Lesson Catalog

This catalog lists all lessons currently available from SKILLPAD

Welcome to Skillpad's extensive catalog of e-Lessons developed specifically for your industry.

SECTOR INDEX

Skillpad - Europe
501 Northwest Business Park,
Ballycoolin, Dublin 15, D15 Y00V, Ireland
email: info@skillpad.com www.skillpad.com
Phone: +353-1-630-1480 - Fax: +353-1-630-1484

Skillpad - United States
55 Madison Avenue, Suite 400 #4100,
Morristown, New Jersey 07960, USA.
email: info@skillpad.com www.skillpad.com
Tel: 973-588-4884 - Fax: 973-588-4885

Finished Dose Lessons

Below is a list of e-lessons targeted specifically to the Finished Dose sector. If you would like to experience any of these lessons, please contact us and we'll set up a tailored demonstration 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. And, because it's available for review online, it is accessible from anywhere, allowing you to review from multiple sites and time zones.

e-Learning that Builds Knowledge

Pharmaceutical GMP - Basics

Code	Lesson Title	Description
PGB-900	Overview of Pharmaceutical Manufacturing	Introduces the pharmaceutical industry, what it manufactures, and the typical departments found in a pharmaceutical plant.
PGB-801	GMP for Finished Dose Forms	What GMP is, how it applies in the manufacture of finished dose products, why it is important for safeguarding the end user, and the laws that govern it.
PGB-902	Regulation of the Pharmaceutical Industry	Who regulates the pharmaceutical industry, how new drugs are approved, types of regulatory inspections, and the role of employees in inspections.
PGB-503	Finished Dose Contamination Prevention	How finished dose products can be contaminated during production and how to minimize contamination through the use of PPE and good sanitation habits.
PGB-504	Dress Codes for Finished Dose Manufacture	Explains dress codes and why they exist in the finished dose pharmaceutical industry. Examples of the different types of clothing required for the different areas within a pharmaceutical plant are shown.
PGB-1105	GMP Goals	Describes the GMP responsibilities of employers and employees and the importance of procedures and records.

Pharmaceutical GMP - Intermediate

Code	Lesson Title	Description
PGI-800	GMP - SOPs in Finished Dose Manufacturing	Defines Standard Operating Procedures (SOPs), why they are necessary, where they are used, the type of information they typically contain, and how they are controlled.
PGI-1101	GMP – Records in Finished Dose Manufacturing	How to complete records required for Finished Dose manufacture. Records include records of materials, production records, equipment records, laboratory records, production review and distribution records.
PGI-810	Personnel and Training	Describes GMP requirements concerning personnel, training, clothing, hygiene and health.
PGI-620	Warehousing	Introduction to Pharmaceutical warehousing. Covers warehouse functions, GMP in the warehouse and QC status for materials and products.
PGI-730	Cleaning of Equipment	Different equipment cleaning methods used in the pharmaceutical industry.
PGI-840	Sampling	The different types of sampling methods found in the pharmaceutical industry. Also includes rules that should be followed when sampling materials.
PGI-770	Preparing for Packaging	Pharmaceutical packaging is introduced and pre-packaging checks required before a packaging operation can begin are explained.
PGI-771	Primary Packaging	Principles of primary packaging and the processes involved.
PGI-772	Secondary & Tertiary Packaging	Principles of secondary & tertiary packaging and the processes involved.
PGI-780	Labeling	The importance of accurate labeling in a pharmaceutical plant. What must be contained on a label, along with label distribution and reconciliation.
PGI-690	Buildings and Facilities	The GMP design requirements for a manufacturing facility. This includes the product flow, environmental controls, cleaning and sanitization.
SER-1100 **PREMIUM LESSON**	Serialization and Product Tracking	An overview of serialization and product tracking including the commercial and regulatory drivers, the technologies involved and the process of implementing a serialization and product tracking solution.
DTI-1001 **PREMIUM LESSON**	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Serialization

NOTE: These lessons form a Strategic Premium Suite and are sold as a group of 6 lessons

Code	Lesson Title	Description
SER-801 **PREMIUM LESSON**	Four Level Serialization Structure	An overview of serialization architecture in the pharmaceutical industry. It describes the four levels of a serialization system and the IT functions associated with each.
SER-802 **PREMIUM LESSON**	Serial Number Generation	How serial numbers are generated, transactions associated with serial numbers, and how serial numbers are classified and sorted.
SER-803 **PREMIUM LESSON**	Serial Number Transmission	How serial numbers are transmitted from point of origin, through the different levels to where they are printed on packaging. It also describes the function of individual devices on the packaging lines.
SER-804 **PREMIUM LESSON**	Serialization - Aggregation and Error Management	How aggregation in serialization is performed, along with aggregation-related concepts such as parent-child relationships and error management.
SER-805 **PREMIUM LESSON**	Serialization - Exception Events, Disaggregation, and Reaggregation	Events that require disaggregation along with procedures for performing disaggregation and reaggregation.
SER-806 **PREMIUM LESSON**	Serialization and the Supply Chain	What happens to serialized products when they leave the production facility, how change of ownership is accomplished and how compliance with the DSCSA and DQSA is achieved.

Finished Dose - Process Understanding

Code	Lesson Title	Description
PUF-301	Dosage Form Introduction	Introduces the concept of dosage forms and the different dosage forms currently in use.
PUF-302	Solid Dosage	Covers solid dose products manufactured by the pharmaceutical industry. It describes what ingredients are used and what manufacturing steps are required.
PUF-303	Semisolid Dosage	Describes semisolid dose products manufactured by the pharmaceutical industry. It describes what ingredients are used and what manufacturing steps are required.
PUF-304	Liquid Dosage	Introduces liquid dose products manufactured by the pharmaceutical industry. It describes what ingredients are used and what manufacturing steps are required.
PUF-305	Aerosol Inhalers	Introduces aerosol inhalers manufactured by the pharmaceutical industry. It describes the different components of aerosol inhalers and how they work.
BPU-1113 **PREMIUM LESSON**	Freeze Drying in Biopharmaceutical Manufacturing	Describes freeze drying, its use in biopharmaceutical manufacturing, the structure of a freeze dryer and the freeze drying process, including critical parameters, cycle phases, process monitoring and control.

