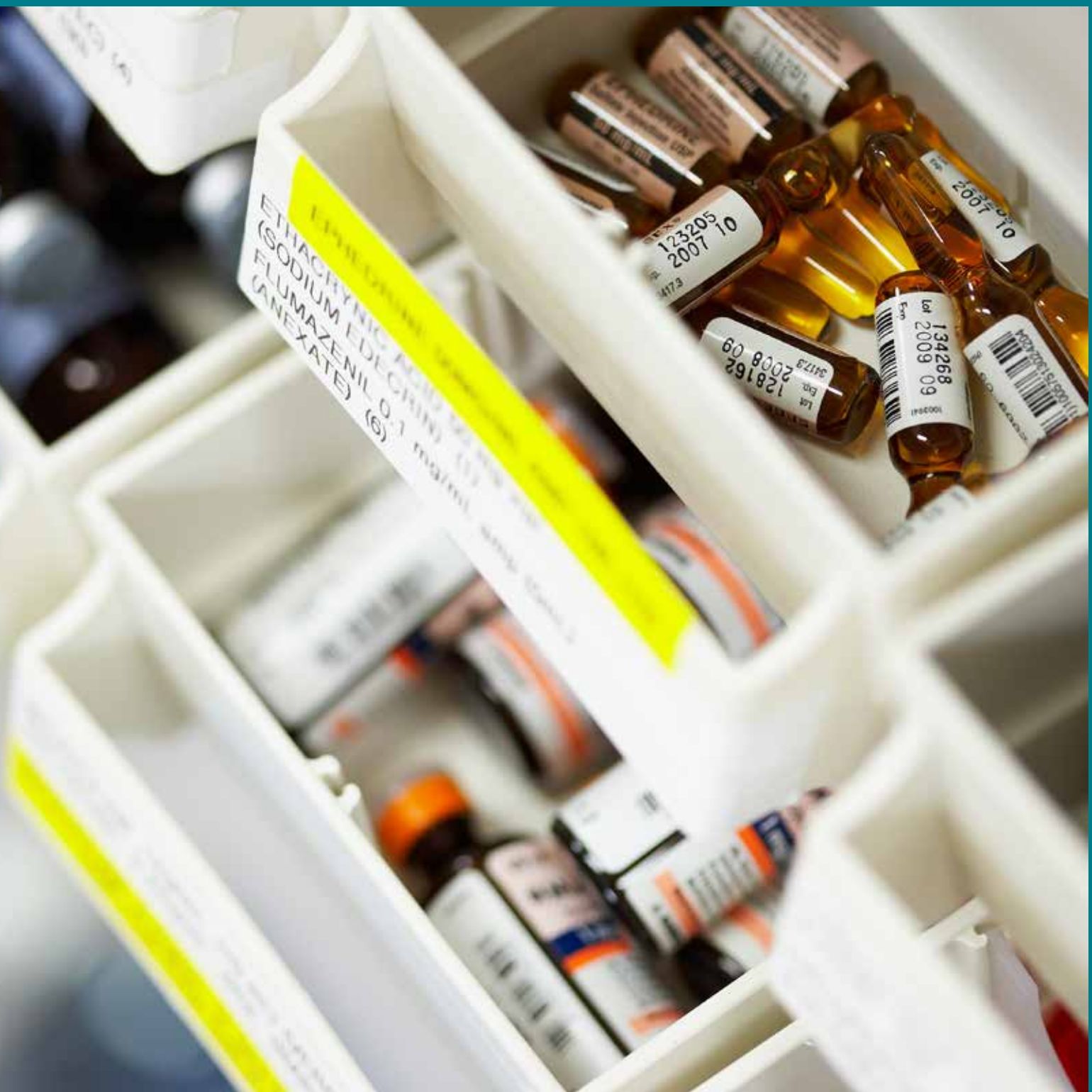
Life & Health

LIBRARY GUIDE:
Clinical Pharmaceutical



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Course Descriptions – Role Based:

Overview:

Clinical Pharmaceutical Curriculum

Profitability rests on product quality, operational efficiency and regulatory compliance. The common denominator of those objectives is the ability of employees – regardless of business function or physical location – to apply the right knowledge needed at the right time to fulfill their job responsibilities.

