

# Postgraduate Certificate

Legal Framework and Standard  
Principles in a Clinical Laboratory



## Postgraduate Certificate Legal Framework and Standard Principles in a Clinical Laboratory

Course Modality: Online

Duration: 2 months.

Certificate: TECH Technological University

6 ECTS Credits

Teaching Hours: 150 hours.

Website: [www.techtitute.com/in/medicine/postgraduate-certificate/legal-framework-standard-principles-clinical-laboratory](http://www.techtitute.com/in/medicine/postgraduate-certificate/legal-framework-standard-principles-clinical-laboratory)

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# 01

# Introduction

The work in the clinical analysis laboratory intervenes in areas in which legal aspects are a determining factor in the way it operates. Knowing the legal framework in which the activity is carried out and the standard principles to which it must adhere is essential to act safely at all times.

In this complete course we offer you the possibility to achieve your qualification in a simple and very efficient way. Through the most developed teaching techniques, you will learn the theory and practice of all the advances needed to work in a clinical analysis laboratory at a high level. With a structure and plan that is totally compatible with your personal and professional life.



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*A course created to learn and understand the standard principles on which the legal framework is based which in turn regulates the work of a clinical laboratory”*

This module provides students with the necessary skills to perform their work with the utmost excellence as clinical personnel in a laboratory. It addresses the legal framework of a clinical laboratory, where the need for standardization of work and quality control of procedures and files is evident, given the high demand for analytical tests.

Therefore, given the molecular variability of diseases in the population, it is necessary to have knowledge of the legal aspects related to the work in the field of clinical analysis. This plays an important role in clinical decision making among medical personnel, and in turn, is used as a link to medicine based on scientific evidence.

A compendium and deepening of knowledge that will lead you to excellence in your profession.



*With this Course you will be able to combine high intensity training with your personal and professional life, achieving your goals in a simple and real way”*

This **Postgraduate Certificate in Legal Framework and Standard Principles in a Clinical Laboratory** offers you the characteristics of a high-level scientific, teaching, and technological course. These are some of its most notable features:

- Highly visual teaching system, supported by graphic and schematic contents that are easy to assimilate and understand.
- Practical cases presented by practising experts.
- State-of-the-art interactive video systems.
- Teaching supported by telepractice.
- Continuous updating and recycling systems.
- Self-regulating learning: full compatibility with other occupations.
- Practical exercises for self-evaluation and learning verification.
- Support groups and educational synergies: questions to the expert, debate and knowledge forums.
- Communication with the teacher and individual reflection work.
- Content that is accessible from any fixed or portable device with an Internet connection.
- Banks of complementary documentation permanently available, even after the course.

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*A highly skilled course which will allow you to become a highly competent professional in a clinical analysis laboratory”*

