Lesson Catalog

This catalog lists all lessons currently available from SKILLPAD

Welcome to Skillpad's extensive catalog of e-Lessons, designed and built specifically for your industry.

SECTOR INDEX

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Finished Dose e-Lessons

Below is a list of e-Lessons targeted specifically to the Finished Dose pharmaceutical sector. If you would like to experience any of these e-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	Title	Description
PGB-900	Overview of Pharmaceutical Manufacturing	The pharmaceutical industry, what it manufactures, and the typical departments found in a pharmaceutical manufacturing facility.
PGB-1101	GMP for Finished Dose Forms	GMP and 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	Regulation of the pharmaceutical industry, how new drugs are approved, types of regulatory inspections, and the role of employees in inspections.
PGB-1203	Finished Dose Contamination Prevention	Overview of how finished dose products can be contaminated during production and how to minimize the risk of contamination through the use of PPE and good hygiene habits.
PGB-1204	Dress Codes for Finished Dose Manufacturing	Overview of dress codes, why they are needed, and how they are used in different areas of a finished dose facility.
PGB-1105	GMP Goals	Describes the GMP responsibilities of employers and employees and the importance of procedures and records.

Pharmaceutical GMP - Intermediate

Code	Title	Description
PGI-1100	SOPs in Finished Dose Manufacturing	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	Records in Finished Dose Manufacturing	Completion of records required for Finished Dose manufacture. Records include records of materials, production records, equipment records, laboratory records, production review and distribution records.
PGI-1110	Personnel and Training	GMP requirements concerning personnel, training, clothing, hygiene and health.
PGI-1220	Warehousing	Warehousing principles and practices including warehouse functions, GMP in the warehouse, and QC status for materials and products.
PGI-1230	Cleaning of Equipment	Overview of different equipment cleaning methods used in the pharmaceutical and biologics industries.
PGI-1240	Sampling	Different sampling techniques used for raw materials, manufactured materials, or final products in the pharmaceutical or biopharmaceutical industries. 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-1271	Primary Packaging	Principles of primary packaging and the processes involved.
PGI-1272	Secondary and Tertiary Packaging	Principles of secondary and tertiary packaging and the processes involved.
PGI-1280	Labeling	Labeling principles and procedures in a pharmaceutical manufacturing facility including the importance of accurate labeling, information contained on a label, and label distribution and reconciliation requirements.
PGI-1290	Buildings and Facilities	The GMP design requirements for a manufacturing facility including product flow, environmental controls, cleaning, sanitization, and maintenance.
SER-1100 PREMIUM LESSON	Serialization and Product Tracking	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	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	Title	Description
SER-1101 PREMIUM LESSON	Four Level Serialization Structure	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-1106 PREMIUM LESSON	Serialization and the Supply Chain	Overview of what happens to serialized products when they leave a regulated production facility, how change of ownership is accomplished, and how compliance with the DSCSA and DQSA is achieved.

Finished Dose - Process Understanding

Code	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-1203	Semisolid Dosage	Overview of semisolid dose products manufactured by the pharmaceutical industry, including their advantages and disadvantages, ingredients used, and the manufacturing steps involved.
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	Overview of 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	Title	Description
PEF-1202	Milling	Overview of milling operations, including different types of milling equipment and techniques, equipment control parameters and safety precautions.
PEF-1203	Blending	Overview of blending operations, including different types of blending equipment, equipment control parameters and safety precautions.
PEF-1204	Filtration for Finished Dose	Overview of filtration, how a plate and frame filter press operates, the equipment control parameters used, and the relevant safety precautions.
PEF-1205	Dryers	Overview of drying in the pharmaceutical industry, how a tray dryer is operated, and its associated 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-1207	Tablet Press	Overview of how a tablet press functions, key process control parameters, required in-process checks and associated safety considerations.
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	Title	Description
PVF-1130	Fundamentals of Process Validation	Introduction to process validation using the DQ, IQ, OQ and PQ 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	Title	Description
PUA-1250	Water Types and Testing	The different grades of water typically used in a pharmaceutical manufacturing plant and the tests used to determine water 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

