Postgraduate Diploma

Processing and Development of Sterile Pharmaceutical Products

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Postgraduate Diploma

Processing and Development of Sterile Pharmaceutical Products

Course Modality: **Online**
Duration: **6 months.**
Certificate: **TECH Technological University**
Official N° of hours: **425 h.**
Website: **www.techtitute.com/pharmacy/postgraduate-diploma/postgraduate-diploma-processing-development-sterile-pharmaceutical-products**

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01

Introduction

The development of industry and the discovery of new synthetic medicines has transformed the concept of medicine. We have gone from an individualized medicine for a specific patient and specific needs, to a global medicine. That is, for a specific disease, but intended for a large number of patients.

The Postgraduate Diploma in Processing and Development of Sterile Pharmaceutical Products contains the most complete, unprecedented and up to date scientific program on the market"

Industrialized medicine has been a breakthrough in current therapeutics, since many patients have found a remedy for their illnesses.

However, this industrialized drug does not cover all therapeutic needs. For various reasons, there are therapeutic gaps that only the Individualized Medicine can fill.

The Master Formulation or, nowadays, "individualized medicine" is the essence of the pharmaceutical profession. It has been the starting point of human medicine therapeutics, when patient care was individualized.

The master formula, understood as the medicine intended for an individualized patient, prepared by or under the direction of a pharmacist, to expressly comply with a detailed medical prescription of the medicinal substances it includes, requires that the professional activity be adjusted to strict and faithfully reproducible procedural guidelines. In this sense, pharmacists need to be updated and promote continuous training in the knowledge and compliance with the standards for the correct preparation and quality control of master formulas in order to achieve the required level of quality.

The objective of this program is to train pharmacists in a discipline unique and exclusive to their profession, training professionals who can respond to therapeutic gaps with the formulation of an individualized drug with the quality and efficacy of an industrialized drug.

This **Postgraduate Diploma in Processing and Development of Sterile Pharmaceutical Products** contains the most complete and up to date scientific program on the market. The most important features of the program include:

- Clinical cases presented by experts in the different specialties. The graphic, schematic, and eminently practical contents of which they are composed provide scientific and practical information on the disciplines that are essential for professional practice
- Sterile Pharmaceuticals Processing and Development News
- Algorithm-based interactive learning system for decision-making in the presented clinical situations
- With a special emphasis on evidence-based medicine and research methodologies in Processing and Development of Sterile Pharmaceutical Products
- All this will be complemented by 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
- Availability of content from any fixed or portable device with an Internet connection.

The Postgraduate Diploma in Processing and Development of Sterile Pharmaceutical Products contains the most complete and up to date scientific program on the market"

This Postgraduate diploma may be the best investment you can make in the selection of a refresher program for two reasons: in addition to updating your knowledge in the Processing and Development of Sterile Pharmaceutical Products, you will obtain a Postgraduate Diploma from TECH Technological University".

Increase your confidence in decision making by updating your knowledge through this Postgraduate diploma in Processing and Development of Sterile Pharmaceutical Products

Don't miss the opportunity to update your knowledge in Processing and Development of Sterile Pharmaceutical Products to improve patient care

Its teaching staff includes health professionals belonging to the field of pharmacology, who bring to this training the experience of their work, in addition to recognized specialists belonging to leading scientific societies.

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 an immersive training program to train in real situations.

This program is designed around Problem Based Learning, whereby the physician must try to solve the different professional practice situations that arise during the course. This will be done with the help of an innovative interactive video system developed by renowned experts in the field of pharmacology with extensive teaching experience.

02

Objectives

The main objective of the program is the development of theoretical and practical learning, so that the health professional can master in a practical and rigorous way the study of Processing and Development of Sterile Pharmaceutical Products.

This refresher program will generate a sense of security in the elaboration of dosage forms, which will help you grow personally and professionally"

General Objectives

- Guarantee the correct preparation, by the pharmacist, of master formulas and office preparations according to current regulations by means of theoretical/practical training complementary to that acquired in the degree/licensure, updating knowledge, forming skills and developing attitudes.
- update knowledge, skills and attitudes developed in this sector.

