

# Postgraduate Certificate Pharmacovigilance





## Postgraduate Certificate Pharmacovigilance

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

Website: [www.techtitute.com/us/veterinary-medicine/postgraduate-certificate/pharmacovigilance](http://www.techtitute.com/us/veterinary-medicine/postgraduate-certificate/pharmacovigilance)

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# 01

# Introduction

Pharmacovigilance is responsible for the detection, analysis and prevention of Adverse Events linked to a drug. A process in which professionals specialized in the field are of enormous relevance, which means that there is an increasing demand for this type of profile in the market. For this reason, TECH has designed a program that seeks to provide the students with the necessary skills to be able to face these responsibilities as efficiently as possible. And this, through a syllabus that addresses topics such as Safety, Adverse Event Management and Pharmacoeconomics. Todo ello, en una modalidad 100% online que da total libertad de organización al alumno y con la total disposición de los mejores materiales pedagógicos.





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*Become a Pharmacovigilance expert in just a few weeks”*

Pharmacovigilance is a science that encompasses the detection, assessment, understanding and prevention of Adverse Events related to a veterinary drug. The figure of the professional specialized in this field is vital for the characterization of this event and the investigation of its relationship with the drug in question. For this reason, the profiles of this type of subject matter experts are in high demand.

For this reason, TECH has designed a Postgraduate Certificate in Pharmacovigilance with which it seeks to provide students with specialized skills and knowledge in this area, so that they can face their work with maximum efficiency and the best quality in their work. For this purpose, different topics such as Crisis Management, Risk-Benefit Analyses, Periodic Safety Reports or Toxicity Studies are addressed throughout the content.

All this, in a comfortable 100% online modality that gives total freedom of organization to the student, who can enjoy the most complete, up-to-date and dynamic contents, without time limits or the need to travel. In addition, all the material can be accessed from day one, from any device with an Internet connection, whether it is a tablet, cell phone or computer.

This **Postgraduate Certificate in Pharmacovigilance** 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 Pharmacovigilance
- ◆ 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 self-assessment can be used 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



*A program designed to help you achieve your most ambitious goals in the veterinary field"*

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*A program with which you will delve into Product Characteristics for Veterinary Medicines and Quality Management System"*

*Enhance your profile in areas such as Security and Adverse Event Management to ensure a promising future career.*

*Acquire specific skills and knowledge in Pharmacovigilance, with no time limits or need to travel.*

The program's teaching staff includes professionals from the field who contribute their work experience to this educational program, as well as renowned specialists from leading societies and prestigious universities.

The multimedia content, developed with the latest educational technology, will provide the professional with situated and contextual learning, i.e., a simulated environment that will provide immersive education programmed to learn in real situations.

This program is designed around Problem-Based Learning, whereby the professional must try to solve the different professional practice situations that arise during the educational year. For this purpose, the students will be assisted by an innovative interactive video system created by renowned and experienced experts.





# 02 Objectives

The objective of this Postgraduate Certificate in Pharmacovigilance is to enhance the skills and provide new knowledge to students, so that they are able to face their work in this field with the highest possible efficiency and quality. All this, through the most complete and innovative theoretical and practical materials on the market.







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*Reach your most demanding goals  
in the veterinary field, in a short  
time and without leaving home"*



## General Objectives

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- ◆ Generate specialized knowledge in the design and interpretation of a clinical trial
- ◆ Examine the key features of clinical trials
- ◆ Analyze key analytical concepts in clinical trials
- ◆ Justify decisions made to solve problems
- ◆ Evaluate behavioral aspects and standardized procedures of clinical trials
- ◆ Review legislation on analytical, toxico-pharmacological and clinical standards and protocols for veterinary drug testing
- ◆ Assess the regulatory environment in relation to clinical trials
- ◆ Develop standards for veterinary clinical trials
- ◆ Generate specialized knowledge to carry out clinical research
- ◆ Establish the correct methodology for conducting veterinary clinical trials
- ◆ Develop advanced knowledge for the development of a protocol for the conduct of a clinical trial with veterinary drugs
- ◆ Analyze the structure of the different regulatory agencies and organizations and their attributions
- ◆ Correctly manage the documentation generated in the framework of the application, follow-up and completion of a veterinary clinical trial