Finished Dose Manufacturing - Equipment Understanding

Code	Lesson Title	Description
PEF-302	Milling	Introduction to milling. Different milling equipment and techniques are described along with equipment control parameters and safety precautions.
PEF-303	Blending	Introduction to blending. Describes different blending equipment and techniques and outlines blending equipment control parameters and safety precautions.
PEF-304	Filtration for Finished Dose	The principle of filtration. Describes the operation of a Plate and Frame Filter Press and outlines equipment control parameters and safety precautions.
PEF-305	Dryers	Introduction to drying. The operation of a Tray Drier is described along with drying equipment control parameters and safety precautions.
PEF-306	Fluidized Beds	The process of granulation and the function of a fluidized bed granulator. Also details the equipment's operation, control parameters, and safety issues.
PEF-307	Tablet Press	Introduction to the workings of a tablet press. It details control parameters, in-process checks and safety for this type of equipment.
PEF-308	Tablet Coater	The theory of the coating process and the equipment needed. Critical process parameters are also included and explained.

Finished Dose Manufacturing - Validation

Code	Lesson Title	Description
PVF-1130	Fundamentals of Process validation	Introduction to process validation using the DQ, IQ, OQ and PQ qualification phase approach. A case study of a tablet manufacturing process is presented. Includes validation masterplan, validation life cycle, specification, qualification and revalidation.

Water - Process Understanding

Code	Lesson Title	Description
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.

Aseptic Processing - Introduction (◆ Available in French)

Code	Lesson Title	Description
PST-1200	Basic Microbiology ◆	Introduces microorganisms and the impact they have on pharmaceutical products.
PST-320	Isolators ◆	Introduces isolators and discusses the components and functions of different types of isolators.

Aseptic Processing - Cleanroom GMP

Code	Lesson Title	Description
ASP-1001 PREMIUM LESSON	Aseptic Processing – Concepts and Controls	Explains why aseptic processing is used by providing an overview of microbial contamination and its effects on products. It describes how this contamination can be prevented by using controls and procedures that minimize bioburden in the manufacturing environment such as cleanrooms, gowning, appropriate behavior of personnel, and environmental monitoring.
ASP-1002 PREMIUM LESSON	Aseptic Processing - Cleanrooms and Control Technologies	Describes how cleanrooms are designed, constructed and operated to prevent contamination of products. This includes descriptions of HVAC and HEPA filters, unidirectional airflow, air locks, cleanroom architecture, pressure cascades and location of key equipment.
ASP-1003 PREMIUM LESSON	Aseptic Processing - Gowning	Describes the different gowning requirements typically used in aseptic manufacturing facilities to prevent contamination of products. It emphasizes the criticality of following correct gowning procedures for different cleanroom classes using ISO 5/6, ISO 7 and ISO 8 as examples.
ASP-1004 PREMIUM LESSON	Aseptic Processing – Contamination Control	Describes the main microbiological contamination threats found in an aseptic processing environment and how they can be contained using personnel gowning, appropriate cleanroom behavior, personal hygiene, and good cleaning and sanitization techniques, as well as microbial monitoring regimes.
ASP-1005 PREMIUM LESSON	Aseptic Processing – Decontamination and Sterilization Technologies	Describes methods typically used to decontaminate and sterilize equipment, consumables, containers and closures, and products before they are used or brought together in aseptic processing. Includes moist heat, dry-heat, VHP, and sterile filtration.

Aseptic Processing - Sterilization (◆ Available in French)

Code	Lesson Title	Description
BPU-760 PREMIUM LESSON	Sterilization and Prevacuum Autoclaving	Describes steam sterilization, different autoclave types and the steam sterilization process including critical parameters, the sterilization cycle, process monitoring and safety precautions.
PST-392	Dry Heat Sterilization ◆	Describes Dry Heat Sterilization and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.
PST-1293	Sterile Filtration ◆	Describes sterile filtration and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.
PST-394	Radiation Sterilization	Describes Radiation Sterilization and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.
PST-395	Gas Sterilization	Describes Gas Sterilization and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.

Regulatory GMP for Management

Code	Lesson Title	Description
RGM-500	Executive Responsibility in Pharmaceutical Manufacturing	The responsibilities of executive management in the pharmaceutical industry. Describes FDA and legal requirements and the corporate and personal consequences of non-compliance.

Health and Safety - General

Code	Lesson Title	Description
PSY-700	Introduction to Safety	Explains the most common routes of chemical and biological contamination, together with the most common types of accidents.
PSY-710	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-730	Safety Symbols	The different types of safety signs and the important role they play in ensuring safety at work.
PSY-754	Manual Handling	The correct procedures for moving and lifting materials in a pharmaceutical plant are explained.

Health and Safety - Laboratory

Code	Lesson Title	Description
PSY-741	Laboratory Safe Work Practices	Explains how to work safely in a laboratory by following SOPs, SDSs and by using the appropriate safety equipment. Safety considerations with common laboratory equipment are also outlined.
PSY-760	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 Title	Description
PSY-721	General Safety Hazards in the Microbiology Lab	The different classes of microorganisms and the hazards with handling each class.
PSY-740	Safe Work Practices in the Microbiology Lab	The different types of safety cabinets found in a Microbiology Lab and the safe work practices involved in their use. Also includes safe work practices for the use of equipment such as syringes and centrifuges.
PSY-761	Microbiological Laboratory Waste [Tailored for European Labs]	The different categories of microbiological waste and the procedures for handling, transport, and storage of this waste. This version depicts 'yellow' biohazard disposal equipment used in Europe and other areas.
PSY-762	Microbiological Laboratory Waste [Tailored for North American labs]	The different categories of microbiological waste and the procedures for handling, transport, and storage of this waste. This version depicts 'red' biohazard disposal equipment used in North America and other areas.

General - Computer Use & Validation (■ Completely Upgraded)

Code	Lesson Title	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.
CSV-901	GxP Computerized Systems Validation ■	Explains the fundamentals of computerized systems validation and the validation process as recommended in the GAMP® guideline. Also introduces the FDA's 21 CFR Part 11 ruling on electronic records and signatures.
GVC-602	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 Title	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-610	Laboratory GMP	GMP in the laboratory, from sample receipt, testing and recording of results to result approval.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Analytical Laboratory - Validation

Code	Lesson Title	Description
PVL-310	Method Validation Parameters	Method Validation in terms of analytical parameters. Parameters discussed include standards, LOD, LOQ, precision and accuracy.
PVL-700	Laboratory Equipment Qualification	Explains what is involved in laboratory equipment qualification. Includes DQ, IQ, OQ and PQ.