Take the opportunity and take the step to get up to date on the latest developments in Processing and Development of Sterile Pharmaceutical Products"

Specific Objectives

Module 1. Application of the quality assurance and control system for officinal preparations. R.D.175/2001

- Explain the use of active ingredients for each of the pharmaceutical form
- Explain the current legislation on elaboration and quality control of magistral formulas and officinal preparations
- Explain resources and sources of consultation in the Master Formulation laboratory
- Describe the proper handling of the tooling
- Proper use of measuring systems
- Explain the significant differences and peculiarities in the elaboration of different topical and oral pharmaceutical forms: emulsions, ointments, solutions, suspensions, colloidal dispersions (gels), papers, capsules and powders

Module 2. Biopharmacokinetics and Pharmacokinetics

- Proper use of measuring systems
- Explain the chemical, therapeutic and biological equivalence of drugs Describe the proper handling of the tooling
- Define the principles of clinical pharmacokinetics
- Explain the release as a limiting factor of absorptionr
- Explain the different mechanisms of absorption
- Describe the physiological factors influencing gastrointestinal absorption
- Explain the physico-chemical factors limiting absorption
- Describe the structure of the skin
- Define the factors influencing the absorption of substances through the skin
- Explain the differences between parenteral aqueous solutions and parenteral delayed solutions.

Module 3. Sterile dosage formsv

- Define the concept of sterile in magistral formulation
- Explain the elaboration of ophthalmic eye drops, as well as the tools, regulations, etc
- Describe the preparation of ophthalmic ointments, as well as tools, regulations, etc
- Explain the elaboration of sterile formulas for parenteral route in all its variants: intravenous, subcutaneous, intramuscular, etc
- Describe the elaboration process of parenteral nutrition according to composition, quality, etc.
- Explain different sterilization systems and their characteristic
- Explain how to establish expiration dates for sterile pharmaceutical forms
- List the most frequent pathologies with therapeutic vacuum in ophthalmology
- Explain the elaboration of an autologous serum eye drops

03

Course Management

This program includes in its teaching staff health professionals of recognized prestige, who belong to the field of pharmacology and who bring to this training the experience of their work.

In addition, renowned specialists, members of prestigious national and international scientific communities, are involved in designing and preparing the program.

Learn from leading professionals the latest advances in Processing and Development of Sterile Pharmaceutical Products"

Management

Dr. Sánchez Guerrero, Amelia

- Head of the Hospital Pharmacy Service at the Puerta del Hierro U.H. In Majadahonda since February 2015
- Doctorate. Doctor Complutense University. Madrid
- Degree in Pharmacy. Complutense University of Madrid. Madrid
- Member of the Teaching Commission. Puerto de Hierro U.H. Majadahonda
- Chairman of the Pharmacy and Therapeutics Committee. Puerto de Hierro U.H. Majadahonda
- Know, understand and value your pharmacist within the hospital. Correo Farmacéutico Award for one of the Best Pharmacy Initiatives of the Year 2017 in the Pharmaceutical Care and Health Education section. Madrid, April 2018.
- Know, understand and value your pharmacist within the hospital. Sanitaria 2000 Award "Visibility of the hospital pharmacist in the hospital setting" organized by the SEFH and Redacción Médica. IV Global Meeting of Hospital Pharmacy. Córdoba, April 2018

Professors

Dr. Santiago Prieto, Elvira

- Head of the non-hazardous sterile, non-sterile and nutritional drug processing area of the Pharmacy Service of HUPHM
- Assistant pharmacist. Jiménez Díaz foundation Puerta de Hierro- Majadahonda
- Specialist Pharmacist in Hospital Pharmacy, hired by the Foundation for Biomedical Research of the Puerta de Hierro University Hospital. 2013-2014
- Resident Pharmacist. Specialization in Hospital Pharmacy. Puerto de Hierro U.H. - Majadahonda. 2009-2013
- Degree in Pharmacy. Faculty of Pharmacy. Complutense University of Madrid
- Master's Degree in Pharmaceutical Sciences. Speciality: "Community pharmacy and quality of care". UCM

Rodríguez Marrodán, Belén

- FEA Specialist in Hospital Pharmacy. Pharmacy Department. Puerto de Hierro U.H. Majadahonda
- Degree in Pharmacy from the Complutense University of Madrid
- Specialist in Hospital Pharmacy. Ministry of Education and Culture
- Member of the Working Group on Safety in the Use of Medication in Pediatrics. Puerta de Hierro U.H. Majadahonda
- Member of the Clinical Research Ethics Committee (CEIm). Puerta de Hierro U.H. Majadahonda
- Hospital Pharmacy Resident Tutor. Puerta de Hierro U.H. Majadahonda
- Member of the Medicines Committee. Spanish Association of Pediatrics
- SMFH Secretariat. Madrid Society of Hospital Pharmacists
- Member of the Quality of Care and Patient Safety Working Group. Spanish Society of Hospital Pediatrics
- Diploma in Pharmaceutical Oncology. University of Valencia