UL EduNeering's systemic approach to employee learning has created a Clinical Pharmaceutical Library that focuses on the specialized knowledge needs of individual business functions in Pharmaceutical, Biotechnology and Biologic companies. Beginning with the core knowledge typically needed by new hires and reassigned workers, to the more advanced needs of managers and supervisors, UL's courses target the function-specific needs of the clinical study team organization – both sponsor and investigator personnel – and provides progressive training for such job functions as:

- Clinical Research Coordinators
- Clinical Research Associates
- Investigators

FDA Partnership

UL's Cooperative Research and Development Agreement (CRADA) with the Food and Drug Administration (FDA) has enabled the FDA to meet its significant training and documentation challenge – and also resulted in course content provided or reviewed and used by the FDA itself and available to FDA-regulated Life Science companies – all delivered in a valid and 21 CFR Part 11-compliant environment. The CRADA was recently renewed through 2019 and expanded to include new technologies.

When the FDA CRADA symbol appears within the course description, it indicates that the content for the course was provided by the US Food and Drug Administration as a result of a CRADA between the FDA and UL.

Regular Content Updates

Regulatory agencies and related information sources are continually monitored, analyzed and incorporated into course updates or new courses.

Driving Employee and External Partner Comprehension

UL's innovative technology-based solution, deployed over the web, enables our customers to cost-effectively drive employee and external partners (e.g. investigators, CROs, study coordinators) comprehension through a combination of advanced learning methods, technology innovations and interactive techniques that engage the individual and promote learning that is integrated into new behaviors. Those new behaviors in turn lead to improved business performance, greater efficiencies and regulatory compliance.

UL's Knowledge Solution for Study Personnel

UL's innovative, web-based Clinical Training Solution enables customers to cost-effectively manage their expanding knowledge expectations of clinical research professionals. The solution uses our validated and 21 CFR Part 11-compliant ComplianceWire® system to deliver, measure, document and track targeted, role-based curricula that can include Good Clinical Practice (GCP) training, protocols, amendments and SOPs that can be recorded with validated e-signature procedures. Custom courses can also be developed that target specific customer process and/or study needs.

All these components, working in concert, enable a customer to efficiently and effectively bridge the knowledge gap, thereby creating optimal site performance and fewer compliance exposures.

The end result is a more knowledgeable, productive and effective clinical research team, which delivers bottom-line improvements through improved clinical quality and compliance with study and regulatory requirements.

LEGEND:

FDA CRADA symbol indicates that the content for this course was provided by the US FDA as a result of a CRADA between the FDA and UL.

Course Descriptions:

Listed Alphabetically

Core Knowledge

A Tour of the FDA (PHDV60)

FDA CRADA

FDA-regulated industries must work closely with the FDA to comply with industry regulations and create safe and effective products. But how well do your employees know the FDA? A Tour of the FDA serves as an excellent introduction to its organizational structure and gives an overview of the different enforcement actions available to this critical Agency. Take a virtual 'tour' of the FDA, learning about the function of each Center along the way. Afterwards, explore different actions the Agency may take in order to achieve compliance.

Topics include:

- FDA background
- The organizational structure of the FDA
- Office of the Commissioner
- Office of Regional Affairs
- The six main program Centers
- Enforcement actions:
  - Informal enforcement
  - Formal enforcement

A Tour of Health Canada (PHDV89)

Health Canada touches the lives of virtually every Canadian, every day. This special tour introduces participants to Health Canada's mission and organization. After the brief introduction, the tour will focus on the Health Products and Food Branch (HPFB) of Health Canada, which directly affects Pharmaceutical manufacturers. After completing this course, you will be familiar with the major branches of Health Canada, the HPFB, and its directorates. In addition, you will be able to identify the unique roles and responsibilities of the three HPFB directorates that most directly affect the Pharmaceutical industry.