Code	Title	Description
PST-1200	Basic Microbiology	Introduction to microorganisms, the contamination threat they pose to products, and how products can be protected from this threat.
PST-1220	Isolators	Overview of how isolators are used in pharmaceutical and biologics processing, the different components of an isolator including transfer mechanisms and protective equipment, and how isolators can be cleaned and sanitized.
PST-1265	Cleanrooms - Rules, Control Parameters, and Testing	Overview of general cleanroom rules and the cleanroom parameters that are controlled, monitored, and tested in pharmaceutical and biologics facilities.
PST-1291	Moist Heat Sterilization - Autoclaves	Overview of moist heat (steam) sterilization via autoclaving, including the equipment used, critical process parameters, and the different stages of a sterilization cycle.

Aseptic Processing - Cleanroom GMP

Code	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

Code	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	Overview of how sterile filtration is used in the pharmaceutical and biologics industries and the equipment and operating parameters involved.
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	Title	Description
RGM-1200	Executive Responsibility in Pharmaceutical Manufacturing	Overview of the regulatory responsibilities of executive management in the pharmaceutical manufacturing industry. It explains both FDA and legal requirements and the corporate and personal consequences of non-compliance.

Health and Safety - General

Code	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	Title	Description
PSY-1241	Laboratory Safe Work Practices	Explains how to work safely in a laboratory through use of Standard Operating Procedures, Safety Data Sheets and use of appropriate safety equipment. Safety considerations associated with common laboratory equipment are also outlined.
PSY-1260	Chemical Laboratory Waste	The different categories of chemical laboratory waste produced in a laboratory and the procedures for handling and storing this waste in a safe manner.

Health and Safety - Micro Laboratory

Code	Title	Description
PSY-1221	General Safety Hazards in the Microbiology Lab	Overview of the hazards associated with the different classes of microorganisms, as well as the precautions that must be taken during activities such as media preparation, handling and transportation of cultures, autoclaving, and the disposal of hazardous waste.
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	Title	Description
GVC-1200	IT Use in Regulated Industries	Describes how Information Technology can be used in GMP-regulated industries, common threats to computer security and how they can be addressed, and some recommended good computer practices.
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-enforced 21 CFR Part 11 ruling on electronic records and signatures.
GVC-1202	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	Title	Description
PGL-1200	Out of Specification and Atypical Results	Overview of out of specification and atypical results in the analytical laboratory, including how they can arise, how they can be investigated, and how they can be prevented.
PGL-1210	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	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	Title	Description
PVL-1210	Method Validation Parameters	Overview of method validation in the analytical laboratory, including why it must be performed and the various parameters that must be examined.
PVL-1200	Laboratory Equipment Qualification	Overview of laboratory equipment qualification, why it is done, the stages and activities involved, and the key role of documentation and other support activities.

Analytical Laboratory - Lab Practices

Code	Title	Description
PPL-1200	Weighing	Laboratory weighing operations including types of balances typically used, pre-weighing checks, and recommended weighing procedures and precautions.
PPL-1201	Glassware	Explains how to choose the correct glassware for preparing and storing solutions in the laboratory, and how to read and use volumetric glassware correctly.
PPL-1202	Solution Preparation	Explains 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-1206	Wet Chemistry	Overview of wet chemistry techniques including use of pipettes and burettes, quantitative transfer of materials, and making dilutions.
PPL-1205	Instrumentation - Error Prevention	Overview of common errors associated with using spectrometry (AA, UV/VIS, IR) and pH measurement techniques and how these errors can be avoided.
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 PREMIUM LESSON	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-1131 PREMIUM LESSON	HPLC Troubleshooting	Describes the troubleshooting of common HPLC equipment problems.

