ZENQMS TRAINING ADD-ONS

GxP Training Courses, Built In

Through partnerships with Biopharma Institute and Evolve e-Learning Solutions—experts in regulatory, validation, compliance, OSHA, HIPAA, and GxP training—ZenQMS now offers over 130 high-quality courses for purchase and direct integration into our QMS platform.

Course Catalogs

Clinical Trials Management and Monitoring	Computer System Validation (CSV)	Drug Safety
Electronic Records	Good Laboratory Practices	Good Manufacturing Practices
Medical Devices	Pharmaceutical Regulatory Affairs	Pharmaceutical Sales and Marketing
Validation	OSHA	HR / EEO
HIPAA	DOT	Compliance

22 COURSES · BIOPHARMA INSTITUTE

Clinical Trials Management and Monitoring

Clinical Trials in Drug Development (Fundamentals)

30 MIN · 0 CPD UNITS

The crucial role of clinical trials in the drug development cycle is examined. Regulatory requirements and financial pressures, and their interaction with trial design, are discussed.

Clinical Trials: Protocol Design (Fundamentals)

30 MIN · 0 CPD UNITS

This session provides an overview of clinical trial protocols. Opportunities to improve a clinical trial protocol for regulatory approval are also discussed.

Clinical Trials: Preparation (Fundamentals)

30 MIN · 0 CPD UNITS

This session provides an overview of the role of the sponsor in supporting and improving quality in the conduct of clinical trials.

Clinical Trials: Endpoints (Fundamentals)

30 MIN | 0 CPD UNITS

This session focuses on clinical trial endpoints. The purpose of endpoints and the types are discussed in this part.

Clinical Trials: Statistical Elements (Fundamentals)

30 MIN | 0 CPD UNITS

This session covers the role of statistics in clinical trial design and analysis, as acknowledged in the International Council for Harmonization (ICH) guideline for Good Clinical Practice (GCP).

Clinical Trials: Study Design (Fundamentals)

30 MIN | 0 CPD UNITS

This session provides an overview of the main types of study design.

Clinical Trials: Data Capture (Fundamentals)

30 MIN | 0 CPD UNITS

This session describes the purpose of data capture and explores efficiencies in data management as part of the evolving regulatory landscape.

GCP: ICH, Harmonization, and Principles of GCP ICH E6(R3)

35 MIN | 0 CPD UNITS

Sets out the scope, objectives and notes on terminology: ICH, harmonization; Principles of GCP and introduces GCP ICH guideline E6(R3); Describes the ICH's role in the harmonization of regulations.

GCP: Clinical Research Teamwork (Fundamentals)

20 MIN | 0 CPD UNITS

The crucial role of clinical trials in the drug development cycle is examined. Regulatory requirements and financial pressures, and their interaction with trial design, are discussed.

GCP: Clinical Trial GCP ICH E6(R3) Records and Data Governance (Fundamentals)

50 MIN | 0 CPD UNITS

Identifies the documents designated by ICH GCP as essential to the conduct of a clinical trial. Describes important examples. Outlines how records should be maintained.

GCP: Clinical Trial Sponsors GCP ICH E6(R3) Responsibilities (Fundamentals)

50 MIN | 0 CPD UNITS

Sets out the scope, objectives and notes on terminology: Sponsor responsibilities; Duties and functions discussed in this session; Risk-based quality management; Selection of investigators; Trial management; Data handling; Record keeping; Finance; Compensation; Regulatory submissions; Management of investigational product(s); Safety reporting; Monitoring; Audit; Dealing with noncompliance; Clinical trial reports

GCP: Clinical Trial Investigators GCP ICH E6(R3) Responsibilities (Fundamentals)

30 MIN | 0 CPD UNITS

Sets out the scope, objectives and notes on terminology: Informed consent; Sets out the principles and requirements of informed consent; Describes the process; Provides examples of practical issues confronting healthcare professionals and subjects

GCP: Clinical Trial Monitors GCP ICH E6(R3) Responsibilities (Fundamentals)

30 MIN | 0 CPD UNITS

Sets out the scope, objectives and notes on terminology: Monitor responsibilities; Explores the responsibilities of the monitor; Provides insight into key challenges; Describes assessment of investigators; Investigational sites; Education and trial initiation; Risk-based monitoring of clinical conduct; Including CRF review and source document verification; Trial

Clinical Trials: How to Conduct Clinical Research Under the EU Clinical Trials Regulation

60 MIN | 1 CPD UNIT

Substantial modifications; Adding an MSC; Notifications; Notices, alerts, and RFIs; Ad hoc assessments; Corrective measures; Reporting adverse events; Reporting SUSARs; Annual safety report; Submitting trial results

Clinical Trials and Drug Development

90 MIN | 1.5 CPD UNITS

The context of the pharmaceutical industry and modern medicine is established. The regulatory frameworks of the USA, Europe and Japan are outlined. International harmonization of requirements through the work of ICH is discussed, with particular reference to Good Clinical Practice. The long and financially risky process of developing a drug is described. The various stages of discovery, nonclinical and clinical development close-out; Discusses noncompliance and how to deal with it.

are detailed. Commercial considerations in drug development are described. Issues such as financial risk, pharmacoeconomics, patent life and generics are discussed.

Clinical Trial Monitoring: Site Evaluation and Set-up

90 MIN | 1.5 CPD UNITS

State the objectives of an investigational site qualification visit and describe how to carry one out. Describe how to prepare for initiation of a clinical trial at an investigational site. State the objectives of a trial initiation visit and describe how to carry one out.

Clinical Trial Monitoring: Documentation and Closure

180 MIN | 2 CPD UNITS

Describe how to prepare for and carry out regular monitoring visits to investigational sites. Describe how to review case report forms (CRFs) and verify consistency of data with source documents. Describe how to close out a trial at a site. Discuss the concept and implications of risk-based monitoring. Identify warning signs that raise suspicion of scientific misconduct or fraud.