## Specific Objectives

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- ◆ Examine the overview of the European regulatory framework contained in Volume 9B of Eudralex (Pharmacovigilance for Medicinal Products for Veterinary Use)
- ◆ Determine the responsibilities of the monitor within the pharmacovigilance system (DDPS) and the responsibilities of the Qualified Person for Pharmaco Vigilance (QPPV)
- ◆ Correctly analyze and present safety reviews of veterinary products
- ◆ Determine the importance of health economics through the economic medicine evaluation
- ◆ Design and perform cost-benefit, cost-effectiveness, cost-utility and cost-minimization analyses Uncover potentially hidden costs: hospitalization days, concomitant medication, treatment of adverse effects, complementary tests, etc

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*A unique program that will equip you with new skills in Risk Assessment and Crisis Communication”*

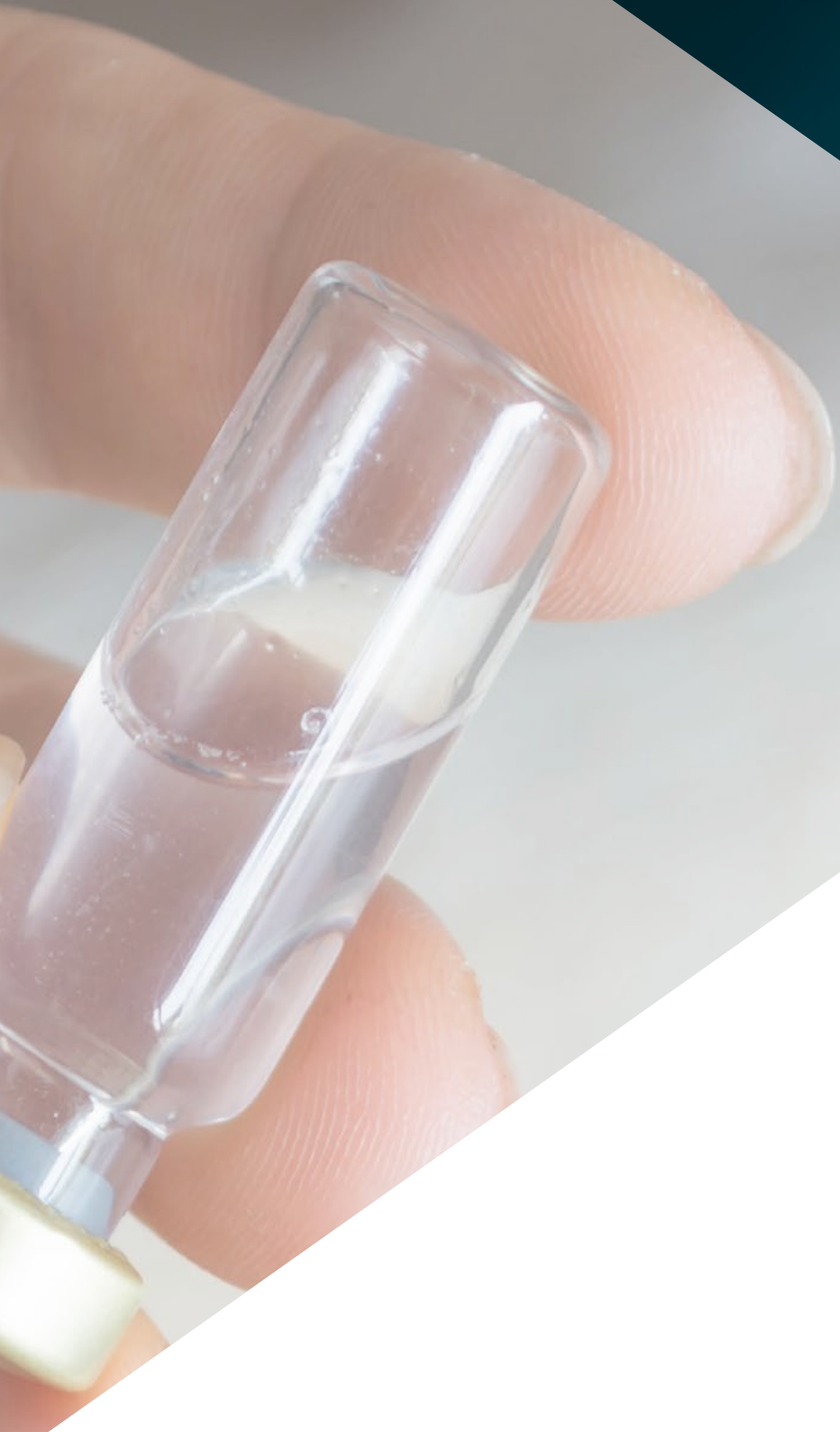
03

# Course Management

The management and teachers of this Postgraduate Certificate in Pharmacovigilance have been selected to guarantee the highest quality of contents and teaching materials. These outstanding professionals are part of TECH's excellent team of experts and have designed a program that meets the most demanding expectations.







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*Succeed with the best and reach your full potential as a Pharmacovigilance expert”*

## Management



### **Dr. Martín Palomino, Pedro**

- ♦ Manager of ALJIBE Veterinary Laboratory
- ♦ Senior program researcher at the Castilla-La Mancha Research Center Spain