Analytical Laboratory - Lab Practices

Code	Lesson Title	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-1202	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-1130	Introduction to HPLC	Describes the basic theory and practice of HPLC. Particular focus is given to reverse phase HPLC. The components of a HPLC are described in detail and significant consideration is given to the explanation of results and peak shape. Analytical considerations of special relevance to HPLC are also presented.
PPL-831	HPLC Troubleshooting	Describes the troubleshooting of common HPLC equipment problems.

Microbiology Laboratory - Lab Practices

Code	Lesson Title	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-713	Staining Techniques	Explains the different staining techniques commonly used in a microbiology laboratory.
PPM-730	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 Title	Description
PGM-700	GMP for Microbiology	The importance of GMP in a microbiology laboratory and the rules and guidelines for handling infectious material.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Operational Excellence

Code	Lesson Title	Description
OPE-1101 NEW PREMIUM LESSON	CAPA for Nonconformities	An overview of the key concepts and terminologies associated with nonconformities, and the CAPA methodology used to address them as part of a company's Quality System. Using a scenario-driven approach, the user is taken through the key steps of a CAPA process from identifying a problem to verifying the effectiveness of the solutions implemented to resolve it. In doing so, users will be better equipped to distinguish between corrections, corrective actions, and preventive actions. The concept of risk and categorization of nonconformities as minor, major, or critical is also covered as are regulatory expectations surrounding nonconformities and CAPA.
OPE-1102 NEW PREMIUM LESSON	GMP Inspection Readiness - Interacting with the Inspector	Using a scenario-driven approach, the types of questions that are typically asked in a GMP inspection situation are detailed along with appropriate responses. Appropriate behaviors that should be exhibited by anyone interacting with an inspector are also explained and illustrated.

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 demonstration 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. And, because it's available for review online, it is accessible from anywhere, allowing you to review from multiple sites and time zones.

e-Learning that Builds Knowledge

API Manufacturing - GMP Basics

Code	Lesson Title	Description
PGB-900	Introduction to the Pharmaceutical Industry	Introduces the pharmaceutical industry, what it manufactures, and the typical departments found in a pharmaceutical plant.
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-603	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-604	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 Title	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.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Pharmaceutical GMP - Intermediate (◆ Available in French, ✳ Available in Spanish)

Code	Lesson Title	Description
PGI-810	Personnel and Training	Describes GMP requirements concerning personnel, training, clothing, hygiene and health.
PGI-620	Warehousing ✳	Introduction to Pharmaceutical warehousing. Covers warehouse functions, GMP in the warehouse and QC status for materials and products.
PGI-730	Cleaning of Equipment ◆	Different equipment cleaning methods used in the pharmaceutical industry.
PGI-780	Labeling	The importance of accurate labeling in a pharmaceutical plant. What must be contained on a label, along with label distribution and reconciliation.
PGI-690	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 Title	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.
BPU-1113 PREMIUM LESSON	Freeze Drying in Biopharmaceutical Manufacturing	Describes freeze drying, its use in biopharmaceutical manufacturing, the structure of a freeze dryer and the freeze drying process, including critical parameters, cycle phases, process monitoring and control.

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-1260	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 Title	Description
PEA-1200	Chemical Reactor Design	How a chemical reactor works and the most important connections needed to carry out a chemical reaction.
PEA-1201	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-641	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.

Manufacturing - Validation

Code	Lesson Title	Description
PVF-1130	Fundamentals of Process validation	Introduction to process validation using the DQ, IQ, OQ and PQ qualification phase approach. A case study of a tablet manufacturing process is presented. Includes validation masterplan, validation life cycle, specification, qualification and revalidation.

Health and Safety - General

Code	Lesson Title	Description
PSY-700	Introduction to Safety	Explains the most common routes of chemical and biological contamination, together with the most common types of accidents.
PSY-710	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-730	Safety Symbols	The different types of safety signs and the important role they play in ensuring safety at work.
PSY-754	Manual Handling	The correct procedures for moving and lifting materials in a pharmaceutical plant are explained.

Health and Safety - Laboratory

Code	Lesson Title	Description
PSY-741	Laboratory Safe Work Practices	Explains how to work safely in a laboratory by following SOPs, SDSs and by using the appropriate safety equipment. Safety considerations with common laboratory equipment are also outlined.
PSY-760	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 Title	Description
PSY-721	General Safety Hazards in the Microbiology Lab	The different classes of microorganisms and the hazards with handling each class.
PSY-740	Safe Work Practices in the Microbiology Lab	The different types of safety cabinets found in a Microbiology Lab and the safe work practices involved in their use. Also includes safe work practices for the use of equipment such as syringes and centrifuges.
PSY-761	Microbiological Laboratory Waste [Tailored for European Labs]	The different categories of microbiological waste and the procedures for handling, transport, and storage of this waste. This version depicts 'yellow' biohazard disposal equipment used in Europe and other areas.
PSY-762	Microbiological Laboratory Waste [Tailored for North American labs]	The different categories of microbiological waste and the procedures for handling, transport, and storage of this waste. This version depicts 'red' biohazard disposal equipment used in North America and other areas.

General - Computer Use & Validation

Code	Lesson Title	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.
CSV-901	GxP Computerized Systems Validation	Explains the fundamentals of computerized systems validation and the validation process as recommended in the GAMP® guideline. Also introduces the FDA's 21 CFR Part 11 ruling on electronic records and signatures.
GVC-602	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 Title	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-610	Laboratory GMP	GMP in the laboratory, from sample receipt, testing and recording of results to result approval.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Analytical Laboratory - Validation

Code	Lesson Title	Description
PVL-310	Method Validation Parameters	Method Validation in terms of analytical parameters. Parameters discussed include standards, LOD, LOQ, precision and accuracy.
PVL-700	Laboratory Equipment Qualification	Explains what is involved in laboratory equipment qualification. Includes DQ, IQ, OQ and PQ.