Clinical Trials: How to Gain Authorization for Clinical Research Under the EU Clinical Trials Regulation

120 MIN | 2 CPD UNITS

Outline the legal and regulatory framework for clinical trials in the European Economic Area. Describe the characteristics and applicability of the Clinical Trials Regulation. Identify online portals and databases essential to authorization and oversight of clinical trials under the Regulation. Specify the timeline for transition to the Regulation from the Clinical Trials Directive. Identify the contents of a clinical trial application (CTA) dossier as required by the Regulation. Describe how to compile and submit a CTA dossier via the Clinical Trials Information System. Describe how a CTA is validated and assessed, and how decisions are reached, by the reporting member state and other member states concerned.

Clinical Trials: Preparing for an Audit or Inspection

150 MIN | 2.5 CPD UNITS

Discuss principles of GCP inspections and audits; Specify activities to be carried out in preparation for an inspection; Describe what happens when a European regulator inspects the site of a sponsor or contract research organization; Describe what happens when a European regulator inspects the site of a clinical investigator; Describe what happens when the US Food and Drug Administration inspects the site of a sponsor or contract research organization; Describe what happens when the US Food and Drug Administration inspects the site of a clinical investigator; Specify post-inspection actions by the regulator and the inspected party

GCP: ICH-GCP Good Clinical Practice E6(R3)

195 MIN | 3 CPD UNITS

Explain why and how the ICH influences clinical research practice through its guideline on Good Clinical Practice (GCP); Identify the principles of GCP; Identify records essential to a clinical trial, explain their function and use, outline their contents, and describe their maintenance; Comply with GCP expectations for data governance; Specify the responsibilities of a trial sponsor; Specify the responsibilities of a clinical investigator; Explain the rationale and execution of the informed consent process, and identify issues that arise in practice; Specify the sponsor's responsibilities for trial monitoring

Clinical Trials: The Investigational New Drug Application (IND) to Conduct FDA-regulated Clinical Trials

180 MIN | 3 CPD UNITS

Specify the role of an IND and the contexts in which it is required; Access key regulatory documents relating to INDs; Describe the contents and format of an IND submission; Describe the process of FDA review of an IND, the possible outcomes and sponsor's responses; Identify actions necessary to maintain an active IND; Specify options for expanded-access use of investigational drugs

Clinical Trials: Preparation and Design

240 MIN · 4 CPD UNITS

Outline the role of clinical trial design in clinical research; Identify the relevant legal documents and guidelines relating to clinical trial design; Recognize the essential statistical components for clinical trial design and how these affect design choice; Define the general principles and concepts for trial design, and describe the implications of design choice on regulatory acceptance; Identify the strategies to improve data capture and management; Describe how electronic data capture can improve clinical trial development.

2 COURSES · BIOPHARMA INSTITUTE

Computer System Validation (CSV)

Validation: Computer System Validation (Part 1 of 2) (Planning)

60 MIN · 1 CPD UNIT

Define computer systems validation; Outline criteria for selecting systems to be validated and for initial estimation of the degree of validation required; Access important guidance documents by industry bodies and regulatory authorities; Identify the phases of the computer systems lifecycle and describe the activities that are performed in each phase; Describe considerations influencing validation strategy; Describe the principles of GAMP5, risk assessment, and risk management; Assess software suppliers and their products; Outline the contents of a validation plan

Validation: Computer System Validation (Part 2 of 2) (Implementation)

60 MIN · 1 CPD UNIT

Describe the design, development and installation phase of projects to validate computerized systems; Describe the validation phase of such projects; Describe the operation and maintenance phase; Determine which systems to validate; Determine the amount of validation required, and the strategy to use

9 COURSES · BIOPHARMA INSTITUTE

Drug Safety

Drug Safety: Urgent Safety Restrictions

45 MIN | 0.75 CPD UNITS

In this session we describe how to prepare for and initiate an Urgent Safety Restriction (USR) for a centrally authorized product and for a product authorized through the Mutual Recognition or Decentralized Procedure. We outline the 24-hour procedure for execution of an USR, and the follow-up actions required, in each case. Finally, we specify the requirements for a variation application following an USR

Drug Safety: Good Pharmacoepidemiology Practice

60 MIN | 1 CPD UNIT

On completion of this module, you should be able to follow good practice in: Planning pharmacoepidemiological research; Collecting data in such research; Analyzing data from pharmacoepidemiological studies; Interpreting and communicating the results of such studies

Drug Safety: Risk Management Planning for Medicinal Products

90 MIN | 1.25 CPD UNITS

In this session we outline regulatory requirements for risk management plans in regions that are major markets for medicinal products: Europe, the USA, and (in a brief sketch) Japan. We describe the structure, main components, and submission requirements for EU Risk Management Plans and US Risk Evaluation and Mitigation Strategies, and we sketch notable aspects of risk management requirements in Japan.

Drug Safety: Signal Detection and Management in Pharmacovigilance

90 MIN | 1.5 CPD UNITS

Identify methods of signal detection and discuss their limitations; Describe how to accumulate evidence on a causal association between a drug and an event; Specify factors that increase the priority assigned to a signal, and describe methods of further investigation; Discuss reassessment of benefit/risk balance in the light of a previously unexpected reaction to a product, and specify actions to minimize risk

Introduction to Pharmacokinetics and Pharmacodynamics in Drug Development and Registration

90 MIN | 1.5 CPD UNITS

Although pharmacokinetic (PK) and pharmacodynamic (PD) studies are routinely carried out in nonclinical and clinical stages of drug development, their role is perhaps less well understood than it ought to be by those who are not specialists in the field. In addition, greater emphasis is being placed by regulators on the value of PK and PD data. Evidence of good practice in the execution of PK and PD studies, and sound understanding of the implications of their findings, are becoming increasingly important in drug registration. In this session we define PK and PD, outline the uses of PK and PD data in a drug development program, and give examples of how good practice in obtaining and interpreting PK and PD data can contribute to the minimization of risk for a drug.