Microbiology Laboratory - Lab Practices

Code	Title	Description
PPM-1200	Principles of Good Aseptic Technique	The principles of good aseptic technique and how they are applied in microbiological testing.
PPM-1210	Basic Microbiological Techniques	The techniques frequently used in microbiology laboratories including media preparation, handling stock cultures, and pure culture techniques.
PPM-1211	Introduction to Microscopy	The role of microscopy in microbiology, including microscope components and functions, different lens types, and various microscopy 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	Title	Description
PGM-1200	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	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	Title	Description
OPE-1101 PREMIUM LESSON	CAPA for Nonconformities	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.
OPE-1102 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 e-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 e-Lessons, please contact us and we'll set up a tailored e-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	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-1203	API Contamination Prevention	How API products can be contaminated during production operations and how the risk of contamination can be minimized through the use of PPE, good hygiene habits, and good production practices.
BGB-1204	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	Title	Description
BGI-1100	SOPs in API Manufacturing	What an SOP is, why SOPs must be followed in API plants and what information they should contain.
BGI-1101	Records in API Manufacturing	Overview of records in API Manufacturing, why these records are essential, how and where they are used, and the type of information they typically contain.
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 requirements.
DTI-1001 PREMIUM LESSON	Data Integrity for GxP Regulated Industries	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

Code	Title	Description
PGI-1110	Personnel and Training	Describes GMP requirements concerning personnel, training, clothing, hygiene, and health.
PGI-1220	Warehousing	Warehousing principles and practices including warehouse functions, GMP in the warehouse, and QC status for materials and products.
PGI-1230	Cleaning of Equipment	Overview of different equipment cleaning methods used in the pharmaceutical and biologics industries.
PGI-1280	Labeling	Overview of labeling principles and procedures in a pharmaceutical manufacturing facility including the importance of accurate labeling, information contained on a label, and label distribution and reconciliation requirements.
PGI-1290	Buildings and Facilities	The GMP design requirements for a manufacturing facility including product flow, environmental controls, cleaning, sanitization, and maintenance.
RGM-1200	Executive Responsibility in Pharmaceutical Manufacturing	Overview of the regulatory responsibilities of executive management in the pharmaceutical manufacturing industry. It explains both FDA and legal requirements and the corporate and personal consequences of non-compliance.

API Manufacturing - Process Understanding

Code	Title	Description
PUA-1200	Chemical Reactions: Overview	Provides an overview of chemical reactions as well as the various process variables that must be controlled.
PUA-1201	Chemical Reactions: Properties	The main physical and chemical properties that are needed to monitor and control a chemical reaction.
PUA-1210	Distillation and Reflux	Introduction to the principles of distillation and reflux. The critical control parameters of each process are described and relevant safety issues are highlighted.
PUA-1220	Crystallization	Introduction to the principles of crystallization, the stages and variables involved in the crystallization process, as well as the actions that can be taken to resolve typical process issues.
PUA-1230	Drying	The importance of drying products in the API industry, as well as the different types of drying equipment, and the control parameters involved in the drying process.
PUA-1240	Filtration	Overview of the theory of filtration, the types of equipment used, and the key process parameters involved.
BPU-1113 PREMIUM LESSON	Freeze Drying in Biopharmaceutical Manufacturing	Overview of 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	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-1210	Centrifuges	The operating principles and parameters of Batch Filtering and Inverting Filter centrifuges are explained.
PEA-1240	Reciprocating Pumps	Overview of reciprocating pumps, their mode of operation, and how they can be used in pharmaceutical and biologics processing.
PEA-1241	Rotary & Centrifugal Pumps	Overview of rotary and centrifugal pumps, their modes of operation, and how they can be used in pharmaceutical processing.
PEA-1250	Valves	The different types of valves commonly used in a pharmaceutical manufacturing facility.

Manufacturing - Validation

Code	Title	Description
PVF-1130	Fundamentals of Process Validation	Introduction to process validation using the DQ, IQ, OQ and PQ 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	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	Title	Description
PSY-1241	Laboratory Safe Work Practices	Explains how to work safely in a laboratory through use of Standard Operating Procedures, Safety Data Sheets and use of appropriate safety equipment. Safety considerations associated with common laboratory equipment are also outlined.
PSY-1260	Chemical Laboratory Waste	The different categories of chemical laboratory waste produced in a laboratory and the procedures for handling and storing this waste in a safe manner.