Topics include:

- Mission
- Organizational structure
- HPFB
- Therapeutic Products Directorate (TPD)
- Biologics and Genetic Therapies Directorate (BGTD)
- Role of the HPFB Inspectorate

A Tour of Health Europe (PHDV90)

The system in Europe for ensuring safe, effective and high-quality health products is composed of national authorities in individual countries as well as bodies in the European Union (EU) and the Council of Europe. After completing this course, participants will know the organisations that oversee the health industry in Europe and the bodies in those organisations that affect Pharmaceutical companies. In addition, participants will know the ways health products can be approved for sale to the public and the system for reporting and tracking defective products.

Topics include:

- Organisations overseeing the health industry in Europe
- How the EU works to ensure the health of Europeans
- The role of the Council of Europe
- Market authorization
- Pharmacovigilance

Aspects of Regulatory History (GCP22)

This course will provide an overview and summary of the regulatory history and requirements by the Food and Drug Administration (FDA) and International Conference on Harmonisation (ICH), which are necessary to ensure proper and successful clinical trial execution. This module is also designed to take you through some of the history behind today's system of drug and device development. It is important to provide you with this perspective to recognize how the industry and the FDA have evolved. Review of the ICH will also provide you with an understanding of its impact on the industry from a global perspective.

Topics include:

- Setting standards
- Organizations
- Regulations
- Guidelines

BIMO (Bioresearch Monitoring Program): Introduction (BIMO001)

FDA CRADA

This is the first in a series of courses that provide an overview of the FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Nonclinical Laboratory, Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo Bioequivalence inspections. This course provides an overview and historical perspective of the FDA's BIMO program.

Topics include:

- Evolution of the FDA's regulatory history
- BIMO terminology
- The purpose of the FDA's BIMO program
- Regulations and expectations that are part of the FDA's BIMO program
- How the FDA implements the clinical BIMO program

Clinical Development Process: Investigational Product, Plan and Data Management (GCP28)

This course will discuss the clinical development process, including the regulatory obligations of the sponsor of a new drug or product. A sponsor can be any person or organization, including nonprofit or for-profit entities and commercial, government, or academic institutions.

Topics include:

- What is the purpose of developing a clinical research plan?
- Who is responsible for the clinical development plan?
- What is required in the clinical development plan for identification of patient population?
- What provisions are included in the clinical development plan for data collection?
- What is the final step of the clinical development process?

Drug Safety and Adverse Event Reporting (GCP15)

Following a review of the historical perspective of the evolution and necessity of drug safety and pharmacovigilance in the United States, this course introduces the learner to the regulatory requirements in the clinical trial and post-marketing environments, as well as drug safety monitoring efforts internationally.

Topics include:

- Significant events in the development of drug safety monitoring and adverse-event reporting
- Drug safety monitoring efforts that exist in the nonclinical trial environment
- Clinical Reports
- Post-marketing
- Post-marketing Reports
- International Safety

Ethical Review Boards (GCP14)

This course addresses the role, responsibilities, and regulatory requirements of Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) in protecting the rights and welfare of human research subjects. In this course the learner will review FDA regulations, ICH GCP guidelines, and an overview of the EU Clinical Trial Directive to gain a better understanding of the relationship among the IRB/IEC, sponsor/monitor, and investigator/subjects.

Upon completing this course, IRB/IEC members, investigators, and sponsors/CROs will understand their obligations in relation to the IRB/IEC and will be able to ensure that policies and procedures developed for compliance will protect and safeguard the research subjects.

Topics include:

- Overview
- Development
- Membership/Procedures
- Review and Approval
- Responsibilities
- Vulnerable Subjects
- Noncompliance
- Compliance Resources
- Challenge

Ethics as the Foundation to Clinical Research (GCP10)

Investigational drugs and biologics are tested and characterized during and after administration to humans in clinical trials. Therefore, human subjects that volunteer for these trials should be treated appropriately and their safety should be the primary consideration of all involved in the design and conduct of these trials. Personal ethics are at the very foundation of decision-making. The historical ethical principles that have been put in place to protect human subject rights should be the moral compass to guide all involved. This course describes the role that ethics plays in protecting human subjects and the design of ethically-sound trials. The course will also enhance awareness around emerging trends to be considered in the future.

Topics include:

- Ethical Documents
- Equipoise
- Making Ethical Decisions
- Emerging trends in clinical research

European Union Clinical Trials Directive (GCP16)

This course introduces the basic structure and contents of the European Union Clinical Trials Directive. The course also introduces the Member States' responsibilities concerning the implementation of the Directive, as well as their current status. Finally, the course discusses the possible effects that the Directive may have on future clinical research.