Conducting Pharmacokinetic and Pharmacodynamic Studies

90 MIN | 1.5 CPD UNITS

Summarize the advantages, and how to counteract the main weakness, of the core design of choice for many pharmacokinetic and pharmacodynamic studies; Adopt good sampling practice; Discuss non-compartmental and compartmental data analysis; Describe the rationale and characteristics of studies in special populations; Describe how to carry out bioequivalence testing

Introduction to Drug Safety and Pharmacovigilance

180 MIN | 2 CPD UNITS

Explain, with examples, why drug safety monitoring / pharmacovigilance is necessary; Describe ways in which drug safety / pharmacovigilance is regulated nationally and internationally, and identify international policy-making bodies; Outline how drug safety/pharmacovigilance responsibilities are organized within pharmaceutical and biotechnology companies; Sketch how a product safety database is compiled, how a product's safety profile is assessed, and how safety information is included in documentation for regulatory authorities, healthcare professionals, and consumers; Apply appropriate terms to describe different types of adverse effect; Specify requirements to report adverse reactions to regulators; Outline requirements for safety data and for risk management plans in applications for marketing approval; List tasks involved in monitoring adverse reactions to marketed products, and sketch how safety signals are detected and tested; Identify factors that influence the evaluation of a product's benefit/risk balance, and list actions that may be taken in response to changes in the balance.

Safety Reporting in Clinical Trials (Adverse Event Reporting)

120 MIN | 2 CPD UNITS

Identify sources of legal requirements, regulatory guidance, and other requirements for the conduct of clinical trials; Define reportable events and reactions in drug trials; Discuss criteria for causality, expectedness, and seriousness of events; Summarize investigators' responsibilities for reporting to sponsors and research ethics committees

Clinical Trial Safety Reporting Requirements in the EU and USA

120 MIN | 2 CPD UNITS

In this session, we set out the legal and regulatory requirements for safety reporting under the EU Clinical Trials Regulation. We specify the responsibilities of investigators and those of sponsors. We distinguish those reports that must be submitted by sponsors to the EudraVigilance portal and those that must be submitted to the Clinical Trials Information System. We specify the format and terminology that must now be used, and we identify the tools and pathways for electronic submission. Finally, we outline significant differences in requirements under the Clinical Trials Directive.

3 COURSES · BIOPHARMA INSTITUTE

Electronic Records

Assuring Data Integrity in the Manufacture of Medicinal Products

60 MIN | 1 CPD UNIT

What do we mean by data? What is data integrity? ALCOA and ALCOA+; Raw data and metadata; Transcription and transformation of data; Static and dynamic data; True copies; Archiving and retention; Validation of computerized systems; Data governance; Key questions to answer; Unacceptable practices; Regulators' responses to data

Assuring Data Integrity in Clinical Research

60 MIN | 1 CPD UNIT

What do we mean by data? What is data integrity? ALCOA, ALCOA+ and ALCOA++; Source data and metadata; Transcription and transformation of data; Static and dynamic data; Certified copies; Archiving and retention; Validation of computerized systems; Data governance; Safeguarding of blinding; Regulators' responses to data integrity failings

Compliance with Regulation 21 CFR Part 11 (Electronic Records and Electronic Signatures)

90 MIN | 1.5 CPD UNITS

Specify criteria to determine which environments, computer systems, electronic records, and electronic signatures must comply with the regulation; Describe procedures and controls required by the regulation for electronic records and electronic signatures; Describe the consequences of the FDA's integrity failings.

discretion in enforcing compliance with some of the provisions of the regulation

3 COURSES · BIOPHARMA INSTITUTE

Good Laboratory Practices

Good Laboratory Practice (GLP)

60 MIN | 1 CPD UNIT

Explain the purpose of Good Laboratory Practice (GLP) and describe the development of the US GLP Regulation and the OECD Principles of GLP. Identify consequences of failure to comply with GLP. Specify GLP requirements for laboratory organization and the responsibilities of personnel. Specify GLP requirements for the planning and performance of studies. Specify GLP requirements for reporting of study results and the storage and retention of records and materials. Identify typical findings of regulatory inspections of laboratories

G(QC)LP: Good Quality Control Laboratory Practice

60 MIN | 1 CPD UNIT

Access guidelines and regulations relevant to G(QC)LP. Outline the role and elements of a laboratory quality system. Specify some basic laboratory safety practices. Identify key types of laboratory document and summaries their contents and relationships. Outline the management of reference standard substances and reagents. Specify good practices for data recording and record keeping. Describe how to handle out-of-specification conditions. Specify some good housekeeping rules for the laboratory, and outline the role of audits and inspections.

Good Clinical Laboratory Practice (GCLP)

60 MIN | 1 CPD UNIT

Identify guidelines and standards relevant to GCLP. Describe various elements of laboratory organization, including quality management, documentation, personnel, safety, equipment, and test materials. Outline the contents of an analytical plan, and identify important considerations in the management of samples. Contribute to method validation, performance verification, and quality control of examination processes. Follow guidance on the reporting of results and the storage of records. Discuss the roles of error management, audits, external quality assessment, certification and accreditation, and regulatory inspections

10 COURSES · BIOPHARMA INSTITUTE

Good Manufacturing Practices

cGMP: What is GMP and Why is it Important (Fundamentals)

30 MIN | 0 CPD UNITS

GMP... what and why: This session explains what GMP is and why it is important, and it gives some lessons from history. It introduces the regulations and guidance documents which are the source of GMP rules. Finally it touches on regulatory inspections and the consequences that can arise from failure to comply with GMP requirements.

cGMP: The Principles of GMP (Fundamentals)

30 MIN | 0 CPD UNITS

In this session we present an overview of the main principles of GMP, and we outline some things that manufacturing personnel need to do to comply with requirements. We identify the principal goals of GMP as: prevention of contamination; prevention of mix-ups; scrupulous documentation; validation and maintenance of processes and equipment; quality assurance by an independent unit; and training. We place GMP in the context of a company's quality

cGMP: Hygiene, Cleaning, and Sanitation (Fundamentals)

30 MIN | 0 CPD UNITS

Hygiene, cleaning, and sanitation: Prevention of contamination is one of the most important goals of GMP. Contamination of product is often difficult to detect, so GMP rules emphasize preventive measures, including: attention to personal health and hygiene, and the wearing of special clothing, by staff; and cleaning and sanitation of premises and equipment. In this session we set out the basics of GMP requirements in these vital areas.

management system.

cGMP: Documentation and Record Keeping (Fundamentals)

30 MIN | 0 CPD UNITS

Documentation and records: Comprehensive documentation of procedures, formulas, work instructions, and specifications, and thorough recording of batch data, are fundamental requirements of GMP. In this session, we explain why documentation is so important, identify different types of document required, and set out some simple rules for recording and correcting data.