Analytical Laboratory - Lab Practices

Code	Lesson Title	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-1202	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-1130	Introduction to HPLC	Describes the basic theory and practice of HPLC. Particular focus is given to reverse phase HPLC. The components of a HPLC are described in detail and significant consideration is given to the explanation of results and peak shape. Analytical considerations of special relevance to HPLC are also presented.
PPL-831	HPLC Troubleshooting	Describes the troubleshooting of common HPLC equipment problems.

Microbiology Laboratory - Lab Practices

Code	Lesson Title	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-713	Staining Techniques	Explains the different staining techniques commonly used in a microbiology laboratory.
PPM-730	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 Title	Description
PGM-700	GMP for Microbiology	The importance of GMP in a microbiology laboratory and the rules and guidelines for handling infectious material.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Operational Excellence

Code	Lesson Title	Description
OPE-1101 NEW PREMIUM LESSON	CAPA for Nonconformities	An overview of the key concepts and terminologies associated with nonconformities, and the CAPA methodology used to address them as part of a company's Quality Management System. Using a scenario-driven approach, the user is taken through the key steps of a CAPA process from identifying a problem to verifying the effectiveness of the solutions implemented to resolve it. In doing so, users will be better equipped to distinguish between corrections, corrective actions, and preventive actions. The concept of risk and categorization of nonconformities as minor, major, or critical is also covered as are regulatory expectations surrounding nonconformities and CAPA.
OPE-1102 NEW PREMIUM LESSON	GMP Inspection Readiness - Interacting with the Inspector	Using a scenario-driven approach, the types of questions that are typically asked in a GMP inspection situation are detailed along with appropriate responses. Appropriate behaviors that should be exhibited by anyone interacting with an inspector are also explained and illustrated.

Biopharmaceutical Lessons

Below is a list of e-lessons targeted specifically to the Biopharmaceutical sector. If you would like to experience any of these lessons, please contact us and we'll set up a tailored lesson demonstration 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. And, because it's available for review online, it is accessible from anywhere, allowing you to review from multiple sites and time zones.

e-Learning that Builds Knowledge

Biotechnology & Biopharmaceuticals - Fundamentals

Code	Lesson Title	Description
BPU-1100 PREMIUM LESSON	Biotechnology and Biopharmaceuticals -	Introduces biopharmaceuticals and their product characteristics. An easy to understand explanation of the science of biotechnology that underlies biopharmaceuticals is provided. This includes the role of DNA and proteins in the body, along with an explanation of Recombinant DNA Technology and Monoclonal Antibody Technology. The characteristics of biopharmaceutical products are explored and compared to traditional small molecule pharmaceuticals, and the main types of products described.
BPU-1108 PREMIUM LESSON	Cell Biology and Recombinant DNA Technology	Following on from BPU-1100, this Lesson goes a level deeper in its explanation of cell biology and how cells can be manipulated to produce therapeutic proteins. An overview is provided of the functioning of mammalian cells, followed by an explanation of the roles played by DNA and RNA in producing proteins in cells. The steps involved in recombinant DNA technology are outlined, including DNA amplification, insertion of target genes into suitable vectors, before cell culturing is explained.

Biopharmaceuticals - Manufacturing

Code	Lesson Title	Description
BPU-1101 PREMIUM LESSON	Clean In Place	Explains key concepts of Clean In Place (CIP) technology commonly used in the biotechnology and pharmaceutical industries. It describes CIP processes and procedures and provides examples of best practices that help ensure optimum performance.
BPU-1102 PREMIUM LESSON	Downstream Processing: Ultrafiltration and Diafiltration	Describes the downstream manufacturing processes of ultrafiltration and diafiltration with an emphasis on post-harvest volume reduction and concentration for therapeutic protein products. The components of an UF/DF skid and control of the UF/DF process are also described.
BPU-1103 PREMIUM LESSON	Downstream Processing: Centrifugation	Describes what centrifugation is and the stages of biopharmaceutical downstream processing it can be used. Primary cell separation using a Disk Stack Centrifuge, and final purification using Ultracentrifugation are explained both in terms of equipment and process.
BPU-1104 PREMIUM LESSON	Bioreactors in Bioprocessing	Describes the function, design, set-up and control of bioreactors in the biopharmaceutical industry. It examines control parameters such as heat management, pH, oxygen, mass transfer, and agitation, and how the type of cells being produced impacts on bioreactor set up and control. It also introduces the meaning of sterility, and bioreactor cleaning using CIP.
BPU-1105 PREMIUM LESSON	Overview of Biopharmaceutical Manufacturing	Explains the principles of biopharmaceutical manufacturing by focusing on the processes typically involved in producing therapeutic proteins. The stages of manufacture from upstream, through downstream, to formulation and fill finish are shown, with explanations of the equipment and processes involved. Key concepts of GMP, environmental control, and cleaning are covered.

BPU-1106 PREMIUM LESSON	Fermentation in Biopharmaceutical Manufacturing	Describes how microorganisms are used in fermentation processes as part of biopharmaceutical manufacturing. Areas covered include growth phases and characteristics and conditions, cell banks, media, bioreactors and modes of operation, and the importance of sterility.
BPU-1107 PREMIUM LESSON	Cell Culture in Biopharmaceutical Manufacturing	Describes mammalian cell culture in the biopharmaceutical industry, how such cultures are controlled and important considerations in maintaining optimal cultures.
BPU-1109 PREMIUM LESSON	Formulation in the Biopharmaceutical Industry	Provides an overview of the principles and practices of formulation and packaging processes in a modern biopharmaceutical manufacturing facility.
BPU-1110 PREMIUM LESSON	Downstream Processing: Protein Purification - Chromatography	Describes the use of various chromatographic methods in downstream protein purification including size exclusion, ion exchange, hydrophobic interaction and affinity chromatographies. The basics of a chromatography set-up are covered along with critical factors affecting protein separation such as column packing, resolution, column capacity, pressure and the gel matrix.
BPU-1111 PREMIUM LESSON	Process Validation: Process Design	An overview of the process design stage of process validation, describing how a biopharmaceutical manufacturing process can be defined using a Quality by Design (QbD) approach that emphasizes accumulated scientific knowledge and quality risk management.
BPU-1112 PREMIUM LESSON	Process Validation: Process Qualification and Control	An overview of the qualification and continuing verification stages of process validation, intended to demonstrate that a biopharmaceutical process is capable of reproducible commercial manufacturing and to provide ongoing assurance that the process remains in a state of control.
BPU-1113 PREMIUM LESSON	Freeze Drying in Biopharmaceutical Manufacturing	Describes freeze drying, its use in biopharmaceutical manufacturing, the structure of a freeze dryer and the freeze drying process, including critical parameters, cycle phases, process monitoring and control.