Topics include:

- The European Union Clinical Trials Directive
- Member States
- Initiation
- Investigational Medicinal Products (IMPs)
- Future Prospects

HIPAA – The Impact On Clinical Research (GCP05)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) evolved from the rapid development of health information technology systems as a response to the challenges posed for maintaining the confidentiality of health information. This course addresses how to best implement the challenges presented by HIPAA requirements in the process of new drug, biologic and device development. Learners will become aware of the impact that HIPPA has on the use of information emanating from clinical trials in the United States.

After completing this course, learners will be able to recognize the definitions of covered and noncovered entities, and Protected Health Information (PHI), as well as identify what is included in limited data sets and de-identified information. Learners will also be able to identify how to properly gain authorization from subjects for release of PHI, how and when authorization may be revoked, the criteria for waiving PHI authorization and exceptions for using PHI without authorization. Finally, the course addresses how HIPAA relates to Informed Consent (IC) requirements, Institutional Review Boards (IRBs), and Privacy Boards (PBs), as well as the penalties for failing to comply with HIPAA regulations.

Topics include:

- Compliance
- PHI
- Enforcements
- ICs, IRBs and PBs
- Waivers
- Limited data sets
- Exceptions
- HIPAA affect on future clinical research

Informed Consent (GCP13)

Following a review of the evolution of Informed Consent (IC) requirements, this course introduces the learner to IC regulations and guidelines, the IC process, and the roles and responsibilities of clinical research professionals in ensuring the protection of human subjects.

Good Clinical Practices (GCPs) for New Product Investigations (PHA36)

FDA CRADA

This course helps the learner to understand the general requirements of Good Clinical Practices (GCPs) and the protection of human subjects, as well as provide information regarding the concepts, individuals and groups involved with them.

Topics include:

- What are Good Clinical Practices
- Regulatory authority approval for clinical trials
- Clinical Trial Teams
- What GCP requirements/international regulations apply
- Five key GCP documents

Good Laboratory Practices (GLPs) (PHDV62)

FDA CRADA

Nonclinical laboratory studies are one of the first steps taken in bringing a new drug, device or biologic to the marketplace, so it is important that practices are in place to ensure the reliability of the study and the safety and efficacy of the product. This lesson is intended to give the learner an introduction to Good Laboratory Practice Regulations (GLPs) and their application to nonclinical laboratory studies.

This lesson provides the learner with an understanding of terminology and acceptable practices for nonclinical laboratory studies and the role that GLPs play in assuring the validity of these studies.

Topics include:

- What are GLPs?
- GLP guidance
- How do GLPs regulate personnel?
- How do GLPs regulate a protocol?
- Documentation required by GLPs
- Why are GLP inspections conducted?

GxPs (PHDV61)

This course provides a basic overview of Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs), and Good Manufacturing Practices (GMPs), collectively known as GxPs. It also provides an outline of the process by which drugs, medical devices and biologics are approved for the marketplace.

This course is intended to be an introduction to more detailed courses that address these regulations.

Topics include:

- Definition
- GLPs
- GCPs
- GMPs

Investigational Product Development (GCP23)

This course provides an overview and summary of the investigational product development process. The course includes information on the different phases of clinical research necessary to file an Investigational New Drug Application (IND) and a New Drug Application (NDA). The course discusses the purpose of each phase, key differences between pharmaceutical and medical device development, and factors that contribute to the size and expense of clinical trials.

Topics include:

- Stages of new product development
- Trial phases
- How the development of medical devices differs from drug products
- FDA approval
- What trials may be conducted after submission for approval

Laboratory Specimens for Clinical Research (GCP25)

This course will introduce you to regulations and guidelines that oversee the process of laboratory sample collection and shipping of human specimens for clinical research use in the United States.

After completing this course, you will be able to identify the rules and regulations that apply to laboratory samples, recognize how a sponsor utilizes the services of a central laboratory, how a principal investigator utilizes a local laboratory, and identify the sponsor and investigator site responsibilities for collection of specimens, as well as specimen packaging for shipping. In addition, you will be provided with compliance resources to ensure that sponsors and investigator sites maintain compliance with mandatory regulations.