GxP: Good Practices (GxP) in Drug Development and Manufacturing

60 MIN | 1 CPD UNIT

This session outlines the process of drug development and manufacture, from the discovery of new molecules, through nonclinical studies and clinical trials, to marketing approval application, manufacturing scale-up and quality management, and pharmacovigilance.

cGMP: Good Documentation Practice (GDocP)

60 MIN | 1 CPD UNIT

Explain why Good Documentation Practice is important, and identify principles that underpin it. List the various types of documents used and explain their functions. Discuss how documents should be created and controlled. Specify requirements for record keeping and data integrity, including those for entering and correcting data

cGMP: Good Manufacturing Practice in Cleaning and Sanitation

60 MIN | 1 CPD UNIT

Understand why cleaning and sanitation are so very important in preventing contamination of product. Adopt good practices in preparing for, carrying out, and recording the cleaning and sanitizing of premises and equipment.

cGMP: Corrective and Preventive Action (CAPA) in Medicinal Product Manufacturing - Including Root Cause Analysis

60 MIN | 1 CPD UNIT

Explain what a CAPA system is and describe how it operates in a company's Quality Management System. Describe how a typical CAPA procedure is carried out. Outline the purpose and practice of root cause analysis. Discuss the role of progress tracking, escalating, and trending of CAPA procedures.

cGMP: Introduction to Good Manufacturing Practice for Medicinal Products

90 MIN | 1.5 CPD UNITS

This session explains what GMP is and why it is important, and it gives some lessons from history. It introduces the regulations and guidance documents which are the source of GMP rules. Finally it touches on regulatory inspections and the consequences that can arise from failure to comply with GMP requirements.

cGMP: Good Manufacturing Practice for the Warehouse

90 MIN | 1.5 CPD UNITS

This course provides an overview of Good Manufacturing Practice (GMP) requirements and best practices as they apply to warehouse environments. It is designed to build awareness and understanding of GMP expectations for personnel working in or supporting GMP-compliant warehouse operations. While the course explains the principles and regulatory importance behind warehouse controls, it is not intended to replace site-specific standard operating procedures (SOPs) or hands-on operational training.

2 COURSES · BIOPHARMA INSTITUTE

Medical Devices

Introduction to the Regulation of Medical Devices

60 MIN | 1 CPD UNIT

In this session we explain what medical devices are and how they differ from medicinal products. We define various special categories of such devices. We identify basic principles of their regulation, including risk classification. We outline requirements for technical documentation, clinical data, and post-market surveillance and vigilance. Finally, we identify the major players in regulation.

Quality Management System Requirements for Medical Devices under ISO 13485:2016 and FDA QMSR

90 MIN | 1.5 CPD UNITS

Manufacturers of medical devices need to provide assurance of the quality of their products. Central to this effort is the establishment and maintenance of a quality management system (QMS). The internationally recognized standard specifying requirements that a medical device QMS should meet is ISO 13485:2016 from the International Organization for Standardization. The US Quality Management System Regulation (QMSR) incorporates this standard by reference, and compliance with it is enforced by the US Food and Drug Administration (FDA) from 2 February 2026. This course lays out requirements of ISO 13485:2016 and the QMSR, setting them in the context of good manufacturing practices for medical devices.

15 COURSES · BIOPHARMA INSTITUTE

Pharmaceutical Regulatory Affairs

Regulatory Affairs: The Regulatory Pathway to Licensing Follow-on Biologics (Biosimilars) in the USA

30 MIN | 0.5 CPD UNITS

The Biologics Price Competition and Innovation Act. Biosimilarity and interchangeability. Criteria for licensure as biosimilar. Exclusivity. Patent infringement issues. FDA guidance. The Biosimilar User Fee Act.

Regulatory Affairs: The 505(b)(2) Application for Marketing Approval in the USA

30 MIN | 0.5 CPD UNITS

In this course, we address issues specific to 505(b)(2) applications. We compare the various pathways and distinguish those circumstances appropriate for a 505(b)(2) NDA from those that are not. We identify particular characteristics of 505(b)(2) applications. We refer the learner to other available courses on NDAs and ANDAs for further details of requirements - for format, content, mode of submission, and FDA review - that are covered there.

Regulatory Affairs: Essentials of Monoclonal Antibodies

60 MIN | 1 CPD UNIT

In this session we discuss the role of natural antibodies and outline how the dream of creating 'magic bullets' to fight disease has been realized. We identify the structural components of antibodies and describe their actions. We distinguish types of monoclonal antibody by their non-human and human components. Finally, we sketch how some therapeutic mAbs can be linked to cell-killing agents to increase their effectiveness against cancer.

Regulatory Affairs: Orphan Drug Application - EU and US

90 MIN | 1.5 CPD UNITS

Explain why and how governments encourage the development of medicines for rare human diseases, and identify important sources of information. Specify incentives offered for the development of medicines for rare diseases in the USA and in Europe. State the criteria for orphan drug designation in the USA and in Europe. List the contents of an application for orphan designation in the USA and in Europe, describe how to make an application in each case, and outline the process of review by the regulatory authority. Outline the sponsor's obligations and options after orphan designation in the USA and in Europe

Regulatory Affairs: Preparing Submissions in the Common Technical Document (CTD) Format

90 MIN | 1.5 CPD UNITS

Explain the rationale for the CTD, and describe the ways in which it is used. Identify regional differences in regulatory requirements for information in a CTD-formatted submission. Describe the structure of the CTD. Access guidance on detailed structure and content of the CTD. Outline formatting requirements for a CTD dossier. Convert EU NTA and US NDA section codes and headings to their CTD equivalents.