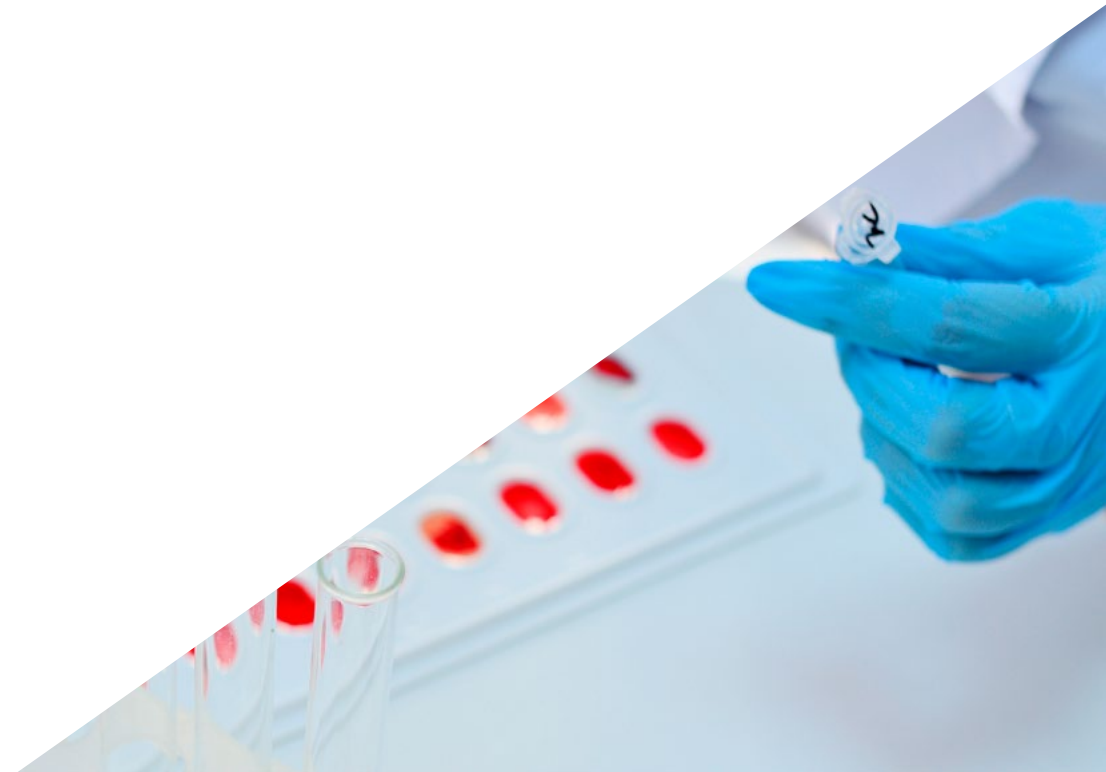
The teachers of this course are professionals currently working in a modern and accredited Clinical Laboratory, with a very solid training base and up to date knowledge in both scientific and purely technical disciplines.

In this way, we ensure that we provide you with the training update we are aiming for. A multidisciplinary team of professionals trained and experienced in different environments, who will cover the theoretical knowledge in an efficient way, but, above all, will put the practical knowledge derived from their own experience at the service of the course: one of the differential qualities of this course.

This mastery of the subject is complemented by the effectiveness of the methodology used in the design of this course on Legal Framework and Standard Principles in a Clinical Laboratory. Developed by a multidisciplinary team of experts, it integrates the latest advances in educational technology. This way, you will be able to study with a range of comfortable and versatile multimedia tools that will give you the operability you need in your training.

The design of this program is based on Problem-Based Learning: an approach that conceives learning as a highly practical process. To achieve this remotely, we will use telepractice: with the help of an innovative interactive video system, and learning from an expert, you will be able to acquire the knowledge as if you were actually dealing with the scenario you are learning about. A concept that will allow you to integrate and fix learning in a more realistic and permanent way.

*Our innovative telepractice concept will give you the opportunity to learn through an immersive experience, which will provide you with a faster integration and a much more realistic view of the contents: “learning from an expert.”*



# 02 Objectives

The objective of this training is to offer professionals who work in clinical analysis laboratories, the necessary knowledge and skills to perform their duties using the most advanced protocols and techniques of the moment. Through a study plan totally adapted to the student, this Postgraduate Certificate will progressively allow you to acquire the skills that will push you towards a much higher professional level.







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*Learn from the best and study the techniques and work procedures of Clinical Analysis to be able to work in the best laboratories in the field”*



## General Objectives

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- Evaluate the ISO standards of a clinical laboratory
- Demonstrate the importance of good safety and sanitary waste management.
- Identify the need for correct management of health documentation.
- Present why quality control is obligatory in a clinical laboratory.
- Define the clinical indicators of analytical quality.
- Identify clinical decision levels within reference ranges.
- Define scientific method and its relationship with medicine based on scientific evidence.





## Specific Objectives

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- ♦ Define workflows within a clinical analysis laboratory.
- ♦ Identify the evacuation plan during a health emergency.
- ♦ Develop the types of sanitary waste.
- ♦ Present the need for process management.
- ♦ Develop the administrative procedure for health documentation.
- ♦ Identify the types of health inspections.
- ♦ Defining ISO accreditations within the framework of an audit.
- ♦ Develop reference intervals through validation guidelines.
- ♦ Analyze the steps of the scientific method.
- ♦ Present scientific evidence levels and their relation with clinical analysis.