Health and Safety - Micro Laboratory

Code	Title	Description
PSY-1221	General Safety Hazards in the Microbiology Lab	Overview of the hazards associated with the different classes of microorganisms, as well as the precautions that must be taken during activities such as media preparation, handling and transportation of cultures, autoclaving, and the disposal of hazardous waste.
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	Title	Description
GVC-1200	IT Use in Regulated Industries	Describes how Information Technology can be used in GMP-regulated industries, common threats to computer security and how they can be addressed, and some recommended good computer practices.
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-enforced 21 CFR Part 11 ruling on electronic records and signatures.
GVC-1202	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	Title	Description
PGL-1200	Out of Specification and Atypical Results	Overview of out of specification and atypical results in the analytical laboratory, including how they can arise, how they can be investigated, and how they can be prevented.
PGL-1210	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	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	Title	Description
PVL-1200	Laboratory Equipment Qualification	Overview of laboratory equipment qualification, why it is done, the stages and activities involved, and the key role of documentation and other support activities.
PVL-1210	Method Validation Parameters	Overview of method validation in the analytical laboratory, including why it must be performed and the various parameters that must be examined.

Analytical Laboratory - Lab Practices

Code	Title	Description
PPL-1200	Weighing	Laboratory weighing operations including types of balances typically used, pre-weighing checks, and recommended weighing procedures and precautions.
PPL-1201	Glassware	Explains how to choose the correct glassware for preparing and storing solutions in the laboratory, and 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-1206	Wet Chemistry	Overview of wet chemistry techniques including use of pipettes and burettes, quantitative transfer of materials, and making dilutions.
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 PREMIUM LESSON	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-1131 PREMIUM LESSON	HPLC Troubleshooting	Describes the troubleshooting of common HPLC equipment problems.

Microbiology Laboratory - Lab Practices

Code	Title	Description
PPM-1200	Principles of Good Aseptic Technique	The principles of good aseptic technique and how they are applied in microbiological testing.
PPM-1210	Basic Microbiological Techniques	The techniques frequently used in microbiology laboratories including media preparation, handling stock cultures, and pure culture techniques.
PPM-1211	Introduction to Microscopy	The role of microscopy in microbiology, including microscope components and functions, different lens types, and various microscopy 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	Title	Description
PGM-1200	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	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	Title	Description
OPE-1101 **PREMIUM LESSON**	CAPA for Nonconformities	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.
OPE-1102 **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 e-Lessons

Below is a list of e-Lessons targeted specifically to the Biopharmaceutical sector including manufacturing of therapeutics, vaccines and diagnostics. If you would like to experience any of these e-Lessons, please contact us and we'll set up a tailored e-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	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 - The Big Picture

Code	Title	Description
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.

Upstream Biopharmaceuticals Manufacturing

Code	Title	Description
BPU-1104 PREMIUM LESSON	Upstream Processing: 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-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-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.

Downstream Biopharmaceuticals Manufacturing

Code	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-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.

Process Validation for Biopharmaceuticals

Code	Title	Description
BPU-1111 PREMIUM LESSON	Process Validation: Process Design	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	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.

Biopharmaceutical Formulation & Freeze Drying

Code	Title	Description
BPU-1109 PREMIUM LESSON	Formulation in the Biopharmaceutical Industry	Overview of the principles and practices of formulation and packaging processes in a modern biopharmaceutical manufacturing facility.
BPU-1113 PREMIUM LESSON	Freeze Drying in Biopharmaceutical Manufacturing	Overview of 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

Code	Title	Description
PST-1200	Basic Microbiology	Introduction to microorganisms, the contamination threat they pose to products, and how products can be protected from this threat.
PST-1220	Isolators	How isolators are used in pharmaceutical and biologics processing, the different components of an isolator including transfer mechanisms and protective equipment, and how isolators can be cleaned and sanitized.