- ♦ PhD in Veterinary Medicine from the University of Extremadura
- ♦ Diploma in Public Health from the National School of Health (ENS) at the Carlos III Health Institute (ISCIII)
- ♦ Master's Degree in Swine Technology from the Faculty of Veterinary Medicine of Murcia at the University of Murcia
- ♦ Professor of Infectious Diseases, Zoonoses and Public Health at the Alfonso X el Sabio University



### **Dr. Fernández García, José Luis**

- ♦ Veterinary Doctor
- ♦ PhD in Veterinary Medicine from the University of Extremadura
- ♦ Graduate in Veterinary with Degree from the University of Extremadura
- ♦ Master's Degree in Biotechnology from the CNB Severo Ochoa
- ♦ Adjunct Veterinarian, University of Extremadura





## Professors

### Mr. Cortés Gamundi, Iván

- ◆ Specialist in Pharmacovigilance in Biomapas
- ◆ Microbiologist Expert in Pharmacovigilance
- ◆ Transition Associate for Pharmacovigilance Operations and Strategies at Novartis
- ◆ Validation Technician at Asyval
- ◆ Pharmacovigilance Technician at Uriach
- ◆ AquaLab Laboratory Technician
- ◆ Master's Degree in Pharmacology from the Autonomous University of Barcelona
- ◆ Graduate in Microbiology from the Autonomous University of Barcelona



*Take the step to get up-to-date on the latest developments in Pharmacovigilance"*

# 04

# Structure and Content

This Pharmacovigilance syllabus has been designed and structured by TECH's leading veterinary experts, who have poured their experience and expertise into creating up-to-date, comprehensive and dynamic content. All of this is based on the most efficient pedagogical methodology, Relearning, which guarantees an optimal, natural and progressive assimilation of the concepts by the students.