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*A boost to your CV that will give you the competitiveness of the best prepared professionals in the labor market"*

03

# Course Management

For our course to be of the highest quality, we are proud to work with a teaching staff of the highest level, chosen for their proven track record. Professionals from different areas and fields of expertise that make up a complete, multidisciplinary team. A unique opportunity to learn from the best.





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*An impressive teaching staff, made up of professionals from different areas of expertise, will be your teachers during your training: a unique opportunity not to be missed”*

## International Guest Director

Jeffrey Jhang, M.D. is a dedicated expert in Clinical Pathology and Laboratory Medicine. He has won several awards in these areas, including the Dr. Joseph G. Fink Award from the Columbia University College of Medicine and Surgery, among other recognitions from the College of American Pathologists.

His scientific leadership has been latent thanks to his exhaustive work as Medical Director of the Clinical Laboratory Center, attached to the Icahn School of Medicine at Mount Sinai. At the same institution, he coordinates the Department of Transfusion Medicine and Cell Therapy. In addition, Dr. Jhang has held management positions in the Clinical Laboratory at the Langone Health Center of New York University and as Chief of the Laboratory Service at Tisch Hospital.

Through these experiences, the expert has mastered different functions such as the supervision and management of laboratory operations, complying with the main regulatory standards and protocols. In turn, he has collaborated with interdisciplinary teams to contribute to the accurate diagnosis and care of different patients. On the other hand, he has spearheaded initiatives to improve the quality, performance and efficiency of analytical technical facilities.



## Dr. Jhang, Jeffrey

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- ♦ Director of Clinical Laboratories at NYU Langone Health, New York, United States
- ♦ Director of Clinical Laboratories at NYU Tisch Hospital, New York
- ♦ Professor of Pathology at the NYU Grossman School of Medicine
- ♦ Medical Director of the Clinical Laboratory Center at Mount Sinai Health System
- ♦ Director of the Blood Bank and Transfusion Service at Mount Sinai Hospital
- ♦ Director of Hematology and Coagulation Specialty Laboratory at Columbia University Irving Medical Center
- ♦ Director of the Parathyroid Tissue Collection and Processing Center at Columbia University Irving Medical Center
- ♦ Assistant Director of Transfusion Medicine at Columbia University Irving Medical Center
- ♦ Transfusion Medicine Specialist at the New York Blood Bank
- ♦ M.D. from the Icahn School of Medicine at Mount Sinai
- ♦ Anatomic and Clinical Pathology Residency at NewYork-Presbyterian Hospital
- ♦ Member of:

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*Thanks to TECH, you will be able to learn with the best professionals in the world”*