Aseptic Processing - Cleanroom GMP

Code	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

Code	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	Overview of how sterile filtration is used in the pharmaceutical and biologics industries and the equipment and operating parameters involved.
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	Title	Description
PUA-1200	Chemical Reactions: Overview	Provides an overview of chemical reactions as well as the various process variables that must be controlled.
PUA-1201	Chemical Reactions: Properties	The main physical and chemical properties that are needed to monitor and control a chemical reaction.
PUA-1210	Distillation and Reflux	Introduction to the principles of distillation and reflux. The critical control parameters of each process are described and relevant safety issues are highlighted.
PUA-1220	Crystallization	Introduction to the principles of crystallization, the stages and variables involved in the crystallization process, as well as the actions that can be taken to resolve typical process issues.
PUA-1230	Drying	The importance of drying products in the API industry, as well as the different types of drying equipment, and the control parameters involved in the drying process.
BPU-1113 PREMIUM LESSON	Freeze Drying in Biopharmaceutical Manufacturing	Overview of 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-1240	Filtration	Overview of the theory of filtration, the types of equipment used, and the key process parameters involved.
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	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-1210	Centrifuges	The operating principles and parameters of Batch Filtering and Inverting Filter centrifuges are explained.
PEA-1240	Reciprocating Pumps	An overview of reciprocating pumps, their mode of operation, and how they can be used in pharmaceutical and biologics processing.
PEA-741	Rotary & Centrifugal Pumps	The operating principles of rotary and centrifugal pumps.
PEA-1250	Valves	The different types of valves commonly used in a pharmaceutical manufacturing facility.

Manufacturing - Validation

Code	Title	Description
PVF-1130	Fundamentals of Process Validation	Introduction to process validation using the DQ, IQ, OQ and PQ 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	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	Title	Description
PSY-1241	Laboratory Safe Work Practices	Explains how to work safely in a laboratory through use of Standard Operating Procedures, Safety Data Sheets and use of appropriate safety equipment. Safety considerations associated with common laboratory equipment are also outlined.
PSY-1260	Chemical Laboratory Waste	The different categories of chemical laboratory waste produced in a laboratory and the procedures for handling and storing this waste in a safe manner.

Health and Safety - Micro Laboratory

Code	Title	Description
PSY-1221	General Safety Hazards in the Microbiology Lab	Overview of the hazards associated with the different classes of microorganisms, as well as the precautions that must be taken during activities such as media preparation, handling and transportation of cultures, autoclaving, and the disposal of hazardous waste.
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	Title	Description
GVC-1200	IT Use in Regulated Industries	Describes how Information Technology can be used in GMP-regulated industries, common threats to computer security and how they can be addressed, and some recommended good computer practices.
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-enforced 21 CFR Part 11 ruling on electronic records and signatures.
GVC-1202	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	Title	Description
PGL-1200	Out of Specification and Atypical Results	Overview of out of specification and atypical results in the analytical laboratory, including how they can arise, how they can be investigated, and how they can be prevented.
PGL-1210	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	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	Title	Description
PVL-1200	Laboratory Equipment Qualification	Overview of laboratory equipment qualification, why it is done, the stages and activities involved, and the key role of documentation and other support activities.
PVL-1210	Method Validation Parameters	Overview of method validation in the analytical laboratory, including why it must be performed and the various parameters that must be examined.

Analytical Laboratory - Lab Practices

Code	Title	Description
PPL-1200	Weighing	Laboratory weighing operations including types of balances typically used, pre-weighing checks, and recommended weighing procedures and precautions.
PPL-1201	Glassware	Explains how to choose the correct glassware for preparing and storing solutions in the laboratory, and 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-1206	Wet Chemistry	Overview of wet chemistry techniques including use of pipettes and burettes, quantitative transfer of materials, and making dilutions.
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 PREMIUM LESSON	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-1131 PREMIUM LESSON	HPLC Troubleshooting	Describes the troubleshooting of common HPLC equipment problems.

