

# COMPU PHARMA

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## Active Pharmaceutical Ingredients Catalog

*E-lessons specifically targeted to the Active Pharmaceutical Ingredients sector*



## Active Pharmaceutical Ingredients Lessons

Below is a list of e-lessons targeted specifically to the Active Pharmaceutical Ingredients [API] sector. If you would like to experience any of these lessons please contact us and we'll set up a tailored lesson plan for you on our online learning management system.

This will allow you to gather stakeholders together to review both the e-lessons and the proposed curriculum at one time, further increasing training efficiency... even from the planning stages. And, because it's available for review online, it is accessible from anywhere, allowing you to review from multiple sites and time zones.

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### API Manufacturing - GMP Basics

Code	Lesson	Description
PGB-500	Introduction to the Pharmaceutical Industry	Introduces the Pharmaceutical Industry, what it manufactures, and the typical departments found in a pharmaceutical plant. * Replaces PGB-101 Introduction to the Pharmaceutical Industry
BGB-501	Introduction to GMP for APIs	What GMP is in terms of the API industry, why it is important for safe guarding the end user, and the laws that govern it?
BGB-502	Regulatory Agencies	Who regulates the API industry, how new drugs are approved, types of regulatory inspections and inspection outcomes, and the role of employees in inspections.
BGB-503	API Contamination Prevention	How API products can be contaminated during production and how to minimize contamination through the use of PPE and good hygiene habits.
BGB-504	Dress Codes for APIs	Explains dress codes and why they are so important in the API Industry. Examples of the different types of clothing required for different tasks are given.
BGB-505	GMP Goals for APIs	GMP from the point of view of the API company, the employee, and the consumer. Also, the implications of non-compliance for each.

## API Manufacturing - GMP Intermediate

Code	Lesson	Description
BGI-500	GMP – SOPs for APIs	What an SOP is, why SOPs must be followed in API plants and what information they should contain.
BGI-501	GMP – Records for APIs	How to complete records required for API manufacture. Records include batch production records (BPR), Master production records, equipment records, records of materials and laboratory sample records.
BGI-580	Labeling in API Plants	The importance of accurate labeling in an API Plant. What must be contained on a label, along with label distribution and reconciliation.

## Pharmaceutical GMP - Intermediate (◆ Available in French, \* Available in Spanish)

Code	Lesson	Description
PQI-510	Personnel and Training	Describes GMP requirements concerning personnel, training, clothing, hygiene and health.
PQI-520	Warehousing *	Introduction to Pharmaceutical warehousing. Covers warehouse functions, GMP in the warehouse and QC status for materials and products.
PQI-730	Cleaning of Equipment ◆	Different equipment cleaning methods used in the Pharmaceutical Industry.
PQI-780	Labeling	The importance of accurate labeling in a pharmaceutical plant. What must be contained on a label, along with label distribution and reconciliation.
PQI-790	Buildings and Facilities	The GMP design requirements for a manufacturing facility. This includes the product flow, environmental controls, cleaning and sanitization.
RGM-500	Executive Responsibility in Pharmaceutical Manufacturing	The responsibilities of executive management in the FDA regulated pharmaceutical industry. Describes the legal requirements and the corporate and personal consequences of non-compliance.

## API Manufacturing - Process Understanding

Code	Lesson	Description
PUA-500	Chemical Reactions – Introduction	Explains how to control a chemical reaction by monitoring the critical process variables.
PUA-501	Chemical Reactions – Properties	The main physical and chemical properties needed to monitor and control a chemical reaction.
PUA-510	Distillation & Reflux	The principles of distillation and reflux. The critical control parameters of each process are described and safety issues are highlighted.
PUA-520	Crystallization	The principles of crystallization, why it is used in the API industry, and the key parameters that affect pharmaceutical crystal production.
PUA-530	Drying	The importance of drying products in the API industry. The different types of drying equipment and the control parameters associated with each type of dryer.
PUA-540	Filtration	The theory of filtration and the various types of equipment used. This lesson also includes the most important parameters that control the filtration process.
PUA-550	Water Types & Testing	The different grades of water required in an API plant and the tests that are used to determine the water's purity.
PUA-551	Water Impurities & Treatment	The most common types of contaminants found and the different treatment steps used to purify water before it can be used in a chemical process.
PUA-560	Process Flow Diagrams (PFDs)	Symbols used to represent key process equipment, pipe-work and gauges and how to interpret basic PFDs.