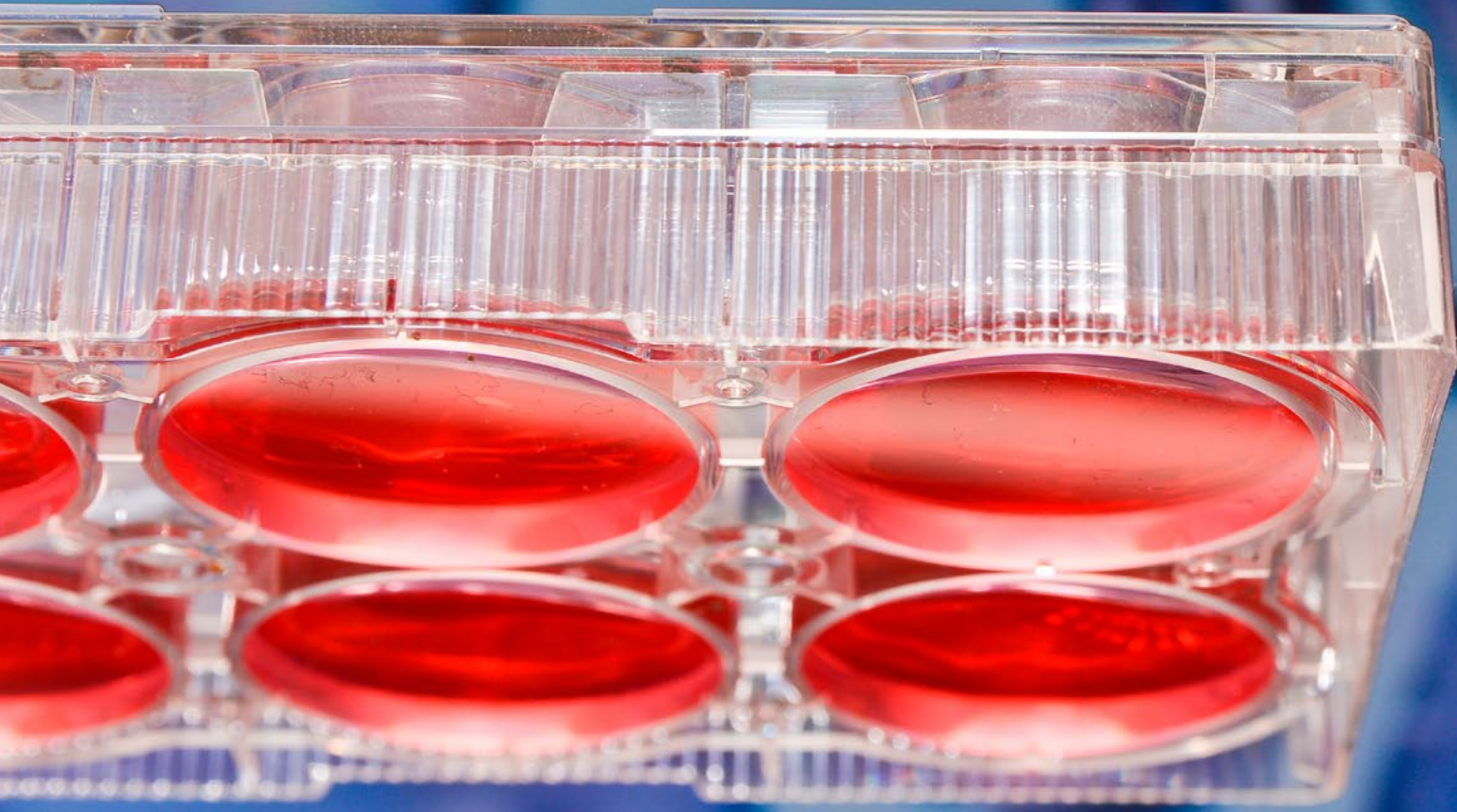
## Management



### **Cano Armenteros, Montserrat**

- ♦ Bachelor's Degree in Biology. University of Alicante
- ♦ Master's Degree in Clinical Trials University of Seville
- ♦ Official Professional Master's Degree in Primary Care Research by the Miguel Hernández University of Alicante for the Doctorate Recognition from the University of Chicago, USA Outstanding.
- ♦ Certificate of Pedagogical Aptitude ( CAP ) University of Alicante





# 04

## Structure and Content

The contents of this Postgraduate Certificate course have been developed by the different experts on this course, with a clear purpose: to ensure that our students acquire each and every one of the necessary skills to become true experts in this field.

A complete and well-structured program that will take you to the highest standards of quality and success.