Microbiology Laboratory - Lab Practices

Code	Title	Description
PPM-1200	Principles of Good Aseptic Technique	The principles of good aseptic technique and how they are is applied in microbiological testing.
PPM-1210	Basic Microbiological Techniques	The techniques frequently used in microbiology laboratories including media preparation, handling stock cultures, and pure culture techniques.
PPM-1211	Introduction to Microscopy	The role of microscopy in microbiology, including microscope components and functions, different lens types, and various microscopy 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	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	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

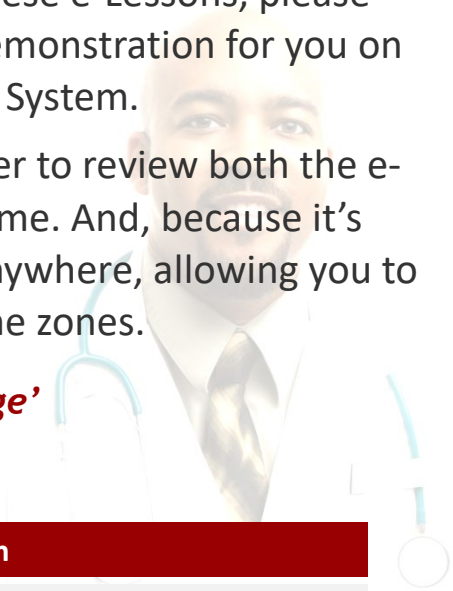
Code	Title	Description
OPE-1101 **PREMIUM LESSON**	CAPA for Nonconformities	Overview of the key concepts and terminologies associated with nonconformities, and the CAPA methodology used to address them as part of a company's Quality Management System. Using a scenario-driven approach, the user is taken 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 **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 e-Lessons

Below is a list of e-Lessons targeted specifically to the Medical Devices sector. If you would like to experience any of these e-Lessons, please contact us and we'll set up a tailored e-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	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	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	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

Code	Title	Description
PGI-1220	Warehousing	Warehousing principles and practices including 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-1271	Primary Packaging	Principles of primary packaging and the processes involved.
PGI-1272	Secondary and Tertiary Packaging	Principles of secondary and tertiary packaging and the processes involved.
PGI-1280	Labeling	Overview of labeling principles and procedures in a GMP-regulated manufacturing facility including the importance of accurate labeling, information contained on a label, and label distribution and reconciliation requirements.
PGI-1290	Buildings and Facilities	The GMP design requirements for a manufacturing facility including product flow, environmental controls, cleaning, sanitization, and maintenance.
SER-1100 PREMIUM LESSON	Serialization and Product Tracking	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	Title	Description
SER-1101 PREMIUM LESSON	Four Level Serialization Structure	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-1106 PREMIUM LESSON	Serialization and the Supply Chain	Overview of what happens to serialized products when they leave a regulated production facility, how change of ownership is accomplished, and how compliance with the DSCSA and DQSA is achieved.

Aseptic Processing - Introduction

Code	Title	Description
PST-1200	Basic Microbiology	Introduction to microorganisms, the contamination threat they pose to products, and how products can be protected from this threat.
PST-1220	Isolators	Overview of how isolators are used in pharmaceutical and biologics processing, the different components of an isolator including transfer mechanisms and protective equipment, and how isolators can be cleaned and sanitized.

Aseptic Processing - Sterilization

Code	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	Overview of how sterile filtration is used in the pharmaceutical and biologics industries and the equipment and operating parameters involved.
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	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	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	Title	Description
PSY-1241	Laboratory Safe Work Practices	Explains how to work safely in a laboratory through use of Standard Operating Procedures, Safety Data Sheets and use of appropriate safety equipment. Safety considerations associated with common laboratory equipment are also outlined.
PSY-1260	Chemical Laboratory Waste	The different categories of chemical laboratory waste produced in a laboratory and the procedures for handling and storing this waste in a safe manner.

