Postgraduate Certificate
Drug Research and Development

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Postgraduate Certificate

Drug Research and Development

- Modality: **online**
- Duration: **12 weeks**
- Certificate: **TECH Global University**
- Credits: **12 ECTS**
- Schedule: **at your own pace**
- Exams: **online**

Website: **www.techtitute.com/us/medicine/postgraduate-certificate/drug-research-development**

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01

Introduction

The development of new drugs is necessary to combat certain pathologies for which there is still no cure or whose current treatments do not offer the expected results. It is therefore important to invest in pharmacological research and to have professionals specialized in this field.

The goal of healthcare is to achieve a cure for diseases and a better quality of life for patients. Investing in research is important, but so is having specialized professionals"

Increased investment in research in the healthcare field to improve the quality of life of patients means that more and more professionals specialized in this field are needed. Hence the importance of expanding information in all areas of research.

This Postgraduate Certificate in Drug Research and Development is designed to specialize professionals from different health branches in pharmacological research, a fundamental facet to find new treatments that allow the improvement of patients.

In this way, students will delve into the study of preclinical drug research, i.e., from the discovery of a molecule with therapeutic activity until it is marketed. Another very important part of this process is to know how to communicate new discoveries, which will allow further research in this field and promote its use.

Within the field of research, the professionals must also be equipped with statistical notions that will enable them to conduct clinical trials as accurately as possible. Statistics play a fundamental role in any clinical trial, from the design, conduct, analysis and reporting, in terms of controlling and minimizing bias and confounding factors, as well as measuring random errors.

Th e use of statistics in clinical trials allows the clinical investigator to reach reasonable and accurate conclusions from the information collected, and to probe decisions when certainties are scarce. Statistics are key to preventing errors and biases in medical research. Therefore, the inclusion of this module in this program is noteworthy.

The **Postgraduate Certificate in Drug Research and Development** contains the most complete and up-to-date educational program on the market. The most important features include:

- The development of practical cases presented by experts in Drug Research and Development
- The graphic, schematic, and practical contents with which they are created, provide scientific and practical information on the disciplines that are essential for professional development
- New developments in drug research and development
- Practical exercises where self-assessment can be used to improve learning
- Special emphasis on innovative methodologies in drug research and development
- 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

Expand your knowledge through this Postgraduate Certificate in Drug Research and Development that will allow you to specialize until you achieve excellence in this field”

This Postgraduate Certificate is the best investment you can make when selecting a refresher program, for two reasons: in addition to updating your knowledge in Drug Research and Development, you will obtain a qualification endorsed by TECH Global University"