Aseptic Processing - Introduction (◆ Available in French)

Code	Lesson Title	Description
PST-1200	Basic Microbiology ◆	Introduces microorganisms and the impact they have on pharmaceutical products.
PST-320	Isolators ◆	Introduces isolators and discusses the components and functions of different types of isolators.

Aseptic Processing - Cleanroom GMP

Code	Lesson Title	Description
ASP-1001 PREMIUM LESSON	Aseptic Processing – Concepts and Controls	Explains why aseptic processing is used by providing an overview of microbial contamination and its effects on products. It describes how this contamination can be prevented by using controls and procedures that minimize bioburden in the manufacturing environment such as cleanrooms, gowning, appropriate behavior of personnel, and environmental monitoring.
ASP-1002 PREMIUM LESSON	Aseptic Processing - Cleanrooms and Control Technologies	Describes how cleanrooms are designed, constructed and operated to prevent contamination of products. This includes descriptions of HVAC and HEPA filters, unidirectional airflow, air locks, cleanroom architecture, pressure cascades and location of key equipment.
ASP-1003 PREMIUM LESSON	Aseptic Processing - Gowning	Describes the different gowning requirements typically used in aseptic manufacturing facilities to prevent contamination of products. It emphasizes the criticality of following correct gowning procedures for different cleanroom classes using ISO 5/6, ISO 7 and ISO 8 as examples.
ASP-1004 PREMIUM LESSON	Aseptic Processing – Contamination Control	Describes the main microbiological contamination threats found in an aseptic processing environment and how they can be contained using personnel gowning, appropriate cleanroom behavior, personal hygiene, and good cleaning and sanitization techniques, as well as microbial monitoring regimes.
ASP-1005 PREMIUM LESSON	Aseptic Processing – Decontamination and Sterilization Technologies	Describes methods typically used to decontaminate and sterilize equipment, consumables, containers and closures, and products before they are used or brought together in aseptic processing. Includes moist heat, dry-heat, VHP, and sterile filtration.

Aseptic Processing - Sterilization (◆ Available in French)

Code	Lesson Title	Description
BPU-760 PREMIUM LESSON	Sterilization and Prevacuum Autoclaving	Describes steam sterilization, different autoclave types and the steam sterilization process including critical parameters, sterilization cycle, process monitoring and safety precautions.
PST-392	Dry Heat Sterilization ◆	Describes Dry Heat Sterilization and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.
PST-1293	Sterile Filtration ◆	Describes sterile filtration and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.
PST-394	Radiation Sterilization	Describes Radiation Sterilization and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.
PST-395	Gas Sterilization	Describes Gas Sterilization and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.

Manufacturing - Process Understanding

Code	Lesson Title	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.
BPU-1113 PREMIUM LESSON	Freeze Drying in Biopharmaceutical Manufacturing	Describes freeze drying, its use in biopharmaceutical manufacturing, the structure of a freeze dryer and the freeze drying process, including critical parameters, cycle phases, process monitoring and control.
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-1260	Process Flow Diagrams (PFDs)	Symbols used to represent key process equipment, pipe-work and gauges and how to interpret basic PFDs.

Manufacturing - Equipment Understanding

Code	Lesson Title	Description
PEA-1200	Chemical Reactor Design	How a chemical reactor works and the most important connections needed to carry out a chemical reaction.
PEA-1201	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 and their modes of operation are explained.

Manufacturing - Validation

Code	Lesson Title	Description
PVF-1130	Fundamentals of Process validation	Introduction to process validation using the DQ, IQ, OQ and PQ qualification phase approach. A case study of a tablet manufacturing process is presented. Includes validation masterplan, validation life cycle, specification, qualification and revalidation.

Health and Safety - General

Code	Lesson Title	Description
PSY-700	Introduction to Safety	Explains the most common routes of chemical and biological contamination, together with the most common types of accidents.
PSY-710	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-730	Safety Symbols	The different types of safety signs and the important role they play in ensuring safety at work.
PSY-754	Manual Handling	The correct procedures for moving and lifting materials in a pharmaceutical plant are explained.

Health and Safety - Laboratory

Code	Lesson Title	Description
PSY-741	Laboratory Safe Work Practices	Explains how to work safely in a laboratory by following SOPs, SDSs and by using the appropriate safety equipment. Safety considerations with common laboratory equipment are also outlined.
PSY-760	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 Title	Description
PSY-721	General Safety Hazards in the Microbiology Lab	The different classes of microorganisms and the hazards with handling each class.
PSY-740	Safe Work Practices in the Microbiology Lab	The different types of safety cabinets found in a Microbiology Lab and the safe work practices involved in their use. Also includes safe work practices for the use of equipment such as syringes and centrifuges.
PSY-761	Microbiological Laboratory Waste [Tailored for European Labs]	The different categories of microbiological waste and the procedures for handling, transport, and storage of this waste. This version depicts 'yellow' biohazard disposal equipment used in Europe and other areas.
PSY-762	Microbiological Laboratory Waste [Tailored for North American labs]	The different categories of microbiological waste and the procedures for handling, transport, and storage of this waste. This version depicts 'red' biohazard disposal equipment used in North America and other areas.

General - Computer Use & Validation

Code	Lesson Title	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.
CSV-901	GxP Computerized Systems Validation	Explains the fundamentals of computerized systems validation and the validation process as recommended in the GAMP® guideline. Also introduces the FDA's 21 CFR Part 11 ruling on electronic records and signatures.
GVC-602	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 Title	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-610	Laboratory GMP	GMP in the laboratory, from sample receipt, testing and recording of results to result approval.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Analytical Laboratory - Validation

Code	Lesson Title	Description
PVL-310	Method Validation Parameters	Method Validation in terms of analytical parameters. Parameters discussed include standards, LOD, LOQ, precision and accuracy.
PVL-700	Laboratory Equipment Qualification	Explains what is involved in laboratory equipment qualification. Includes DQ, IQ, OQ and PQ.