Dr. Gumiel Baena, Inés

- Inpatient pharmaceutical care. Puerto de Hierro U. Hospital Majadahonda. Madrid
- Degree in Pharmacy. Complutense University of Madrid, Spain. 2010-2015
- Speciality in Hospital Pharmacy. Puerto de Hierro University Hospital Majadahonda, Madrid -2016 -2020
- Master's Degree in Health Products. University of Granada. –Feb-Dic 2019
- Pharmacokinetics. Severo Ochoa University Hospital
- Primary Care Pharmacy. Northwest Assistance Directorate. SERMAS
- General Subdirectorate of Pharmacy and Health Products. Health Council of SERMAS
- Antibiotic optimization program. Getafe University Hospital

04

Structure and Content

The structure of the contents has been designed by a team of professionals knowledgeable about the implications of training in daily pharmaceutical practice, aware of the relevance of current training in order to develop individualized dosage forms in a safe and efficient manner and committed to quality teaching through new educational technologies.

This Postgraduate Diploma in Processing and Development of Sterile Pharmaceutical Products contains the most complete and up to date scientific program on the market"

Module 1. Application of the Quality Assurance and Control System for Master Formulas and Office Preparations. R.D.175/2001

1.1. Standards of Correct Elaboration and Quality Control
- 1.1.1. Quality Management Systems
- 1.1.2. Personal
  - 1.1.2.1. Responsibilities
  - 1.1.2.2. Training
  - 1.1.2.3. Hygiene
- 1.1.3. Premises and Tools
  - 1.1.3.1. General Characteristics of the Premises
  - 1.1.3.2. General Equipment Characteristics
    - 1.1.3.2.1. General Equipment
    - 1.1.3.2.2. Specific Equipment
- 1.1.4. Documentation
  - 1.1.4.1. General Documentation
  - 1.1.4.2. Documentation related to Raw Materials
  - 1.1.4.3. Packaging Material Documentation
  - 1.1.4.4. Documentation related to Master Formulas and Official Preparations
- 1.1.5. Raw Materials and Packaging Material
  - 1.1.5.1. Origin
    - 1.1.5.1.1. Raw Materials Acquired from an Authorized Center
    - 1.1.5.1.2. Raw Materials Acquired from Other Entities
    - 1.1.5.1.3. Raw Materials Centralized by the Administration
    - 1.1.5.1.4. Packaging Material
      - 1.1.5.1.4.1. Glass
      - 1.1.5.1.4.2. Plastic
        - 1.1.5.1.4.2.1. PVC
        - 1.1.5.1.4.2.2. PET
        - 1.1.5.1.4.2.3. PP
        - 1.1.5.1.4.2.4. PE
  - 1.1.5.2. Reception and Quarantine
  - 1.1.5.3. Conformity Control
  - 1.1.5.4. Documentation
- 1.1.6. Production
  - 1.1.6.1. Production by Third Parties
- 1.1.7. Dispensing and Labeling
  - 1.1.7.1. Patient Information
  - 1.1.7.2. Labelling

1.2. General Procedures
- 1.2.1. Introduction
- 1.2.2. Objectives
- 1.2.3. General Procedures
  - 1.2.3.1. PG for Internal Documentation Management
  - 1.2.3.2. GP for the Development of Procedures
  - 1.2.3.3. GP for Managing Records
  - 1.2.3.4. PG for Cleaning and Disinfection Premises and Equipment
  - 1.2.3.5. GP for Personnel Hygiene and Clothing
  - 1.2.3.6. GP of Subcontracting
  - 1.2.3.7. GP of Shopping
  - 1.2.3.8. GP for Product Storage, Conservation and Disposal
  - 1.2.3.9. GP for Team Management
  - 1.2.3.10. GP for Toration and Qualification
  - 1.2.3.11. GP for the Study, Elaboration and Dispensing of Master Formulas and Office Preparations
  - 1.2.3.12. GP for the Labeling and Dispensing of Master Formulas and Office Preparations