Health and Safety - Micro Laboratory

Code	Title	Description
PSY-1221	General Safety Hazards in the Microbiology Lab	Overview of the hazards associated with the different classes of microorganisms, as well as the precautions that must be taken during activities such as media preparation, handling and transportation of cultures, autoclaving, and the disposal of hazardous waste.
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 and Validation

Code	Title	Description
GVC-1200	IT Use in Regulated Industries	Describes how Information Technology can be used in GMP-regulated industries, common threats to computer security and how they can be addressed, and some recommended good computer practices.
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-enforced 21 CFR Part 11 ruling on electronic records and signatures.
GVC-1202	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	Title	Description
PGL-1200	Out of Specification and Atypical Results	Overview of out of specification and atypical results in the analytical laboratory, including how they can arise, how they can be investigated, and how they can be prevented.
PGL-1210	Laboratory GMP	GMP in the laboratory, from sample receipt, testing and recording of results to result approval.

Analytical Laboratory - Lab Practices

Code	Title	Description
PPL-1200	Weighing	Laboratory weighing operations including types of balances typically used, pre-weighing checks, and recommended weighing procedures and precautions.
PPL-1201	Glassware	Explains how to choose the correct glassware for preparing and storing solutions in the laboratory, and 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 PREMIUM LESSON	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-1131 PREMIUM LESSON	HPLC Troubleshooting	Describes the troubleshooting of common HPLC equipment problems.

Analytical Laboratory - Validation

Code	Title	Description
PVL-1210	Method Validation Parameters	Overview of method validation in the analytical laboratory, including why it must be performed and the various parameters that must be examined.
PVL-1200	Laboratory Equipment Qualification	Overview of laboratory equipment qualification, why it is done, the stages and activities involved, and the key role of documentation and other support activities.

Microbiology Laboratory - Lab Practices

Code	Title	Description
PPM-1200	Principles of Good Aseptic Technique	The principles of good aseptic technique and how they are applied in microbiological testing.
PPM-1210	Basic Microbiological Techniques	The techniques frequently used in microbiology laboratories including media preparation, handling stock cultures, and pure culture techniques.
PPM-1211	Introduction to Microscopy	The role of microscopy in microbiology, including microscope components and functions, different lens types, and various microscopy 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	Title	Description
PGM-1200	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	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	Title	Description
PVF-1130	Fundamentals of Process Validation	Introduction to process validation using the DQ, IQ, OQ and PQ 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	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	Title	Description
OPE-1101 PREMIUM LESSON	CAPA for Nonconformities	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.
OPE-1102 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 e-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 e-Lessons, please contact us and we'll set up a tailored e-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	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	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	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	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. . Key tasks are explained, including confirming the inspection, identifying the key people, defining roles, identifying training/ coaching requirements, and kicking off the project.
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. An interactive scenario driven section on the types of questions that are typically asked in an inspection situation is included, along with appropriate responses. The lesson also contains an example of a Project Plan.
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. Key tasks explained include discussing known issues and available intelligence, preparing a standard list of questions and answers; preparing key documents, and then executing the Plan when the inspection begins. The lesson contains sample GCP Audit Questions.
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. This includes preparing for the close out meeting, performing the close out meeting with the inspector, responding to observations (483s), finalising the internal report, and defining lessons learned.

Nonclinical Laboratory Studies

Code	Title	Description
PGL-1220	GLP – An Introduction	Overview of GLP, its key terms and areas of application, and how nonclinical laboratory studies fit into the overall drug approval process.
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	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	Title	Description
PPL-1200	Weighing	Laboratory weighing operations including types of balances typically used, pre-weighing checks, and recommended weighing procedures and precautions.
PPL-1201	Glassware	Explains how to choose the correct glassware for preparing and storing solutions in the laboratory, and 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-1206	Wet Chemistry	Overview of wet chemistry techniques including use of pipettes and burettes, quantitative transfer of materials, and making dilutions.
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

PREMIUM LESSON		to the explanation of results and peak shape. Analytical considerations of special relevance to HPLC are also presented.
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Operational Excellence

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Nutraceutical e-Lessons

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Nutraceutical GMP

Code	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:

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