Analytical Laboratory - Lab Practices

Code	Lesson Title	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-1202	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-1130	Introduction to HPLC	Describes the basic theory and practice of HPLC. Particular focus is given to reverse phase HPLC. The components of a HPLC are described in detail and significant consideration is given to the explanation of results and peak shape. Analytical considerations of special relevance to HPLC are also presented.
PPL-831	HPLC Troubleshooting	Describes the troubleshooting of common HPLC equipment problems.

Microbiology Laboratory - Lab Practices

Code	Lesson Title	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-713	Staining Techniques	Explains the different staining techniques commonly used in a microbiology laboratory.
PPM-730	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 Title	Description
PGM-700	GMP for Microbiology	The importance of GMP in a microbiology laboratory and the rules and guidelines for handling infectious material.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Operational Excellence

Code	Lesson Title	Description
OPE-1101 NEW PREMIUM LESSON	CAPA for Nonconformities	An overview of the key concepts and terminologies associated with nonconformities, and the CAPA methodology used to address them as part of a company's Quality Management System. Using a scenario-driven approach, the user is taken through the key steps of a CAPA process from identifying a problem to verifying the effectiveness of the solutions implemented to resolve it. In doing so, users will be better equipped to distinguish between corrections, corrective actions, and preventive actions. The concept of risk and categorization of nonconformities as minor, major, or critical is also covered as are regulatory expectations surrounding nonconformities and CAPA.
OPE-1102 NEW PREMIUM LESSON	GMP Inspection Readiness - Interacting with the Inspector	Using a scenario-driven approach, the types of questions that are typically asked in a GMP inspection situation are detailed along with appropriate responses. Appropriate behaviors that should be exhibited by anyone interacting with an inspector are also explained and illustrated.

Medical Device Lessons

Below is a list of e-lessons targeted specifically to the Medical Devices sector. If you would like to experience any of these lessons, please contact us and we'll set up a tailored lesson demonstration 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. And, because it's available for review online, it is accessible from anywhere, allowing you to review from multiple sites and time zones.

e-Learning that Builds Knowledge

Medical Device Manufacturing - GMP Basics

Code	Lesson Title	Description
MGB-500	Introduction to Medical Devices	Introduces the Medical Device Industry and the typical departments found in a medical device plant.
MGB-501	Introduction to GMP for Medical Devices	What GMP is, why it is important for safe guarding the end user, and the laws that govern it.
MGB-502	Regulatory Agencies for Medical Devices	Who regulates the Medical Device Industry, what the role of the FDA is for medical devices, how a regulatory inspection is carried out, and the role of each employee in an inspection.
MGB-503	Hygiene for Medical Devices	The importance of personal hygiene in a medical device plant and the implications of poor hygiene practices for the product and the employee.
MGB-504	Dress Codes for Medical Devices	Explains dress codes and why they are so important in the Medical Device Industry. Examples of the different types of clothing required for different tasks are given.
MGB-505	GMP Goals for Medical Devices	GMP from the point of view of the medical device company, the employee, and the consumer. Also, the implications of non-compliance for each.

Medical Device Manufacturing - GMP Intermediate

Code	Lesson Title	Description
MGI-500	GMP - SOPs for Medical Devices	What an SOP is, why SOPs must be followed in Medical Device Plants and what information they should contain.
MGI-501	GMP - Records for Medical Devices	Outlines the fundamental rules for completing records and discusses the requirements for several of the most frequently encountered records. Records include Device History Records, Equipment Records and Acceptance Activity Records.
MGI-510	Medical Devices - Personnel & Training	The qualifications and training that medical device employees need in order to comply with GMP. Who must be trained and why.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

GMP - Intermediate (✳ Available in Spanish)

Code	Lesson Title	Description
PGI-620	Warehousing ✳	Introduction to Pharmaceutical warehousing. Covers warehouse functions, GMP in the warehouse and QC status for materials and products.
PGI-770	Preparing for Packaging	Pharmaceutical packaging is introduced and pre-packaging checks required before a packaging operation can begin, are explained.
PGI-771	Primary Packaging	Principles of primary packaging and the processes involved.
PGI-772	Secondary & Tertiary Packaging	Principles of secondary & tertiary packaging and the processes involved.
PGI-780	Labeling	The importance of accurate labeling in a pharmaceutical plant. What must be contained on a label, along with label distribution and reconciliation.
PGI-690	Buildings and Facilities	The GMP design requirements for a manufacturing facility. This includes the product flow, environmental controls, cleaning and sanitization.
SER-1100 PREMIUM LESSON	Serialization and Product Tracking	An overview of serialization and product tracking including the commercial and regulatory drivers, the technologies involved and the process of implementing a serialization and product tracking solution.

Serialization

NOTE: These lessons form a Strategic Premium Suite and are sold as a group of 6 lessons

Code	Lesson Title	Description
SER-801 PREMIUM LESSON	Four Level Serialization Structure	An overview of serialization architecture in the pharmaceutical industry. It describes the four levels of a serialization system and the IT functions associated with each.
SER-802 PREMIUM LESSON	Serial Number Generation	How serial numbers are generated, transactions associated with serial numbers, and how serial numbers are classified and sorted.
SER-803 PREMIUM LESSON	Serial Number Transmission	How serial numbers are transmitted from point of origin, through the different levels to where they are printed on packaging. It also describes the function of individual devices on the packaging lines.
SER-804 PREMIUM LESSON	Serialization - Aggregation and Error Management	How aggregation in serialization is performed, along with aggregation-related concepts such as parent-child relationships and error management.
SER-805 PREMIUM LESSON	Serialization - Exception Events, Disaggregation, and Reaggregation	Events that require disaggregation along with procedures for performing disaggregation and reaggregation.
SER-806 PREMIUM LESSON	Serialization and the Supply Chain	What happens to serialized products when they leave the production facility, how change of ownership is accomplished and how compliance with the DSCSA and DQSA is achieved.