Topics include:

- Clinical Laboratories
- Clinical Laboratory Improvement Amendments (CLIA) Certification
- Sponsor Role
- Site Responsibility and Documentation
- Medical Waste Disposal
- Packaging and Transport of Specimens

Overview of the Clinical Research Process (GCP11)

A drug, biologic or device product may not be introduced into commerce unless the regulatory agency of the country where it will be marketed has approved its product application. The sponsor of the product must demonstrate by adequate scientific evidence that it is safe and by substantial evidence that it is effective for the conditions prescribed, recommended or suggested in the product's proposed labeling. The safety and efficacy of the product is approved via clinical trials in humans and by investigators that have demonstrated that the research was conducted under the auspices of Good Clinical Practices (GCPs).

The principles and applications of GCPs are essential in the process of new drug, biologic and device product development. They are based on regulations, directives and guidelines meeting global regulatory demands in the conduct of clinical research. The components of GCPs comprise ethical obligations of investigators, sponsors and monitors with the purpose of protecting human subjects' rights. However, all personnel involved in new product development, from the "bench scientists" who discover the compounds or devices, to every person involved in the research processes up to and including the marketing and sales personnel should be aware of what is necessary to bring a new pharmaceutical or device product to market. This basic course is designed to give an understanding of the new drug, biologic and device approval process and the significance of how important it is to develop products that meet regulatory requirements for global registrations.

Topics include:

- What are drugs, biologics, and devices?
- Regulations, directives and guidelines that govern new product development
- GCP
- Technical documents required to gain approval to market new drugs, biologics and devices
- Phases of clinical research that follow GCP
- Timelines and costs
- Final stages in the clinical research process

Overview of the Preparation Requirements for the ICH Common Technical Document (CTD) M4 (GCP06)

Investigational drugs and biologicals are extensively tested and characterized in in vitro systems and in vivo animal models (preclinical/nonclinical research effort or "Safety"), during the definition and establishment of manufacturing processes for the drug substance and drug product (chemistry, manufacturing and control [CMC] effort or "Quality"), and in clinical trials to determine the human safety, efficacy and pharmacokinetic profiles (clinical research effort or "Efficacy") of the drug substance in a drug product. The results from these research studies are used to prepare submissions to regulatory authorities for marketing approval of a drug product for the treatment of a human disease or disorder. This course presents an overview of how these completed research studies are to be organized and summarized to be in compliance with the International Conference on Harmonisation (ICH) Common Technical Document (CTD) M4 guideline.

Preparation Requirements for ICH CTD M4E – Efficacy (GCP07)

Investigational drugs and biologicals are tested and characterized during and after administration to humans in clinical trials. These clinical research studies include experimentation to characterize the human safety, pharmacokinetics and efficacy of the drug substance in a drug product. This course describes how these completed clinical trials are to be organized and summarized to be in compliance with the International Conference on Harmonisation (ICH) Common Technical Document (CTD) on Efficacy M4E.

Prerequisite:

Learners requiring more detailed information on the CTD process should complete the course An Overview on the Preparation Requirements for the ICH Common Technical Document.

Preparation Requirements for ICH CTD M4Q – Quality (GCP08)

Investigational drugs and biologicals are tested and characterized in in vitro systems and animal models during nonclinical evaluations and in humans during clinical trials. These research studies are conducted with a drug substance that has been well characterized and formulated to produce a drug product that has also been characterized. This course describes how documentation generated to explain the preparation (i.e., manufacturing processes) and characterization of the drug substance and drug product are to be organized and summarized to be in compliance with the International Conference on Harmonisation (ICH) Common Technical Document (CTD) on Quality M4Q.

Prerequisite:

Learners requiring more detailed information on the CTD process should complete the course An Overview on the Preparation Requirements for the ICH Common Technical Document.

Preparation Requirements for ICH CTD M4S – Safety (GCP09)

Investigational drugs and biologics are tested and characterized prior to being administered to humans in clinical trials. These nonclinical evaluations continue during clinical trials and include in vitro and animal experimentation to characterize the pharmacology, pharmacokinetics, and toxicology of the drug substance in the drug product. This course describes how these completed nonclinical studies are to be organized and summarized to be in compliance with the International Conference on Harmonisation (ICH) Common Technical Document (CTD) on Safety M4S.