1.3. Development of Standard Operating Procedures
- 1.3.1. Weighing Work SOPs
- 1.3.2. Powder Mixing and Production SOPs
- 1.3.3. Disaggregation SOPs
- 1.3.4. SOPs for the Manufacture of Hard Gelatin Capsules
- 1.3.5. SOP for the Production of Gastroresistant Capsules
- 1.3.6. SOPs for Gel Production
- 1.3.7. SOPs for Solutions Production
- 1.3.8. SOPs for Ointment and Paste Production
- 1.3.9. SOPs for Emulsions Production
- 1.3.10. SOPs for Suspensions Production
- 1.3.11. SOPs for the Production of Paper Rolls
- 1.3.12. SOPs for Sterile Preparations

Module 2. Biopharmaceutics and Pharmacokinetics

2.1. New Aspects of Galenic Pharmacy
- 2.1.1. Introduction
- 2.1.2. Chemical, Therapeutic and Biological Equivalence of Medicines
- 2.1.3. Biopharmaceutics and Basic Pharmacokinetics
- 2.1.4. Pharmaceutic Technology
- 2.1.5. Clinical Pharmacokinetics

2.2. Evolution of Medicines in the Body
- 2.2.1. LADME
- 2.2.2. Kinetics of LADME Processes
- 2.2.3. Release as a Limiting Factor for Absorption

2.3. Absorption Mechanisms
- 2.3.1. Passive Diffusion
- 2.3.2. Convective Diffusion
- 2.3.3. Active Transport
- 2.3.4. Facilitated Transport
- 2.3.5. Ion Pairs
- 2.3.6. Pinocytosis

2.4. Routes of Administration
- 2.4.1. Oral Route
  - 2.4.1.1. Physiological Factors Affecting Gastrointestinal Absorption
  - 2.4.1.2. Physicochemical Factors that Limit Absorption
- 2.4.2. Topical Route
  - 2.4.2.1. Structure of the Skin.
  - 2.4.2.2. Factors Influencing the Absorption of Substances Through the Skin
  - 2.4.2.3. Parenteral Route
    - 2.4.2.3.1. Parenteral Aqueous Solutions
    - 2.4.2.3.2. Delayed Parenteral Solutions

Module 3. Sterile Dosage Forms

- 3.1. Definition of Sterile in Master Formulation
- 3.2. Expiration Dates of Sterile Dosage Forms
  - 3.2.1. Protocols for Producing Sterile Products
    - 3.2.1.1. Work GP
    - 3.2.1.2. Microbiological Control SOPs
    - 3.2.1.3. Lyophilization Protocol
- 3.3. Sterilization
  - 3.3.1. Heat Sterilization
    - 3.3.1.1. Humid Heat
    - 3.3.1.2. Dry Heat
      - 3.3.1.2.1. Sterilization of Oils
      - 3.3.1.2.2. Sterilization of Glass Materials
      - 3.3.1.2.3. Tindalization
  - 3.3.2. Sterilization by Filtration
    - 3.3.2.1. Types of Filtration
  - 3.3.3. Other Types of Sterilization
  - 3.3.4. Disinfectants
    - 3.3.4.1. Most Frequent Disinfectants
- 3.4. External Sterile Pharmaceutical Forms. Eye Drops and Ointments
- 3.5. Internal Sterile Pharmaceutical Forms: Parenterals and Freeze-Dried