Aseptic Processing - Introduction (◆ Available in French)

Code	Lesson Title	Description
PST-1200	Basic Microbiology ◆	Introduces microorganisms and the impact they have on pharmaceutical products.
PST-320	Isolators ◆	Introduces isolators and discusses the components and functions of different types of isolators.

Aseptic Processing - Sterilization (◆ Available in French)

Code	Lesson Title	Description
BPU-760 PREMIUM LESSON	Sterilization and Prevacuum Autoclaving	Describes steam sterilization, different autoclave types and the steam sterilization process including critical parameters, sterilization cycle, process monitoring and safety precautions.
PST-392	Dry Heat Sterilization ◆	Describes Dry Heat Sterilization and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.
PST-1293	Sterile Filtration ◆	Describes sterile filtration and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.
PST-394	Radiation Sterilization	Describes Radiation Sterilization and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.
PST-395	Gas Sterilization	Describes Gas Sterilization and the products that can be sterilized by this process. Also covers the equipment and procedures used and the critical sterilization parameters.

Aseptic Processing - Cleanroom GMP

Code	Lesson Title	Description
ASP-1001 PREMIUM LESSON	Aseptic Processing – Concepts and Controls	Explains why aseptic processing is used by providing an overview of microbial contamination and its effects on products. It describes how this contamination can be prevented by using controls and procedures that minimize bioburden in the manufacturing environment such as cleanrooms, gowning, appropriate behavior of personnel, and environmental monitoring.
ASP-1002 PREMIUM LESSON	Aseptic Processing - Cleanrooms and Control Technologies	Describes how cleanrooms are designed, constructed and operated to prevent contamination of products. This includes descriptions of HVAC and HEPA filters, unidirectional airflow, air locks, cleanroom architecture, pressure cascades and location of key equipment.
ASP-1003 PREMIUM LESSON	Aseptic Processing - Gowning	Describes the different gowning requirements typically used in aseptic manufacturing facilities to prevent contamination of products. It emphasizes the criticality of following correct gowning procedures for different cleanroom classes using ISO 5/6, ISO 7 and ISO 8 as examples.
ASP-1004 PREMIUM LESSON	Aseptic Processing – Contamination Control	Describes the main microbiological contamination threats found in an aseptic processing environment and how they can be contained using personnel gowning, appropriate cleanroom behavior, personal hygiene, and good cleaning and sanitization techniques, as well as microbial monitoring regimes.
ASP-1005 PREMIUM LESSON	Aseptic Processing – Decontamination and Sterilization Technologies	Describes methods typically used to decontaminate and sterilize equipment, consumables, containers and closures, and products before they are used or brought together in aseptic processing. Includes moist heat, dry-heat, VHP, and sterile filtration.

Health and Safety - General

Code	Lesson Title	Description
PSY-700	Introduction to Safety	Explains the most common routes of chemical and biological contamination, together with the most common types of accidents.
PSY-710	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-730	Safety Symbols	The different types of safety signs and the important role they play in ensuring safety at work.
PSY-754	Manual Handling	The correct procedures for moving and lifting materials in a pharmaceutical plant are explained.

Health and Safety - Laboratory

Code	Lesson Title	Description
PSY-741	Laboratory Safe Work Practices	Explains how to work safely in a laboratory by following SOPs, SDSs and by using the appropriate safety equipment. Safety considerations with common laboratory equipment are also outlined.
PSY-760	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 Title	Description
PSY-721	General Safety Hazards in the Microbiology Lab	The different classes of microorganisms and the hazards with handling each class.
PSY-740	Safe Work Practices in the Microbiology Lab	The different types of safety cabinets found in a Microbiology Lab and the safe work practices involved in their use. Also includes safe work practices for the use of equipment such as syringes and centrifuges.
PSY-761	Microbiological Laboratory Waste [Tailored for European Labs]	The different categories of microbiological waste and the procedures for handling, transport, and storage of this waste. This version depicts 'yellow' biohazard disposal equipment used in Europe and other areas.
PSY-762	Microbiological Laboratory Waste [Tailored for North American labs]	The different categories of microbiological waste and the procedures for handling, transport, and storage of this waste. This version depicts 'red' biohazard disposal equipment used in North America and other areas.

General - Computer Use & Validation

Code	Lesson Title	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.
CSV-901	GxP Computerized Systems Validation	Explains the fundamentals of computerized systems validation and the validation process as recommended in the GAMP® guideline. Also introduces the FDA's 21 CFR Part 11 ruling on electronic records and signatures.
GVC-602	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 Title	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-610	Laboratory GMP	GMP in the laboratory, from sample receipt, testing and recording of results to result approval.

Analytical Laboratory - Lab Practices

Code	Lesson Title	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-1202	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-1130	Introduction to HPLC	Describes the basic theory and practice of HPLC. Particular focus is given to reverse phase HPLC. The components of a HPLC are described in detail and significant consideration is given to the explanation of results and peak shape. Analytical considerations of special relevance to HPLC are also presented.
PPL-831	HPLC Troubleshooting	Describes the troubleshooting of common HPLC equipment problems.

Analytical Laboratory - Validation

Code	Lesson Title	Description
PVL-310	Method Validation Parameters	Method Validation in terms of analytical parameters. Parameters discussed include standards, LOD, LOQ, precision and accuracy.
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 Title	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-713	Staining Techniques	Explains the different staining techniques commonly used in a microbiology laboratory.
PPM-730	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 Title	Description
PGM-700	GMP for Microbiology	The importance of GMP in a microbiology laboratory and the rules and guidelines for handling infectious material.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Manufacturing - Validation

Code	Lesson Title	Description
PVF-1130	Fundamentals of Process validation	Introduction to process validation using the DQ, IQ, OQ and PQ qualification phase approach. A case study of a tablet manufacturing process is presented. Includes validation masterplan, validation life cycle, specification, qualification and revalidation.

Water - Process Understanding

Code	Lesson Title	Description
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.