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*A comprehensive and exciting curriculum that will lead you through the learning process safely and reliably”*

## Module 1. Legal Framework and Standard Parameters of the Clinical Analysis Laboratory

- 1.1. ISO Standards Applicable to a Modernized Clinical Laboratory
  - 1.1.1. Work Flow and Free of Waste
  - 1.1.2. Continuous Mapping of Procedures
  - 1.1.3. Physical Filing of Personnel Functions
  - 1.1.4. Monitoring of Analytical Stages with Clinical Indicators
  - 1.1.5. Internal and External Communication Systems
- 1.2. Safety and Management of Sanitary Waste
  - 1.2.1. Safety in a Laboratory Clinic
    - 1.2.1.1. Emergency Evacuation Plan
    - 1.2.1.2. Risk Assessment
    - 1.2.1.3. Standardized Rules of Work
    - 1.2.1.4. Unsupervised Work
  - 1.2.2. Management of Sanitary Waste
    - 1.2.2.1. Classes of Sanitary Waste
    - 1.2.2.2. Packaging
    - 1.2.2.3. Destination
- 1.3. Standardization Model for Sanitary Processes
  - 1.3.1. Concepts and Objectives of the Standardization Processes
  - 1.3.2. Clinical Variability
  - 1.3.3. Need for Process Management
- 1.4. Health Care Documentation Management
  - 1.4.1. Archive Installation
    - 1.4.1.1. Established Conditions
    - 1.4.1.2. Incident Prevention
  - 1.4.2. Safety in the Archives
  - 1.4.3. Administrative Procedures
    - 1.4.3.1. Standardized Work Plan
    - 1.4.3.2. Records
    - 1.4.3.3. Location



- 1.4.3.4. Transfer
- 1.4.3.5. Conservation
- 1.4.3.6. Withdrawal
- 1.4.3.7. Elimination
- 1.4.4. Electronic Archive Records
- 1.4.5. Quality Guarantee
- 1.4.6. Closing the Archive
- 1.5. Quality Control in a Clinical Laboratory
  - 1.5.1. Legal Context of Health Care Quality
  - 1.5.2. Personnel Functions as a Quality Guarantee
  - 1.5.3. Health Inspections
    - 1.5.3.1. Concept
    - 1.5.3.2. Types of Inspections
      - 1.5.3.2.1. Studies
      - 1.5.3.2.2. Installations
      - 1.5.3.2.3. Processes
  - 1.5.4. Clinical Data Audits
    - 1.5.4.1. Concept of an Audit
    - 1.5.4.2. ISO Accreditation
      - 1.5.4.2.1. Laboratory ISO 15189, ISO 17025
      - 1.5.4.2.2. ISO 17020, ISO 22870
    - 1.5.4.3. Certifications
- 1.6. Evaluation of Analytical Quality: Clinical Indicators
  - 1.6.1. System Description
  - 1.6.2. Work Flowchart
  - 1.6.3. Importance of Quality in the Laboratory
  - 1.6.4. Procedure Management in Clinical Analyses
    - 1.6.4.1. Quality Control
    - 1.6.4.2. Extraction and Management of Samples
    - 1.6.4.3. Verification and Validation in the Methods
- 1.7. Clinical Decision Levels within Reference Ranges.
  - 1.7.1. Clinical Laboratory Analysis
    - 1.7.1.1. Concept
    - 1.7.1.2. Standard Clinical Parameters
  - 1.7.2. Reference Intervals
    - 1.7.2.1. Laboratory Ranges International Units
    - 1.7.2.2. Analytical Method Validation Guide
  - 1.7.3. Clinical Decision Levels
  - 1.7.4. Sensitivity and Specificity in Clinical Results
  - 1.7.5. Critical Values Variability
- 1.8. Processing of Requests for Clinical Trials
  - 1.8.1. Most Common Types of Requests
  - 1.8.2. Efficient Use vs. Excess Demand
  - 1.8.3. Practical Example of Requests in the Hospital Field
- 1.9. Scientific Method in Clinical Analysis
  - 1.9.1. PICO Question
  - 1.9.2. Protocol
  - 1.9.3. Bibliographic Search
  - 1.9.4. Study Design
  - 1.9.5. Obtaining Results
  - 1.9.6. Statistical Analysis and Interpretation of Results
  - 1.9.7. Publication of Results
- 1.10. Medicine Based on Scientific Evidence Application in Clinical Analysis
  - 1.10.1. Concept of Scientific Evidence
  - 1.10.2. Classification of the Scientific Evidence Levels
  - 1.10.3. Routine Clinical Practice Guidelines
  - 1.10.4. Evidence Applied in Clinical Analysis Magnitude of Benefit

# 05

# Methodology

This training program provides you with a different way of learning. Our methodology uses a cyclical learning approach: ***Re-learning***.