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

05

Methodology

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

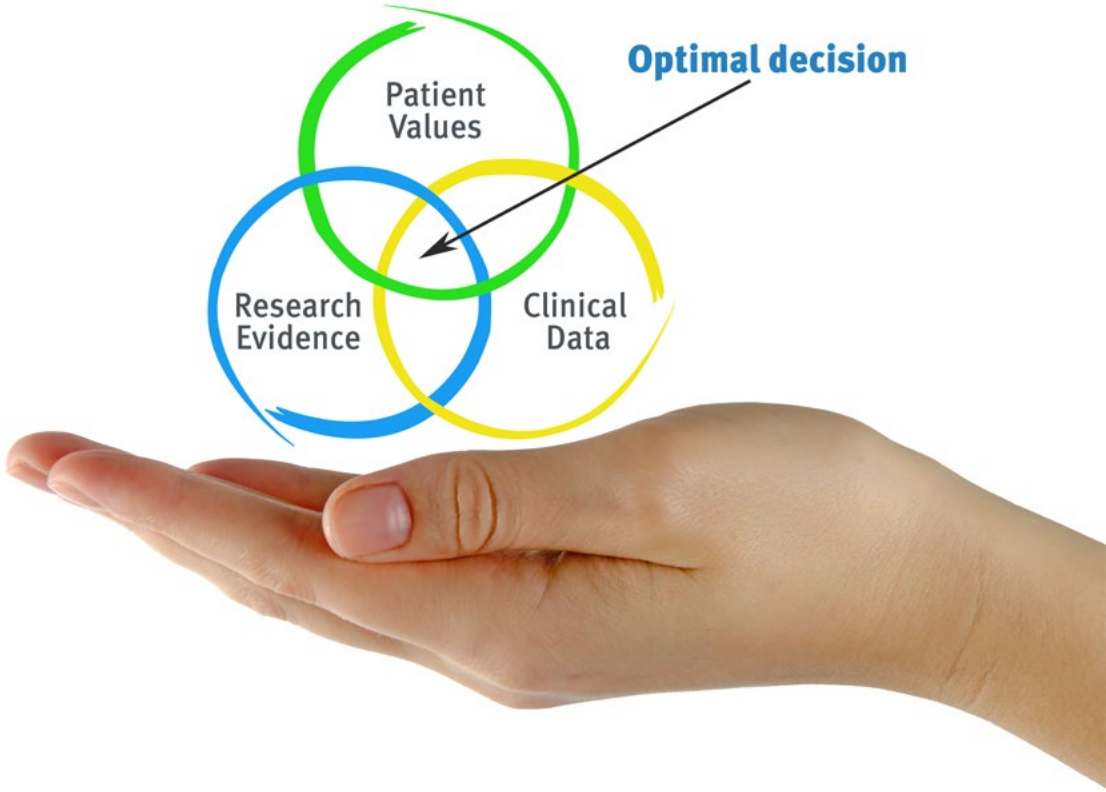
This teaching system is used, for example, in the most prestigious medical schools in the world, and major publications such as the **New England Journal of Medicine** have considered it to be one of the most effective.

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 be confronted with multiple simulated clinical cases based on real patients, in which they will have to investigate, establish hypotheses and ultimately, resolve the situation. There is an abundance of scientific evidence on the effectiveness of the