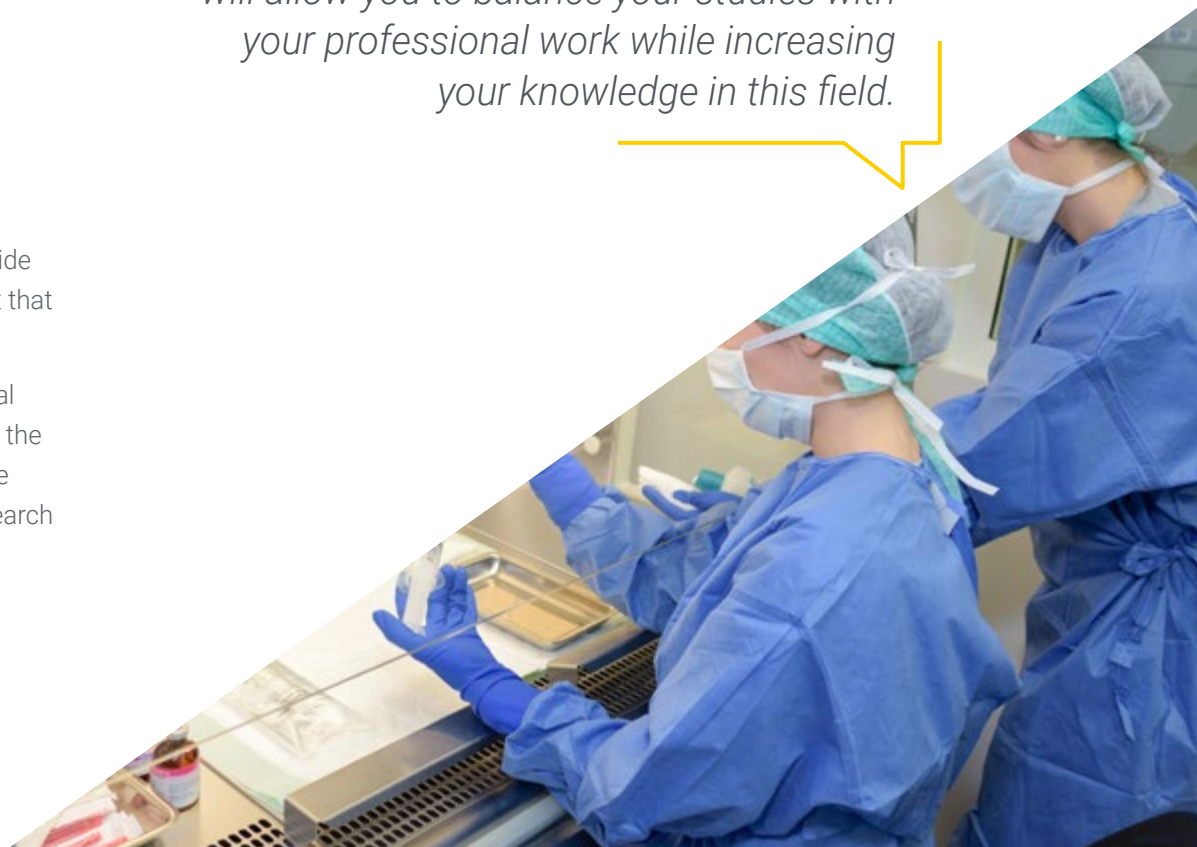
Do not hesitate to take this training with us. You will find the best teaching material with virtual lessons.

This 100% online Postgraduate Certificate will allow you to balance your studies with your professional work while increasing your knowledge in this field.

The teaching staff includes professionals from the Health sector, who bring their experience to this training 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 training programmed to train in real situations.

This program is designed around Problem-Based Learning, whereby the professional must try to solve the different professional practice situations that arise throughout the program. For this purpose, the professor will be assisted by an innovative interactive video system created by renowned and experienced experts in the field of drug research and development.



02

Objectives

The Postgraduate Certificate in Drug Research and Development is aimed at facilitating the performance of the research professional with the latest advances and most innovative treatments in the sector.

Thanks to this program you will be able to specialize in Drug Research and Development, and learn about the latest advances in the field"

General Objectives

- Establish the phases involved in the development of a new drug
- Analyze the steps prior to the development of a clinical trial (preclinical research)
- Examine how a drug is introduced into the market after the clinical trial has been conducted
- Develop knowledge that provides a basis or opportunity to be original in the development and/or application of ideas, often in a research context
- Apply the acquired knowledge and resolution skills in the development of protocols
- Structure statistical methods and techniques
- Communicate and transmit statistical results through the preparation of different types of reports, using terminology specific to the fields of application
- Compile, identify and select sources of public biomedical information, from international agencies and scientific organizations, on the study and dynamics of populations
- Analyze the scientific method and work on skills in the management of information sources, bibliography, protocol elaboration and other aspects considered necessary for the design, execution and critical assessment
- Demonstrate logical thinking and structured reasoning in determining the appropriate statistical technique

Specific Objectives

- Explain the pharmacokinetic processes that a drug undergoes in the organism
- Identify the legislation that regulates each of the steps in the development and authorization of a drug
- Define the specific regulation of some drugs (biosimilars, advanced therapies).
- Define the use in special situations and their types
- Examine the process of financing a drug
- Specify strategies for the dissemination of research results
- Present how to read scientific information critically
- Compile sources of information on drugs and their types
- Identify and incorporate in the advanced mathematical model, which represents the experimental situation, those random factors involved in a high-level biosanitary study
- Design, collect and clean a data set for subsequent statistical analysis
- Identify the appropriate method for determining the sample size
- Distinguish between different types of studies and choose the most appropriate type of design according to the research objective
- Communicate and transmit statistical results correctly, through the preparation of reports
- Acquire an ethical and social commitment

03

Course Management

The program's teaching staff includes leading experts in research and health, who bring the experience of their work to this training. Additionally, other recognized experts participate in its design and preparation, completing the program in an interdisciplinary manner.