This teaching system is used 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.



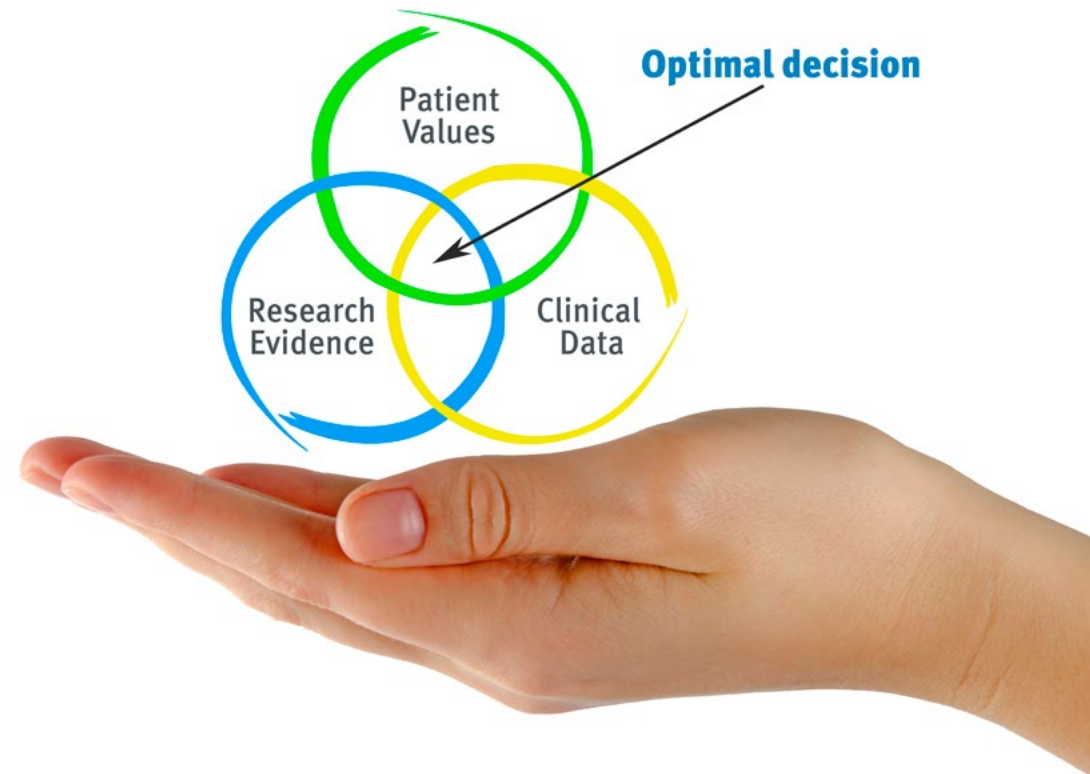
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*Discover Re-learning, a system that abandons conventional linear learning, to take you through cyclical teaching systems: a way of learning that has proven to be extremely effective, especially in subjects that require memorization"*

## At TECH we use the Case Method

In a given situation, what would you do? Throughout the program, you will be presented with multiple simulated clinical cases based on real patients, where you will have to investigate, establish hypotheses and, finally, resolve the situation. There is abundant scientific evidence on the effectiveness of the method. Specialists learn better, faster, and more sustainably over time.

*With TECH you can experience a way of learning 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 potential 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 professional medical practice.



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*Did you know that this method was developed in 1912 at Harvard for law students? The case method consisted of presenting students with real-life, complex situations for them to make decisions and justify their decisions on how to solve them. In 1924, Harvard adopted it as a standard teaching method”*

The effectiveness of the method is justified by four fundamental achievements:

1. Students who follow this method not only 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 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.