Regulatory Affairs: The European Centralized Procedure (CP)

90 MIN | 1.5 CPD UNITS

An introduction to the Centralized Procedure. This session provides background information. It specifies the types of product for which the CP is mandatory and those for which it is optional. It discusses the types of Marketing Authorization Application, and characteristics of the application procedure.

Regulatory Affairs: The Mutual Recognition Procedure (MRP)

120 MIN | 2 CPD UNITS

Provide an overview of the MRP process. Describe the pre-submission and submission actions in relation to timeline deadlines. Specify the responsibilities of the Reference Member State (RMS), the Concerned Member States (CMSs) and the applicant.

Regulatory Affairs: The Decentralized Procedure (DCP)

120 MIN | 2 CPD UNITS

An introduction to the Decentralized Procedure - This session provides background information. It covers products for which the DCP can be used, the types of Marketing Authorization Application, and characteristics of the application procedure.

Regulatory Affairs: Electronic Common Technical Document (eCTD)

150 MIN | 2.5 CPD UNITS

Describe the structure, requirements and functionality of the eCTD. Outline XML basics and the architecture of the eCTD. Discuss Document Type Definitions (DTDs) and schemas. Explain how to build an eCTD. Specify regional differences. Discuss life cycle and change management. List criteria that will make an electronic application technically valid. Initiate electronic transfer to a regulatory authority. Create, submit and maintain an eCTD dossier throughout the life of a drug product.

Regulatory Affairs: Essentials for Human Medicinal Products - EU and US

180 MIN | 3 CPD UNITS

Describe the role and responsibilities of regulatory affairs within the pharmaceutical industry in both the EU and the USA. Identify the main legislative instruments relating to medicinal products in both the EU and USA. Understand the main phases of the drug development process and be aware of the regulatory requirements that

Regulatory Affairs: Registration of Drugs Based on Monoclonal Antibodies

180 MIN | 3 CPD UNITS

Discuss key quality issues in the manufacture of mAb-based products. Discuss key issues in nonclinical studies of mAb-based products. Discuss key issues in the clinical investigation and use of mAb-based products. Identify specific considerations for radiolabeled mAb-based products. Identify the pathways for

Regulatory Affairs: How to Gain Approval to Market Generic Drugs in the USA

180 MIN | 3 CPD UNITS

List the criteria for therapeutic equivalence of drugs. Outline the types of patent classification for an ANDA submission. Explain how to use the Orange Book in the development of a generic drug. Describe methods for determining bioequivalence of drug products. Outline the content and format requirements for an ANDA apply. Describe the requirements for applications for marketing approval and the procedures to be followed in both the EU and USA. Identify post-marketing regulatory activities in both the EU and USA.

applications to conduct clinical trials and to market mAb-based products in Europe and the USA

submission. Describe the ANDA review and approval process. Outline the provisions of the Generic Drug User Fee Amendments and summarize their effects on generics sponsors.

Regulatory Affairs: Submitting a New Drug Application (NDA) to Obtain Approval to Market in the USA

210 MIN | 3.5 CPD UNITS

Summarize the content and format requirements for a New Drug Application. Outline the procedural requirements for an NDA submission to the FDA. Describe the role of the FDA in the NDA review and approval process. List the principal provisions available from the FDA for expedited drug development and review, and summarize the criteria that apply to them.

Regulatory Affairs: Variations to Marketing Authorizations in Europe

210 MIN | 3.5 CPD UNITS

Define the concept of variations to marketing authorizations in the EEA. Identify which type of variation is appropriate for each kind of change to be made. Identify the documentation required to support the variation. Describe how to prepare and submit variation notifications or applications appropriate for each type of variation and route of regulatory approval, including options for grouping of variations and for work sharing of assessment.

Regulatory Affairs: The Biologics License Application (BLA) for Marketing Approval in the USA

210 MIN | 3.5 CPD UNITS

In this session we describe the role of the BLA, define biological product, and outline the legal basis of the regulation of such products in the USA. We specify key criteria for licensure of biologics. We identify, by product type, the Centers within the US Food and Drug Administration (FDA) to which a BLA must be submitted for review and approval. We emphasise the importance of good communication between the agency and the sponsor of a BLA before submission. We set out the high-level structure of the electronic Common Technical Document, with which BLA submissions must comply.

4 COURSES · BIOPHARMA INSTITUTE

Pharmaceutical Sales and Marketing

Pharmaceutical Sales & Marketing: Legal and Regulatory Framework for Advertising and Promotion of Prescription Drugs in the USA

60 MIN | 1 CPD UNIT

Sales and marketing personnel need to understand the legal and regulatory requirements of Good Promotional Practices (GPP) that must be met when advertising and promoting prescription drugs in the USA. In addition, this module will be of particular benefit to regulatory affairs and legal personnel involved with aspects of marketing

Pharmaceutical Sales & Marketing: Consumer-directed Advertising and Online Promotion of Prescription Drugs in the USA

60 MIN | 1 CPD UNIT

Direct-to-consumer (DTC) advertising: The big picture, Information generally expected in DTC ads, Modified requirements for communications in print media, Omit some prescription information, Use consumer-friendly language.

Pharmaceutical Sales & Marketing: Marketing of Prescription Drugs in the USA- Interactions with Healthcare Professionals

60 MIN | 1 CPD UNIT

Statutes and regulations. Regulatory and industry guidance. Anti-Kickback Statute. False Claims Act. Major settlements under FCA/AKS. Physician Payments Sunshine Act. Drug samples. Distribution of reprints and other publications. Detailing by sales representatives. Speaker programs. Third-party scientific and educational events. Medical advisory boards. Responding to unsolicited requests for off-label information. Gifts of educational or non-educational items. Assessment.