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*Acquire new knowledge and skills in a dynamic, practical and progressive way, thanks to TECH's excellent teaching methodology, Relearning"*

## Module 1. Pharmacovigilance and Pharmacoeconomics

- 1.1. Safety of Veterinary Medications in Animals
  - 1.1.1. Design and Implementation of the Pharmacovigilance System in a Clinical Trial
  - 1.1.2. Development and updating of Standard Operating Procedures (SOPs)
  - 1.1.3. Initial Assessment
- 1.2. Personal Safety
  - 1.2.1. Active Substance Toxicity Data
  - 1.2.2. Conducting Toxicity Studies
  - 1.2.3. Exposure Scenarios
  - 1.2.4. Risk Management
- 1.3. Environmental Safety
  - 1.3.1. Active Substance Metabolites
  - 1.3.2. Biodegradation
  - 1.3.3. Recommended Studies
- 1.4. Adverse Event Management
  - 1.4.1. Registration (Adverse Reactions, Side Effects and Expected Unfavorable Reactions)
  - 1.4.2. Control Methods
  - 1.4.3. Adverse Events Communication
- 1.5. Summary of Product Characteristics (SPC) for Veterinary Medication
- 1.6. Elaboration and Maintenance of the Pharmacovigilance System Description
  - 1.6.1. Detailed Description of the Pharmacovigilance System
  - 1.6.2. Qualified Person Responsible for Pharmacovigilance (QPPV)
  - 1.6.3. Organisation
  - 1.6.4. Databases
  - 1.6.5. Quality Management System
- 1.7. Periodic Safety Reports (PSRs)
  - 1.7.1. VedDRA Code (Veterinary Dictionary for Regulatory Activities)







- 1.8. Risk-Benefit Analysis
  - 1.8.1. Concept and Components
  - 1.8.2. Quantitative Methods
    - 1.8.2.1. Relationship Between Benefit and Harm Impact Measures
    - 1.8.2.2. Incremental Benefit-Risk Ratio
    - 1.8.2.3. Multi-Criteria Analysis
  - 1.8.3. Cohort Simulation
- 1.9. Crisis Management
  - 1.9.1. Risk Assessment
  - 1.9.2. Response Coordination
  - 1.9.3. Risk and Crisis Communication
- 1.10. Pharmacoeconomics
  - 1.10.1. Cost-Benefit Analysis
  - 1.10.2. Cost-Effectiveness Analysis
  - 1.10.3. Cost-Utility Analysis
  - 1.10.4. Cost Minimization

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*Bet on your future and enroll now to secure a successful position in one of the most promising areas in the veterinary field”*

# 05 Methodology

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

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







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

## At TECH we use the Case Method

What should a professional do in a given situation? 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 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, in an attempt to recreate the actual conditions in a veterinarian's professional 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. Veterinarians who follow this method not only manage to assimilate concepts, but also develop their mental capacity through exercises to evaluate real situations and knowledge application
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. The feeling that the effort invested is effective becomes a very important motivation for veterinarians, which translates into a greater interest in learning and an increase in the 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.



*Veterinarians 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 65,000 veterinarians have been trained with unprecedented success in all clinical specialties, regardless of the surgical load. Our teaching method is developed in a highly demanding environment, where the students have a high socio-economic profile and an average age of 43.5 years.

*Relearning will allow you to learn with less effort and better performance, involving you more in your training, developing a critical mindset, defending arguments, and contrasting opinions: a direct equation for 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.



### Latest Techniques and Procedures on Video

TECH introduces students to the latest techniques, the latest educational advances and to the forefront of current and procedures of veterinary 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 suggesting that observing third-party experts can be useful. Learning from an Expert strengthens knowledge and memory, and generates confidence in future difficult decisions.



#### Quick Action Guides

TECH offers the most relevant contents of the course in the form of worksheets or quick action guides. A synthetic, practical, and effective way to help students progress in their learning.



06

# Certificate

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





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

This **Postgraduate Certificate in Pharmacovigilance** contains the most complete and up-to-date scientific on the market.

After the student has passed the assessments, they will receive their corresponding **Postgraduate Certificate** issued by **TECH Technological University** via tracked delivery\*.

The 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 Pharmacovigilance**

Official N° of Hours: **150 h.**



\*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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