Leading experts in Drug Research and Development have come together to show you all their knowledge in this field"

Management

Dr. Gallego Lago, Vicente

- Doctoral studies with the qualification of Outstanding
- Honors Degree in Pharmacy from the Complutense University of Madrid
- Resident Internal Pharmacist Examination obtaining the No. 1 in this selective test
- Military pharmacist at HMC Gómez Ulla. Madrid
- Resident Internal Pharmacist (F.I.R) of the Pharmacy Service of the "12 de Octubre" Hospital. Madrid

Teachers

Ms. Martín-Arriscado Arroba, Cristina

- Biostatistics at the Research and Scientific Support Unit of the 12 de Octubre University Hospital (i+12) and the Clinical Research Units and Clinical Trials Platform (SCReN)
- Member of the Drug Research Ethics Committee of the 12 de Octubre University Hospital

Dr. Valtueña Murillo, Andrea

- Pharmaceutical Industry. Community pharmacy. Hospital Pharmacy
- Master's Degree in Pharmaceutical and Parapharmaceutical Industry at CESIF | November 2018 - November 2019
- Degree in Pharmacy from the Complutense University Madrid | 2013– 2018

A unique, key, and decisive training experience to boost your professional development"

04

Structure and Content

The structure of the content has been designed by leading professionals in the Drug Research and Development Sector, with extensive experience and recognized prestige in the profession, backed by the volume of cases reviewed, studied, and diagnosed, and with extensive knowledge of new technologies applied to Drug Research and Development.

The Postgraduate Certificate in Drug Research and Development contains the most complete and up-to-date scientific program on the market"

Module 1. Drug research and development

1.1. Development of New Drugs
- 1.1.1. Introduction
- 1.1.2. Development Phases of New Drugs
- 1.1.3. Discovery Phase
- 1.1.4. Preclinical Phase
- 1.1.5. Clinical Phase
- 1.1.6. Approval and Registration

1.2. Discovery of an Active Substance
- 1.2.1. Pharmacology
- 1.2.2. Seeding Trials
- 1.2.3. Pharmacological Interactions

1.3. Pharmacokinetics
- 1.3.1. Methods of Analysis
- 1.3.2. Absorption
- 1.3.3. Distribution
- 1.3.4. Metabolism
- 1.3.5. Excretion

1.4. Toxicology
- 1.4.1. Single Dose Toxicity
- 1.4.2. Repeated Dose Toxicity
- 1.4.3. Toxicokinetics
- 1.4.4. Carcinogenicity
- 1.4.5. Genotoxicity
- 1.4.6. Reproductive Toxicity
- 1.4.7. Tolerance
- 1.4.8. Dependency

1.5. Regulation of Drugs for Human Use
- 1.5.1. Introduction
- 1.5.2. Authorization Procedures
- 1.5.3. How a Drug is Evaluated: Authorization Dossier
- 1.5.4. Technical Data Sheet, Package Leaflet and EPAR
- 1.5.5. Conclusions

1.6. Pharmacovigilance
- 1.6.1. Pharmacovigilance in Development
- 1.6.2. Pharmacovigilance in Marketing Authorization
- 1.6.3. Post-authorization Pharmacovigilance

1.7. Uses in Special Situations
- 1.7.1. Introduction
- 1.7.2. Regulations
- 1.7.3. Examples

1.8. From Authorization to Commercialization
- 1.8.1. Introduction
- 1.8.2. Drug Financing
- 1.8.3. Therapeutic Positioning Reports

1.9. Special Forms of Regulation
- 1.9.1. Advanced Therapies
- 1.9.2. Accelerated Approval
- 1.9.3. Biosimilars
- 1.9.4. Conditional Approval
- 1.9.5. Orphan Drugs

1.10. Dissemination of Research
- 1.10.1. Scientific Article
- 1.10.2. Types of Scientific Articles
- 1.10.3. Quality of Research *Checklist*
- 1.10.4. Drug Information Sources