method. Pharmacists learn better, more quickly 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, attempting to recreate the actual conditions in a pharmacist'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:

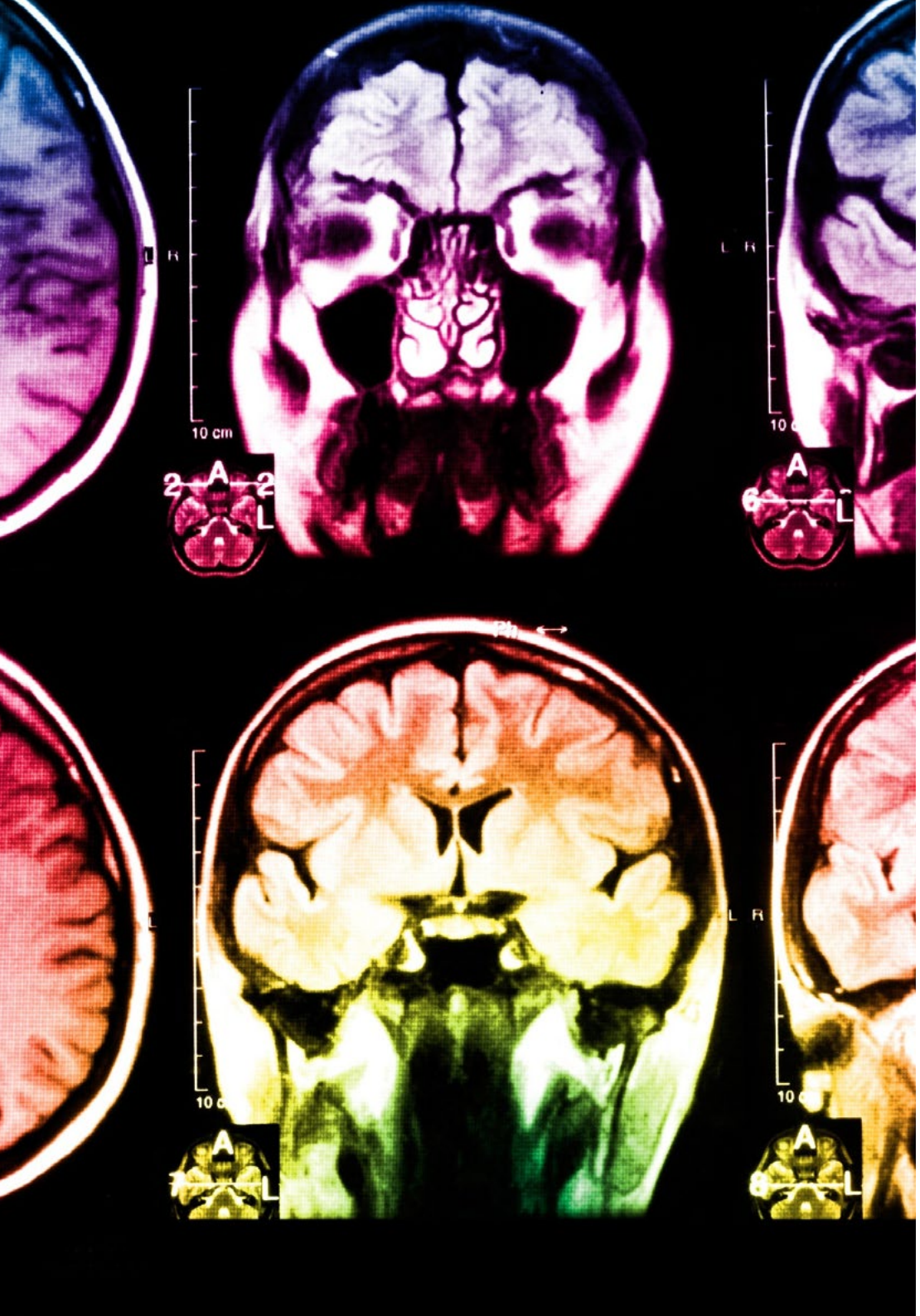
1. Pharmacists who follow this method not only grasp concepts, but also develop their mental capacity, by evaluating real situations and applying their knowledge.
2. Learning is solidly translated into practical skills that allow the student to better integrate into the real world.
3. Ideas and concepts 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 Harvard case method with the best 100% online teaching methodology available: Relearning.