## Re-Learning Methodology

At TECH we enhance the Harvard case method with the best 100% online teaching methodology available: Re-learning.

Our 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, which represent a real revolution with respect to simply studying and analyzing cases.



*The physician 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 Re-learning method has managed to improve the overall satisfaction levels of professionals who complete their studies, with respect to the quality indicators of the best Spanish-speaking online university (Columbia University).

With this methodology we have trained more than 250,000 physicians with unprecedented success, in all clinical specialties regardless of the surgical load. All this in a highly demanding environment, where the students have a strong socio-economic profile and an average age of 43.5 years.

*Re-learning 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 (we learn, unlearn, forget, and re-learn). Therefore, we combine each of these elements concentrically.

The overall score obtained by our learning system is 8.01, according to the highest international standards.



In this program you will have access to the best educational material, prepared with you in mind:



#### Study Material

All teaching material is produced specifically for the course by the specialists who teach the course, so that the teaching content is highly specific and precise.

This content is then adapted in an audiovisual format that will create our way of working online, with the latest techniques that allow us to offer you high quality in all of the material that we provide you with.



#### Latest 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 this, in first person, with the maximum rigor, explained and detailed for your assimilation and understanding. And best of all, you can watch them as many times as you want.



#### Interactive Summaries

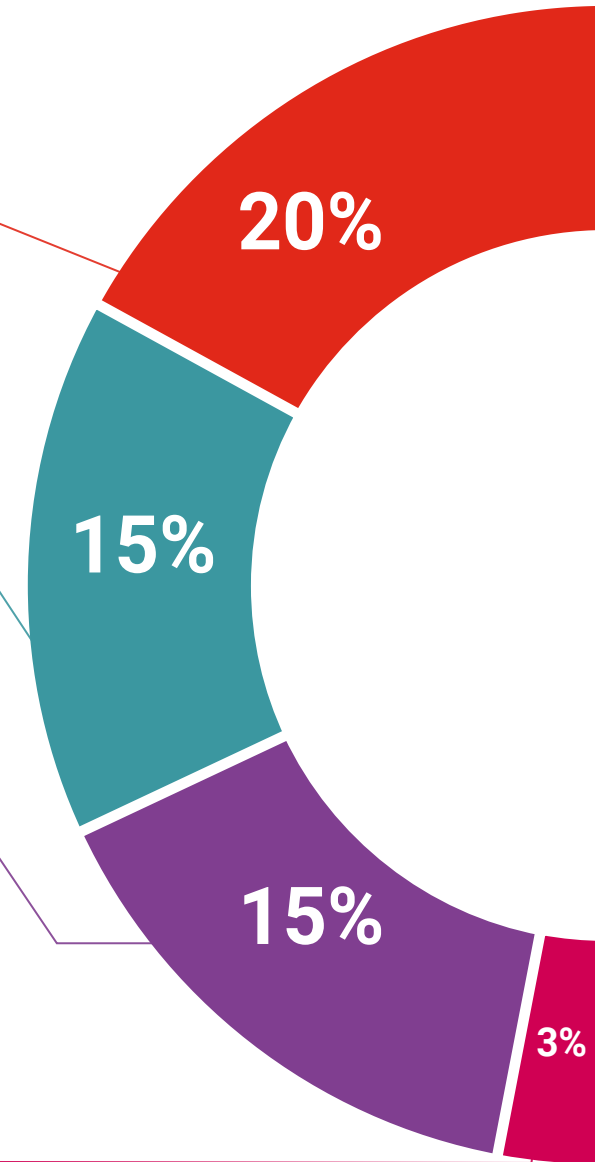
We present the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