Module 2. Biostatistics

2.1. Study Design
- 2.1.1. Research Question
- 2.1.2. Population to be Analyzed
- 2.1.3. Classification
  - 2.1.3.1. Comparison between Groups
  - 2.1.3.2. Maintenance of the Described Conditions
  - 2.1.3.3. Assignment to Treatment Group
  - 2.1.3.4. Blinding Degree
  - 2.1.3.5. Modality of Intervention
  - 2.1.3.6. Centers Involved

2.2. Types of Randomized Clinical Trials Validity and Biases
- 2.2.1. Types of Clinical Trials
  - 2.2.1.1. Superiority Study
  - 2.2.1.2. Equivalence or Bioequivalence Study
  - 2.2.1.3. Non-Inferiority Study
- 2.2.2. Analysis and Validity of Results
  - 2.2.2.1. Internal Validity
  - 2.2.2.2. External Validity
- 2.2.3. Biases
  - 2.2.3.1. Selection
  - 2.2.3.2. Measurement
  - 2.2.3.3. Confusion

2.3. Sample Size Protocol Deviations
- 2.3.1. Parameters to be Used
- 2.3.2. Protocol Justification
- 2.3.3. Protocol Deviations

2.4. Methodology
- 2.4.1. Missing Data Handling
- 2.4.2. Statistical Methods
  - 2.4.2.1. Description of Data
  - 2.4.2.2. Survival
  - 2.4.2.3. Logistic Regression
  - 2.4.2.4. Mixed Models
  - 2.4.2.5. Sensitivity Analysis
  - 2.4.2.6. Multiplicity Analysis

2.5. When Does the Statistician Become Part of the Project
- 2.5.1. Statistician Role
- 2.5.2. Points of the Protocol to be Reviewed and Described by the Statistician
  - 2.5.2.1. Study Design
  - 2.5.2.2. The Primary and Secondary Objectives of the Study
  - 2.5.2.3. Sample Size Calculation
  - 2.5.2.4. Variables:
  - 2.5.2.5. Statistical Justification
  - 2.5.2.6. Material and Methods used to Study the Objectives of the Study

2.6. Design of the CRF (Case Report Form)
- 2.6.1. Information Gathering Variables Dictionary
- 2.6.2. Variables and Data Entry
- 2.6.3. Database Security, Testing and Debugging

2.7. Statistical Analysis Plan
- 2.7.1. Statistical Analysis Plan
- 2.7.2. When to Perform a Statistical Analysis Plan
- 2.7.3. Statistical Analysis Plan Parts

2.8. Intermediate Analysis
- 2.8.1. Reasons for an Early Stopping of a Clinical Trial
- 2.8.2. Implications of Early Termination of a Clinical Trial
- 2.8.3. Statistical Designs

2.9. Final Analysis
- 2.9.1. Final Report Criteria
- 2.9.2. Plan Deviations
- 2.9.3. Guidelines for the Elaboration of the Final Report of a Clinical Trial

2.10. Statistical Review of a Protocol
- 2.10.1. *Checklist*
- 2.10.2. Frequent Errors in the Review of a Protocol

This will be a key learning experience to advance your career"

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:

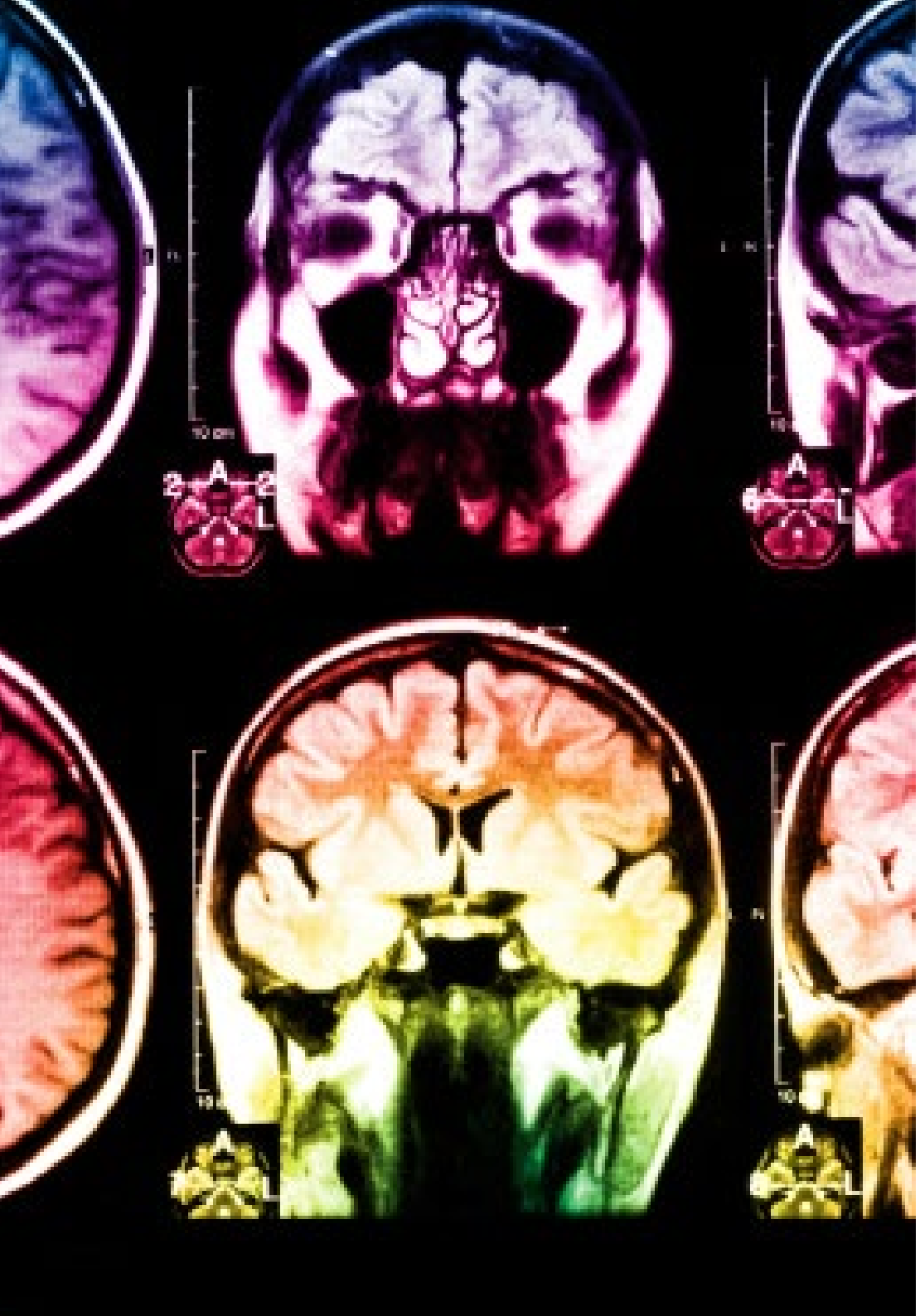
1. Students who follow this method not only achieve the assimilation of concepts, but also a development of their mental capacity, through exercises that evaluate real situations and the application of knowledge.
2. Learning is solidly translated into practical skills that allow the student to better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