Pharmaceutical Sales & Marketing: Regulatory Requirements and Guidance on Advertising and Promotion of Prescription Drugs in the USA

90 MIN · 1.5 CPD UNITS

Avoid the pitfalls of: selective presentation of favorable information, broadening or inadequate representation of indications, use of out-of-date information, misuse of statistics, misleading juxtaposition of information, and misbranding of an investigational drug.

5 COURSES · BIOPHARMA INSTITUTE

Validation

Validation: Introduction to Validation

90 MIN · 1.5 CPD UNITS

This session emphasizes the need to comply with regulatory requirements and guidance on validation, identifying important regulatory authorities and international collaborations. It identifies the phases of equipment qualification, describes the purpose of process validation in relation to process control, and defines important terms relevant to validation.

Validation: Operational and Performance Qualification (OQ/PQ)

60 MIN · 1 CPD UNIT

This session explains how to identify equipment, systems and services to which Operational Qualification (OQ) applies. It identifies typical responsibilities of company staff and vendors for OQ. It specifies prerequisites for OQ and describes steps in the OQ process. It identifies tests required of equipment, systems and services during OQ. The learner is shown how to develop, review and execute protocols that specify the tests required, and to write OQ reports.

Validation: Plans and Documentation

90 MIN · 1.5 CPD UNITS

Describe the purpose and scope of validation master plans, outline their typical structure and contents, and explain their importance to management. Contribute to the creation of project validation plans and protocols. Identify important validation documents, specify their interrelationships, and describe how they are created and maintained. Prepare and use validation schedules and resource plans, explain the basics of change control, and outline regulatory requirements for reporting and validating manufacturing changes.

Validation: Commissioning and Installation Qualification (IQ)

90 MIN · 1.5 CPD UNITS

Define commissioning and Installation Qualification activities and scope. Explain the purposes of, and differences between, commissioning and qualification. Determine qualification requirements based on an impact assessment. Prepare and execute

Validation: Equipment Cleaning Validation

90 MIN · 1.5 CPD UNITS

Define cleaning validation terminology, and explain regulatory requirements. Determine the scope of cleaning validation. Carry out and validate tests of cleanliness. Determine acceptance criteria. Develop and execute a cleaning validation protocol. Analyze and report cleaning validation results,

IQ protocols. Describe requirements for the content and approval of IQ reports.

and outline an ongoing cleaning and monitoring program.

29 COURSES · EVOLVE E-LEARNING SOLUTIONS

OSHA

Active Shooter Response

20 MIN

This active shooter training course describes how to spot warning signs of potential violent behavior, actions you can take in an active shooter situation and how to respond when law enforcement arrives.

Back Care/Ergonomics

25 MIN

This course is designed to bring awareness of the risks of back injuries and other MSDs in the workplace and to provide an overview of ergonomic and musculoskeletal principles and practical information on risk factors and prevention. In this lesson you will learn about muscle injury caused by repetitive stress, ways to minimize accidents and injuries and tips on how to arrange your work station to avoid ergonomic injuries.

Biohazardous Waste Handling, Storage, and Disposal

20 MIN

This course identifies the types and sources of hazardous waste and explains safe handling, storage and proper packaging and disposal procedures and identifies the regulatory agencies overseeing safe biohazardous waste storage, handling and disposal.

Blood-borne Pathogens for Healthcare Workers

This course introduces the student to what bloodborne pathogens are, how to reduce the risk of exposure, and precautionary practices that are recommended by OSHA (Occupational Safety and Health Administration) and CDC (Center for Disease Control and Prevention). This course is a must for anyone who has contact with infectious or potentially infectious bodily fluids and materials.

Chemical Safety

The healthcare industry is a high-risk industry to the workers it employs, particularly when it comes to chemical use. If improperly used, handled, or stored, chemicals can cause serious harm to healthcare workers and patients. This course informs healthcare workers on chemical hazards and how to safely use, store and handle chemicals.

Compressed Gas Safety

Gases for medical use are prescription drugs that must be carefully used, moved, and stored per regulations and guidelines from the Occupational Safety and Health Administration, the National Fire Protection Association, and the Food and Drug Administration. This course informs healthcare workers about the uses, hazards and safe use, handling and storage of compressed gases.

Electrical Safety for Healthcare

This courses provides a basic understanding of electricity, how to identify electrical hazards in the workplace, safe work practices, safety tips to reduce your potential for electric shock, and how to respond to an emergency situation involving electricity.

Goal: To educate workers on the hazards of electricity in the healthcare environment as well as safe electrical work practices.

Emergency Response Plan

15 MIN

When an emergency happens, healthcare employers must be prepared to keep their staff, patients, and visitors safe. This course describes the purpose and key elements of an emergency response plan, details the types of emergencies that can occur and provides the life-saving actions employees need to know to protect themselves, patients and visitors.

Environmental Cleaning-Exam Rooms

20 MIN

Healthcare-associated infections (HAI), and other illnesses can easily be transmitted in healthcare facilities. This course focuses on ways to control contamination and transmission of infectious diseases in the exam rooms of clinics, doctors' offices, and outpatient facilities.

Fire Safety and Emergency Evacuation

20 MIN

This course covers the precautions to take to prevent fires, how to protect yourself, other staff, visitors and patients from fire and smoke, how to respond in a fire emergency, and how to use a portable fire extinguisher. This course addresses OSHA's general industry standards for fire safety and emergency evacuation.

Flammable Liquid Safety

The National Fire Protection Association or NFPA, estimates around 1,400 fires occur annually in which flammable or combustible liquids first were ignited. This course gives workers the knowledge they need to avoid accidental fires and explosions and informs them about the hazards and safe use, handling and storage of flammable and combustible liquids.