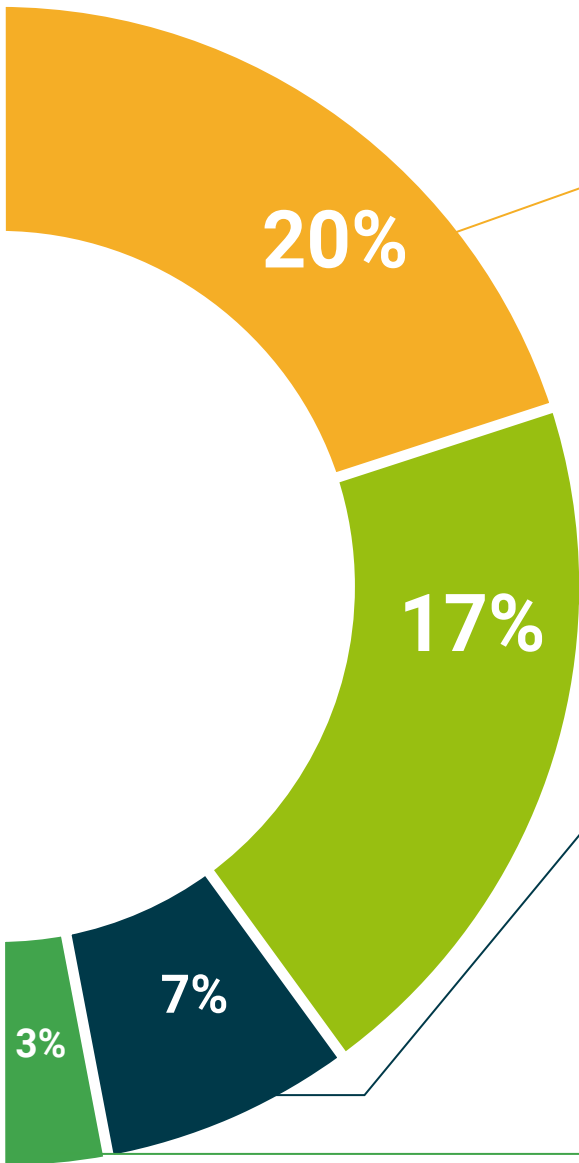
This unique multimedia content presentation training system was awarded by Microsoft as a "European Success Story".



#### Additional Reading

Recent articles, consensus documents, international guides. in our virtual library you will have access to everything you need to complete your training.





**Expert-Led Case Studies and Case Analysis**

Effective learning ought to be contextual. Therefore, we will present you with real case developments in which the expert will guide you through focusing on and solving the different situations: a clear and direct way to achieve the highest degree of understanding.



**Testing & Re-Testing**

We periodically evaluate and re-evaluate your knowledge throughout the program, through assessment and self-assessment activities and exercises: so that you can see how you are achieving your 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 our future difficult decisions.



**Quick Action Guides**

We offer you the most relevant contents of the course in the form of worksheets or quick action guides. A synthetic, practical, and effective way to help you progress in your learning.



# 06

## Certificate

Through a different and stimulating learning experience, you will be able to acquire the necessary skills to take a big step in your training. An opportunity to progress, with the support and monitoring of a modern and specialized university, which will propel you to another professional level.



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*Include in your training a Postgraduate Certificate in Legal Framework and Standard Principles in a Clinical Laboratory: a highly qualified added value for any professional in this field"*

This **Postgraduate Certificate in Legal Framework and Standard Principles in a Clinical Laboratory** contains the most complete and up-to-date scientific program on the market.

After students have passed the assessments, they will receive their **Postgraduate Certificate** issued **TECH Technological University**.

The certificate issued by **TECH Technological University** will reflect the qualification obtained in the master's degree, and meets the requirements commonly demanded by labor exchanges, competitive examinations, and professional from career evaluation committees.

Title: **Postgraduate Certificate in Legal Framework and Standard Principles in a Clinical Laboratory**

ECTS: 6

Official Number of Hours: 150 h.





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



**Postgraduate Certificate**  
Legal Framework and  
Standard Principles  
in a Clinical Laboratory

Course Modality: **Online**

Duration: **2 months.**

Certificate: **TECH Technological University**

**6 ECTS Credits**

Teaching Hours: **150 hours.**

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