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.

Pharmacists 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 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 115.000 pharmacists have been trained with unprecedented success in all clinical specialties, regardless of the surgical load. This pedagogical methodology is developed in a highly demanding environment, with a university student body with a high socioeconomic 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 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 created specifically for the course by specialist pharmacists who will be teaching the course, so that the didactic development is highly specific and accurate.

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.

Video Techniques and Procedures

TECH introduces students to the latest techniques, to the latest educational advances, to the forefront of current pharmaceutical care procedures. All of this, first hand, and explained and detailed with precision to contribute to assimilation and a better understanding. And best of all, you can watch them as many times as you want.

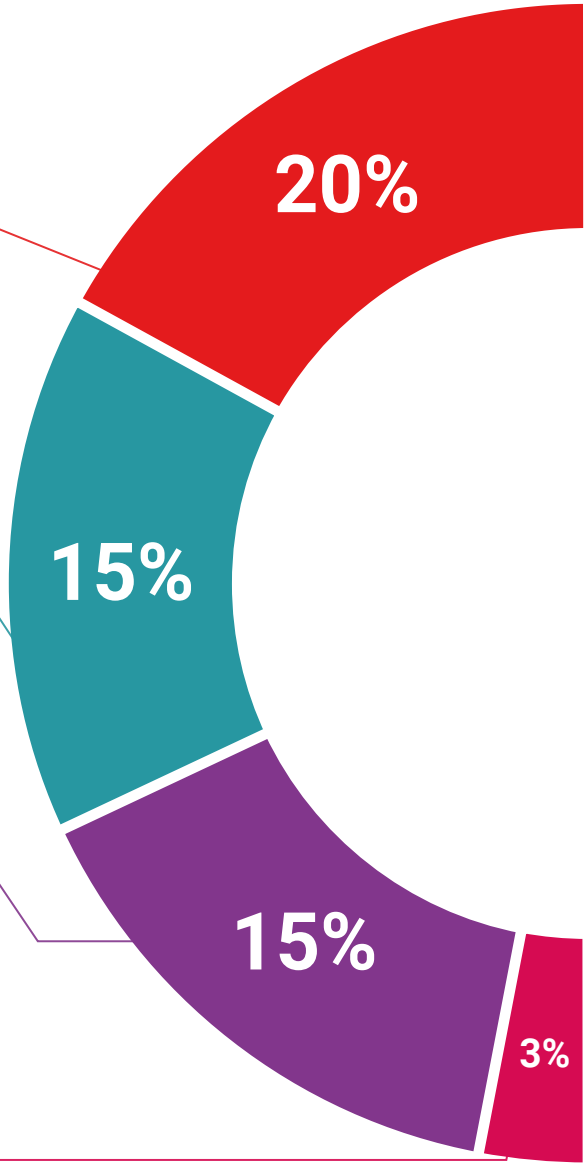
Interactive Summaries

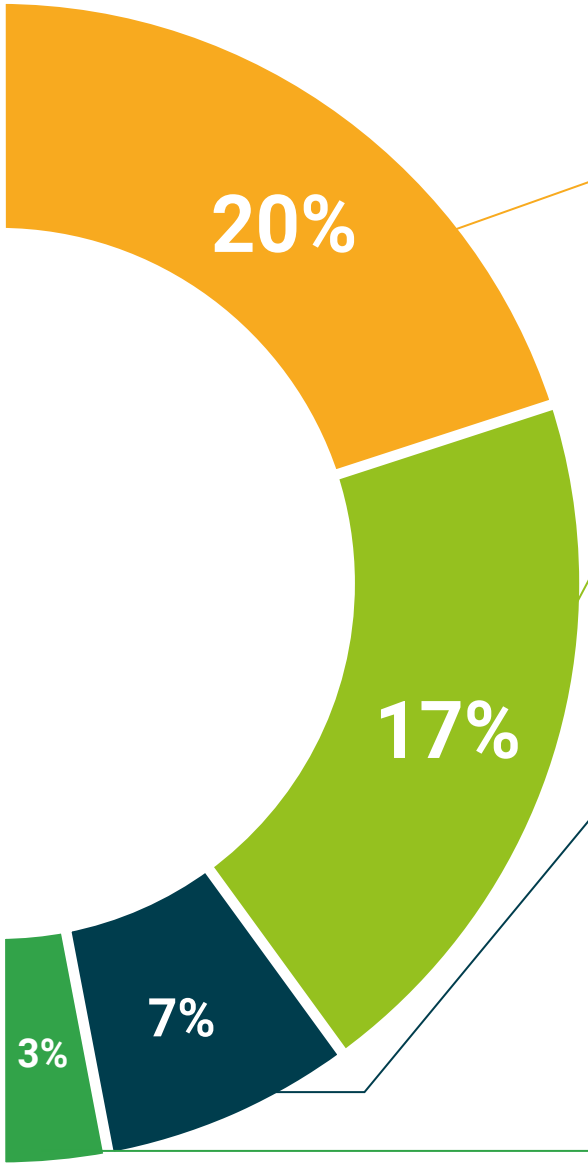
The TECH team presents the contents attractively and dynamically in multimedia lessons that include audio, videos, images, diagrams, and concept maps in order to reinforce knowledge.

This unique multimedia content presentation training system 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, 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 & 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 your goals.

Classes

There is scientific evidence on the usefulness of learning by observing experts: The system termed Learning from an Expert strengthens knowledge and recall capacity, and generates confidence in the face of difficult decisions in the future.

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 Diploma in Processing and Development of Sterile Pharmaceutical Products guarantees, in addition to the most rigorous and update training, access to a Postgraduate Diploma issued by TECH Technological University.

Successfully complete this training and receive your university degree without travel or laborious paperwork"

This **Postgraduate Diploma in Processing and Development of Sterile Pharmaceutical Products** contains the scientific most complete and update program on the market.

After you have passed the evaluations,, you will receive your corresponding byv **Postgraduate Diploma** issued by **TECH Technological University** via tracked delivery*.

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

Title: **Postgraduate diploma in Processing and Development of Sterile Pharmaceutical Products**

Official N° of hours **425 h.**


tech technological university

Awards the following

CERTIFICATE

to

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

For having passed and accredited the following program

POSTGRADUATE DIPLOMA

in

Processing and Development of Sterile Pharmaceutical Products

This is a qualification awarded by this University, equivalent to 425 hours, with a start date of dd/mm/yyyy and an end date of dd/mm/yyyy.

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

June 17, 2020

Tere Guevara Navarro

Dean

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

*Apostille Convention. In the event that the student wishes to have their paper certificate issued with an apostille, TECH EDUCATION will make the necessary arrangements to obtain it, at an additional cost.

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