Formaldehyde Safety

It is estimated that over four million people work with formaldehyde. This course educates the learner on the uses and dangers of formaldehyde and safe work practices when using it in the workplace.

Hand Hygiene

Hand hygiene plays a critical role in infection control in healthcare settings. This hand hygiene training course includes an overview of the recommended practices for hand antisepsis as outlined by CDC, WHO, OSHA and JCAHO as well as proper hand hygiene techniques and the difference between soap and water handwashing, antibacterial soap and alcohol based handrubs.

Hazard Communications for Healthcare

This course provides a detailed overview OSHA's hazard communication standard and includes information on the incorporation of GHS into the standard. The revised Hazard Communication Standard (HCS) requires that workers be re-trained within two years of the publication of the final rule to facilitate recognition and understanding of the new labels and safety data sheets.

Incident Reporting in Healthcare

An incident is any event that affects patient, employee, visitor or vendor safety. This incident report training course provides the information employees need to understand what incidents to report and why it is important to conduct incident reporting. It also presents the information required to be included in an incident report and includes the “do's” and “don'ts” of completing an incident report.

Infection Control for Healthcare Professionals

Upon completion of this course the learner will be able to:

- Explain what a Healthcare-associated Infection is.
- Understand the importance of infection control.
- Identify the six links in the chain of infection.
- Differentiate between the most common infections agents.
- Explain the importance of proper hand hygiene.
- Effectively and correctly use standard precautions.

Laboratory Safety

The purpose of this online laboratory safety training course is to teach employees lab safety requirements to ensure that they know how to prevent accidents, injuries, and illness on the job. By completing this course learners will be able to understand the Chemical Hygiene Plan, identify laboratory hazards, take proper precautions to protect themselves, and act effectively in an emergency.

Laser Safety

Understanding how lasers work, their hazards and how to work safely with them, will protect you, your coworkers, patients and clients. This course educates healthcare workers about the risks associated with laser use in the workplace and ways to safely work with lasers and protect themselves, co-workers and patients.

Latex Allergy

It is estimated that 8-12 percent of healthcare workers are latex sensitive, with reactions ranging from irritant contact dermatitis to immediate, possibly life-threatening, sensitivity. This course informs healthcare workers about products and practices that can trigger a latex allergy and how to lessen the chance of an allergic reaction.

Lockout/Tagout Control of Hazardous Energy

This course is for employees who perform maintenance or repair work on machinery and equipment and are exposed to injuries from the unexpected energization, startup, or release of stored energy in the equipment. Topics covered include the definition and common types of hazardous energy; the components of an employer's energy control program, the responsibilities and functions of Authorized Employees, Affected Employees, and Other Employees as defined by OSHA.

Patient Abuse & Neglect

Abuse and neglect can happen to any patient; however, elderly and mentally or physically disabled patients are at a higher risk, as are those in long-term care facilities. Often, healthcare professionals miss the signs of patient abuse because they haven't had adequate training on detecting abuse. This course provides the information healthcare workers need recognize patient abuse and neglect and how to prevent it from happening.

Patient Rights

Just as important as physical care is making sure providers and workers abide by and protect the rights, guaranteed by law, patients have. This course informs healthcare workers on patient rights so they are able to identify and protect against any violation of those rights.

Personal Protective Equipment for Healthcare Workers

Personal protective equipment (PPE) is not a luxury, nor an optional convenience. This personal protective equipment training course covers the types of PPE used in healthcare settings, its requirements and limitations and also teaches the learner how to properly don, doff, maintain and dispose of contaminated PPE.

Preventing Needlestick Injuries

15 MIN

Needlestick injuries are a serious hazard and can expose you to over 20 types of infectious bloodborne pathogens, or BBPs. This course informs workers on the hazards and prevention strategies of working with needles during patient care and other healthcare settings.

Preventing Workplace Violence in Healthcare Settings

25 MIN

More assaults occur in the healthcare and social service industries than in any other. This course addresses workplace violence in healthcare settings and offers ways to prevent and minimize the threat of workplace violence in healthcare settings as well as practical ways to deal violent incidents should one occur.

Radiation Safety

This course informs healthcare workers on the sources and hazards of radiation in the workplace and safe work practices for radiation safety.

Safe Patient Handling

Nurses, aids, physical therapists, emergency workers, clinic staff and other healthcare workers all face the hazards associated with patient lifting and handling. This course informs healthcare workers on safe and proper patient handling techniques in order to reduce and prevent injuries to workers and patients.

Slips, Trips & Falls

Slips, trips or falls are the number one cause of work-related accidents with over 200,000 accidents reported each year. This course provides the causes of slips, trips and falls and the simple, practical steps that can be taken by both employers and employees to greatly reduce and often eliminate hazards.

TB Protection for Healthcare Workers

This course addresses the risks, treatment, and prevention of tuberculosis in hospitals and other medical facilities. It will also provide information about the work practices recommended by the Centers for Disease Control and Prevention (CDC) that are designed to help prevent transmission of the disease.

15 COURSES · EVOLVE E-LEARNING SOLUTIONS

HR / EEO

Cultural Competence in Healthcare

90 MIN

Diversity and Inclusion in the Workplace

This course explains the factors contributing to increases in workforce diversity and how the concept of inclusion fits into a diverse workplace. It provides strategies employees can use to create and support an inclusive workplace and to recognize behaviors that aren't inclusive and the corrective actions to take.

Driver Safety

Driving a motor vehicle, whether for work or personal use, is one of the riskiest things a person can do on any given day. There are ways to minimize the risks drivers face and this course addresses the basic defensive and safe driving practices and habits so individuals can drive more safely, carefully and responsibly.

Drug & Alcohol Free Workplace

20 MIN

Substance abuse is a problem that affects the safety of all employees and the workplace. This course details ways to recognize possible substance abuse, steps organizations can take to prevent substance abuse, how to get help, and the appropriate reporting procedures.

Ethics in the Workplace

This course describes the elements of an ethics programs and the six principles of ethics. Scenarios are presented for students to learn by applying the concepts presented in the course. Students also learn of the channels for reporting code violations should the need arise.