## API Manufacturing - Equipment Understanding

Code	Lesson	Description
PEA-700	Chemical Reactor Design	How a chemical reactor works and the most important connections needed to carry out a chemical reaction.
PEA-701	Working with Reactors	Explains the main tasks involved in operating a chemical reactor such as weighing, charging and taking samples.
PEA-710	Centrifuges	The operating principles and parameters of Batch Filtering and Inverting Filter centrifuges are explained.
PEA-740	Reciprocating Pumps	The operating principles of reciprocating pumps.
PEA-741	Rotary & Centrifugal Pumps	The operating principles of rotary and centrifugal pumps.
PEA-750	Valves	The different types of valves used in a pharmaceutical plant are explained.

## Health and Safety - General

Code	Lesson	Description
PSY-101	Introduction to Safety	Explains the most common routes of chemical and biological contamination, together with the most common types of accidents.
PSY-110	General Safety Rules	Why safety rules are important and the key areas of concern for both personal and general safety.
PSY-720	Chemical Hazards & Terminology	The terminology used in describing the hazardous properties of chemicals.
PSY-130	Safety Symbols	The different types of safety signs and the important role they play in ensuring safety at work.
PSY-305	Storage and Handling	The correct storage and handling procedures for hazardous chemicals.
PSY-306	Waste Disposal	The different types of waste generated in a pharmaceutical plant and how each type is collected and stored prior to disposal.
PSY-307	Fire Safety	The types of fire extinguishers found in a pharmaceutical plant and the different classes of fire that each extinguisher is designed for.
PSY-314	Hazardous Chemicals	The correct storage and handling procedures for hazardous chemicals.
PSY-754	Manual Handling	The correct procedures for moving and lifting materials in a pharmaceutical plant are explained.

## Health and Safety - Laboratory

Code	Lesson	Description
PSY-141	Laboratory Safe Work Practices	Explains how to work safely in a laboratory by following SOPs, MSDSs and by using the appropriate safety equipment. Safety considerations with common laboratory equipment are also outlined.
PSY-160	Chemical Laboratory Waste	The different categories of chemical laboratory waste and the procedures for storing this waste in a safe manner.

## Health and Safety - Micro Laboratory

Code	Lesson	Description
PSY-161	Microbiological Laboratory Waste	The different categories of microbiological waste and the procedures for handling, transport, and storage of this waste.

## General - Computer Use & Validation

Code	Lesson	Description
GVC-700	IT Use in Regulated Industries	Explains the basics of Information Technology and Good Computer Practice and looks at how IT is used in regulated industries.
GVC-701	Computerized Systems Validation	Explains the fundamentals of computer validation and the validation process. Also introduces the FDA's 21 CFR Part 11 ruling on electronic records and signatures.
GVC-702	Introduction to 21 CFR Part 11	Explains 21 CFR Part 11 in detail and its impact on regulated industries. Particular emphasis on electronic records and signatures (ERES).

## Analytical Laboratory - GMP

Code	Lesson	Description
PGL-500	Out of Specification & Atypical Results	Discusses Out of Specification (OOS) and Atypical results. It includes their possible causes, the investigation process and preventive measures.
PGL-510	Laboratory GMP	GMP in the laboratory, from sample receipt, testing and recording of results to result approval.
PGL-304	Testing Categories	The types of tests that a laboratory analyst performs. Topics include material and product testing and physical, chemical, and microbiological tests.
PGL-306	Laboratory Information Management Systems	Description and explanation of a Laboratory Information Management System (LIMS) and how it works.