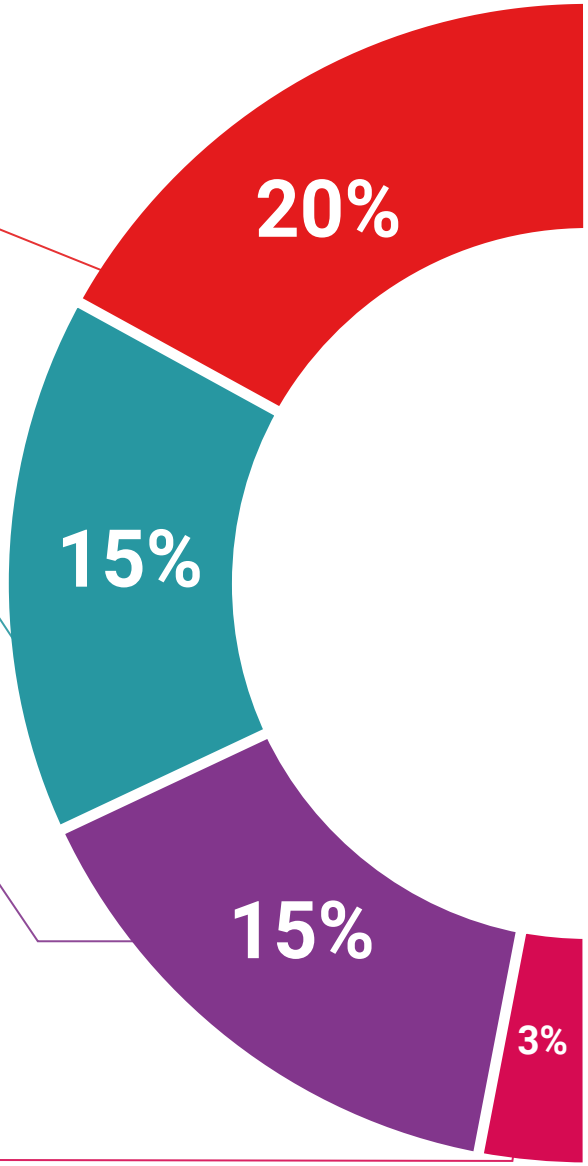
Interactive Summaries

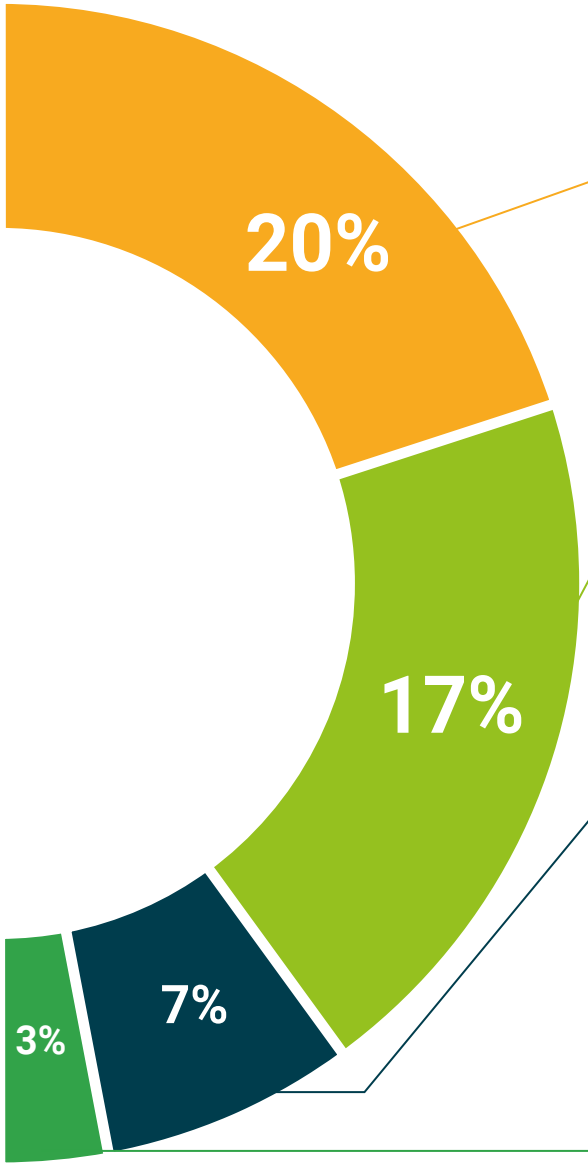
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

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 Drug Research and Development guarantees students, in addition to the most rigorous and up-to-date education, access to a Postgraduate Certificate issued by TECH Global University.

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

This program will allow you to obtain your **Postgraduate Certificate in Drug Research and Development** 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 Certificate in Drug Research and Development**

Modality: **online**

Duration: **12 weeks**

Accreditation: **12 ECTS**


tech global university

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

Postgraduate Certificate in Drug Research and Development

This is a program of 360 hours of duration equivalent to 12 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

Dr. Pedro Navarro Illana
Rector

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 Global University will make the necessary arrangements to obtain it, at an additional cost.

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