Preventing Harassment and Discrimination for Employees CA - English/Español

60 MIN

This harassment and discrimination prevention course provides employees with an awareness of the laws and issues relating to harassment, discrimination and bullying in the workplace. Scenarios, text and audio detail necessary actions and responsibilities for avoiding discriminatory practices, associated with race, color, religion, sex, national origin, age, and physical or mental disability to create a workplace free of harassment and discrimination.

Preventing Harassment and Discrimination for Managers

40 MIN

Preventing Harassment and Discrimination for Supervisors - CA

Preventing Sexual Harassment for Employees

20 MIN

This course provides employers, managers and supervisors an awareness of the laws and issues relating to discrimination and bullying in the workplace. It details the actions and responsibilities for avoiding discriminatory practices, associated with race, color, religion, sex, national origin, age, and physical or mental disability to create a workplace free of harassment and discrimination and understanding their responsibilities around responding to incidents of harassment.

120 MIN

The goal of this course is to train supervisors and managers to recognize, prevent, and correct sexual harassment and abusive conduct, respond to complaints, identify retaliation, and promote a discrimination-free workplace. The course conforms with the training requirements of California AB 1825 sexual harassment prevention, AB 2053 prevention of abusive conduct and SB 396 for training inclusive of harassment based on gender identity, gender expression and sexual orientation and SB 1343.

This course provides the information to educate workers on behaviors that could be considered sexual harassment in the workplace and to provide strategies for dealing with harassing behavior.

Preventing Sexual Harassment for Employees - Illinois

35 MIN

This course provides employees an awareness of the Illinois laws and issues relating to sexual harassment in the workplace. Through scenarios, text and audio, it details the actions and responsibilities employees have to understand their rights and responsibilities when it comes to sexual harassment in the workplace.

The WTA amends the IHRA to expand the definition of unlawful harassment to mean discrimination against a person because of his or her “actual or perceived” class or status and requires all Illinois employers to provide annual sexual harassment training to all employees. This also includes out-of-state employers who have employees who work in Illinois.

Preventing Sexual Harassment for Employees – New York - English/Español

30 MIN

This course provides employees an awareness of the New York laws and issues relating to sexual harassment in the workplace. Through scenarios, text and audio, it details the actions and responsibilities employees have to understand their rights and responsibilities when it comes to sexual harassment in the workplace.

Preventing Sexual Harassment for Managers

35 MIN

This course provides supervisors and managers with the knowledge to recognize harassing behaviors and how to stop them. Through text, audio, scenarios and knowledge checks, this course details the costs and consequences of sexual harassment on both the victim and the workplace, describes how managers should respond to sexual harassment complaints, stop retaliation against those who report it and their own role in developing strategies to prevent and correct sexual harassment and creating a harassment free workplace.

Preventing Sexual Harassment for Managers – New York

40 MIN

This course provides employers, managers and supervisors with an awareness of the New York laws and issues relating to sexual harassment in the workplace and why preventing sexual harassment is important. Through scenarios, text and audio, it details the actions and responsibilities managers have for responding to sexual harassment complaints and strategies to prevent and correct sexual harassment.

Preventing Sexual Misconduct

This course educates learners on what is considered sexual misconduct and ways to avoid the perception of misconduct. It also describes the practice of proper care and sensitivity during patient encounters, and describes five ways healthcare providers can reduce potential sexual misconduct liability.

Cyber Security Awareness

From malware, spyware, and viruses to social engineering attacks such as phishing, pretexting and baiting, there are multiple ways hackers can steal valuable information. This course educates the learner on how to protect their office and home computers and other portable and mobile devices from the many computer security threats.

5 COURSES · EVOLVE E-LEARNING SOLUTIONS

HIPAA

HIPAA Privacy & Security Awareness

This course provides an overview of the components of the Privacy & Security components of the Health Insurance Portability and Accountability Act (HIPAA). It includes updates from the Omnibus Final Rule.

HIPAA Privacy & Security for Business Associates

Business associates have many of the same requirements as covered entities for protecting and disclosing patient health information. This course provides an overview of the privacy and security components of the Health Insurance Portability and Accountability Act (HIPAA) and the additional requirements mandated by the HITECH Act and the Omnibus Final Rule and business associates' responsibilities.

HIPAA Privacy & Security for Covered Entities

Covered entities have specific requirements they must follow for the protection and disclosure of patient health information. This course provides an overview of the privacy and security components of the Health Insurance Portability and Accountability Act (HIPAA) and the additional requirements mandated by the HITECH Act and the Omnibus Final Rule.

HIPAA Privacy & Security for Students

This course was created for students enrolled in medical programs who are working at covered entities as part of their studies. It provides an overview of the privacy and security components of the HIPAA rules and gives practical guidance on protecting and disclosing PHI and proper social media use.

Texas HB300 & HIPAA Compliance

45 MIN

This course provides an overview of the privacy and security components of the Health Insurance Portability and Accountability Act (HIPAA), the additional requirements mandated by the HITECH Act and the Omnibus Final Rule and the specific privacy requirements mandated by Texas HB300.

1 COURSE · EVOLVE E-LEARNING SOLUTIONS

DOT

Shipping Infectious Substances

Shipping and transporting infectious substances used in a laboratory, can be dangerous for the shipper, carrier, and recipient of the package. This course will focus on the requirements for shipping infectious substances and miscellaneous dangerous goods like dry ice, by air and ground transport.

1 COURSE · EVOLVE E-LEARNING SOLUTIONS

Compliance

Medicare Compliance: Fraud and Abuse

Financial losses from fraud and abuse cost approximately $300 billion annually. This course provides an overview of the principle laws used to combat fraud against government healthcare programs; the False Claims Act, Anti-kickback statute, and the Stark Law and also the communication mandates from The Deficit Reduction Act. The course also details employer responsibilities in preventing and employees' responsibilities in identifying and preventing fraud and abuse in the workplace.

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