## Analytical Laboratory - Lab Practices

Code	Lesson	Description
PPL-500	Weighing	The importance of good weighing techniques to analytical results. The main types of balances used in the laboratory and procedures for their use.
PPL-501	Glassware	Choosing the correct glassware for preparing and storing solutions in the laboratory. How to read and use volumetric glassware correctly.
PPL-502	Solution Preparation	How to accurately prepare quantitative solutions from solids and liquids. This includes organization of work area, choosing correct grade of materials, quantitative transfer, dissolving solids and topping up.
PPL-710	Understanding Dissolution	The influence of pH, temperature and stirring on how well a solid will dissolve in a liquid. How a drug dissolves in the human body and how in vitro dissolution testing can be used.
PPL-711	In Vitro Dissolution	The stages of in vitro dissolution testing and the equipment used.
PPL-712	Dissolution Equipment Set-Up	How to prepare dissolution media, standards, apparatus and sampling equipment prior to dissolution testing.
PPL-713	Dissolution Testing	How to program the dissolution equipment, carry out media temperature checks, add dosage forms and remove samples. How to calculate dissolution results and when to retest.
PPL-302	Laboratory Calculations/Errors	The statistical calculations that are applied to analytical results. Also the different categories of errors and the difference between precision and accuracy.
PPL-304	HPLC/GC	Introduction to HPLC and GC analysis, the common problems associated with each, and the necessary instrument parameter checks.
PPL-305	Instrumentation	UV/VIS, AA and IR techniques and common problems associated with each.
PPL-306	Wet Chemistry	How to use laboratory glassware correctly, focusing on pipettes, burettes and volumetric glassware.

### Analytical Laboratory - Validation

Code	Lesson	Description
PVL-310	Method Validation Parameters	Method Validation in terms of analytical parameters. Parameters discussed include standards, LOD, LOQ, precision and accuracy.
PVL-312	System Suitability Parameters (HPLC)	What system suitability checks are and why they must be run prior to analysis.
PVL-700	Laboratory Equipment Qualification	Explains what is involved in laboratory equipment qualification. Includes DQ, IQ, OQ and PQ.

### Microbiology Laboratory - Lab Practices

Code	Lesson	Description
PPM-700	Principles of Good Aseptic Technique	The importance of good aseptic technique and the major steps involved in applying it to microbiological testing.
PPM-710	Basic Microbiological Techniques	The techniques used frequently by microbiologists including media preparation, pure culture techniques and the pour plate technique.
PPM-711	Introduction to Microscopy	The importance of microscopy in microbiology. The main components of a microscope and microscopic techniques.
PPM-712	Introduction to Staining	How to prepare and heat fix a smear correctly. Introduction to three main categories of staining i.e. simple, differential and structural.
PPM-113	Staining Techniques	Explains the different staining techniques commonly used in a microbiology laboratory.
PPM-130	Unknown Bacterial Identification	Introduces the concept of unknown bacterial contamination and the morphological and cultural tests carried out to identify these unknowns.

### Microbiology Laboratory - GMP

Code	Lesson	Description
PQM-700	GMP for Microbiology	The importance of GMP in a microbiology laboratory and the rules and guidelines for handling infectious material.

## Manufacturing - Validation (◆ Available in French)

Code	Lesson	Description
PVF-310	The Validation Stages ◆	A complete validation process is described. The DQ, IQ, OQ, and PQ of a V-blender are used as an example. The process validation is then described along with revalidation.
PVF-710	The Validation Stages	A complete validation process is described. The DQ, IQ, OQ, and PQ of a V-blender are used as an example. The process validation is then described along with revalidation.

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*So... for a no obligation and easy to arrange demonstration please contact us today  
using the information below*

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