

TECH Global University is a university officially recognized by the Government of Andorra on the 31st of January of 2024, which belongs to the European Higher Education Area (EHEA).

In Andorra la Vella, on the 28th of February of 2024



<sup>\*</sup>Apostille Convention. In the event that the student wishes to have their paper diploma issued with an apostille, TECH Global University will make the necessary arrangements to obtain it, at an additional cost.

health confidence people information tutors guarantee as a editation teaching technology learning community community



# Postgraduate Diploma Medical Affairs

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