Operational Excellence

Code	Lesson Title	Description
OPE-1101 NEW PREMIUM LESSON	CAPA for Nonconformities	An overview of the key concepts and terminologies associated with nonconformities, and the CAPA methodology used to address them as part of a company's Quality Management System. Using a scenario-driven approach, the user is taken through the key steps of a CAPA process from identifying a problem to verifying the effectiveness of the solutions implemented to resolve it. In doing so, users will be better equipped to distinguish between corrections, corrective actions, and preventive actions. The concept of risk and categorization of nonconformities as minor, major, or critical is also covered as are regulatory expectations surrounding nonconformities and CAPA.
OPE-1102 NEW PREMIUM LESSON	GMP Inspection Readiness - Interacting with the Inspector	Using a scenario-driven approach, the types of questions that are typically asked in a GMP inspection situation are detailed along with appropriate responses. Appropriate behaviors that should be exhibited by anyone interacting with an inspector are also explained and illustrated.

Clinical Trials and Non-Clinical Lessons

Below is a list of e-lessons targeted specifically to the Clinical Trials and Non-Clinical studies sectors. If you would like to experience any of these lessons, please contact us and we'll set up a tailored lesson demonstration 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. And, because it's available for review online, it is accessible from anywhere, allowing you to review from multiple sites and time zones.

e-Learning that Builds Knowledge

Clinical Trials GCP Intermediate

Code	Lesson Title	Description
CTM-900	New Drug Development and Clinical Trials	Describes the most important characteristics of drug products and explains why the development and testing of new drug products must be regulated. It provides an overview of the drug development process and the various phases of clinical trials. It also introduces the concept of Good Clinical Practice (GCP).
CTM-1101	Roles and Responsibilities Under ICH GCP	Describes the roles and responsibilities of the different parties involved in initiating, conducting, and overseeing clinical trials according to ICH Good Clinical Practice. After explaining the need for ICH GCP, the module describes the part played by sponsors, investigators and IRB/IEC. The roles of other key contributors to the clinical trial process are also described.
CTM-1102	Anatomy of a Clinical Trial	Provides an overview of the structure and key activities of a clinical trial. It describes the trial process from the planning stages through to implementation and completion. The Lesson reviews key concepts and elements of clinical trial design and introduces basic trial design principles.
CGI-502	GCP Essential Documents: Investigator's Brochure & Study Protocol	Describes the essential documentation associated with the clinical trials process with emphasis on the Investigator's Brochure and Study Protocol.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

GCP Inspection Readiness

NOTE: These lessons form a Strategic Premium Suite and are sold as a group of 4 lessons

Code	Lesson Title	Description
CIR-800 **PREMIUM LESSON**	Inspection Readiness - Initiate	Provides practical techniques and strategies for the Initiate phase of preparing for a Good Clinical Practice (GCP) Inspection using project management principles.
CIR-801 **PREMIUM LESSON**	Inspection Readiness – Plan *(How to Handle Audit Questions)*	Provides practical techniques and strategies for the Plan phase of preparing for a Good Clinical Practice (GCP) Inspection using project management principles.
CIR-802 **PREMIUM LESSON**	Inspection Readiness – Execute and Monitor	Provides practical techniques and strategies for the Execute and Monitor phase of a Good Clinical Practice (GCP) Inspection using project management principles.
CIR-803 **PREMIUM LESSON**	Inspection Readiness - Close	Provides practical techniques and strategies for the Close phase of a Good Clinical Practice (GCP) Inspection using project management principles.

Nonclinical Laboratory Studies

Code	Lesson Title	Description
PGL-520	GLP Introduction	Describes what GLP is, the areas covered by GLP, where nonclinical laboratory studies fit into the overall drug approval process, why GLP was developed and the main GLP terms used.
PGL-521	GLP - Working in the Laboratory	The function of the laboratory for nonclinical testing. Focus on GLP as it relates to sample receipt, preparing for testing, testing, recording of results, and result approval.
DTI-1001 **PREMIUM LESSON**	Data Integrity for GxP Regulated Industries	An overview of data integrity in regulated industries and its essential role in assuring product quality. Key data integrity concepts in GxP environments are explored along with regulatory requirements and expectations. The critical role of personal responsibility in maintaining data integrity compliance is also covered.

Laboratory Practices

Code	Lesson Title	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-610	Laboratory GMP	GMP in the laboratory, from sample receipt, testing and recording of results to result approval.
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-1202	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 four stages of in vitro dissolution testing and the equipment used for the dissolution and sampling phases.
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-1130	Introduction to HPLC	Describes the basic theory and practice of HPLC. Particular focus is given to reverse phase HPLC. The components of a HPLC are described in detail and significant consideration is given to the explanation of results and peak shape. Analytical considerations of special relevance to HPLC are also presented.

PPL-831	HPLC Troubleshooting	Describes the troubleshooting of common HPLC equipment problems.
PVL-700	Laboratory Equipment Qualification	Explains what is involved in laboratory equipment qualification. Includes DQ, IQ, OQ and PQ.
PVL-310	Method Validation Parameters	Method Validation in terms of analytical parameters. Parameters discussed include standards, LOD, LOQ, precision and accuracy.

Operational Excellence

Code	Lesson Title	Description
OPE-1101 NEW PREMIUM LESSON	CAPA for Nonconformities	An overview of the key concepts and terminologies associated with nonconformities, and the CAPA methodology used to address them as part of a company's Quality Management System. Using a scenario-driven approach, the user is taken through the key steps of a CAPA process from identifying a problem to verifying the effectiveness of the solutions implemented to resolve it. In doing so, users will be better equipped to distinguish between corrections, corrective actions, and preventive actions. The concept of risk and categorization of nonconformities as minor, major, or critical is also covered as are regulatory expectations surrounding nonconformities and CAPA.
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Nutraceutical Lessons

Below is a list of e-lessons targeted specifically to the Nutraceutical sector. If you would like to experience any of these lessons, please contact us and we'll set up a tailored lesson demonstration for you on our online Learning Management System.

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e-Learning that Builds Knowledge

Nutraceutical GMP

Code	Lesson Title	Description
NGI-800	GMP - SOPs in Nutraceutical Manufacturing	Defines Standard Operating Procedures (SOPs), why they are essential in the manufacture of nutraceuticals, where they are used, the type of information they typically contain, and how they are controlled.
NGI-801	GMP – Records in Nutraceutical Manufacturing	Defines records, why they are essential in the manufacture of nutraceuticals, how and where they are used, the type of information they typically contain, and the rules for how they should be completed.

To discuss your training needs and arrange a demonstration, please contact us today:

USA:	973-588-4884
Rest of world:	+353-1-630-1480
Email:	info@skillpad.com