Prerequisite:

Learners requiring more detailed information on the CTD process should complete the course An Overview on the Preparation Requirements for the ICH Common Technical Document.

Protection of Human Subjects in Clinical Trials (PHA46)

FDA CRADA

This course provides the learner with a working knowledge of Informed Consent (IC) regulations, Institutional Review Board (IRB)/Independent Ethics Committee (IEC) responsibilitie, and the obligations of the individuals responsible for protecting patient rights and welfare.

Topics include:

- Protecting subjects
- Consent forms
- Consent process
- Consent exceptions
- IRB/IEC
- Responsibilities
- Procedures and records

Recruitment and Retention of Study Patients (GCP29)

This course will discuss the recruitment and retention of patient volunteers within a clinical trial. Patient enrollment into active clinical trials has always been challenging. Recruiting a patient into a clinical trial can prove to be difficult. Retaining a patient for the duration of the trial can be even more challenging. With few evidenced-based resources on recruiting styles, the focus of recruitment and retention in this course will be limited to the discussion of ethical and regulatory guidelines for the clinical investigator.

Topics include:

- Overview
- Patient Recruitment
- Institutional Review Board (IRB) Sites
- Recruiting Methods
- Special Populations
- Enrollment and Retention

Selecting and Managing Clinical Contract Research Organizations (CROs) (GCP12)

This course provides information on the processes commonly used to select and manage a clinical Contract Research Organization (CRO) and other supportive contract service providers for the clinical stages of the investigational product development process and the requirements for obtaining an appropriately completed study coordinated, at least in part, by a CRO.

Topics include:

- Outsourcing
- Sponsor's responsibilities when using a CRO in clinical research
- Pre-Selection Criteria
- Selection Techniques
- Managing CROs
- Sponsors Communicating with CROs

Role-Based Courses

Administrative Roles of the Clinical Research Associate (GCP26)

This course examines the administrative roles and responsibilities of the Clinical Research Associate (CRA) specific on-site monitor visits conducted at the principal investigator location on behalf of a sponsor. The term "CRA" can be used synonymously and interchangeably with "monitor" in this course instruction. This course is limited to the discussion of the on-site monitoring role of the CRA and required pre- and post-site visit responsibilities.

Topics include:

- Good Clinical Practices
- Compliance
- Monitoring Plan
- Source Documents
- Site Monitoring

Administrative Roles of the Clinical Research Coordinator (GCP27)

This course addresses the administrative roles and responsibilities of the Clinical Research Coordinator (CRC) who has been delegated by a principal investigator to coordinate multiple aspects of a clinical trial at an investigative site. The CRC is the individual who oversees completion of the protocol procedures by coordinating both schedules of patients and staff. While this course addresses the tasks required to fulfill the administrative roles and responsibilities of a designated CRC, the same tasks are required of any clinical trial. Upon completion of this course, you will be able to identify the CRC role throughout a clinical trial, as well as recognize applicable Good Clinical Practice standards.

Topics include:

- Principal Investigator
- Educational Background
- Regulations
- Investigator Responsibilities
- CRC Responsibilities
- Prestudy Process
- Ongoing Process
- Closeout Activities

Clinical Trial Audits and Consequences of Noncompliance (GCP21)

Sponsors can put measures in place in an attempt to dissuade researchers from being noncompliant, but those measures are only as effective as the personnel applying them. This course will provide a description of the clinical trial audit process and how audits help to ensure trials are conducted in accordance with regulatory requirements. Actions that can be taken if investigators are not compliant will also be discussed.

Topics include:

- Clinical Trial Audit
- The Audit Process
- FDA Inspection
- Noncompliance

GCP Obligations of Sponsors and Monitors (GCP04)

This course addresses sponsor and monitor's requirements and responsibilities for the conduct of clinical trials in support of new drug and biologics applications. Good Clinical Practices for the US Code of Federal Regulations, International Conference on Harmonisation (ICH) Guidelines, and most European Union Clinical Trials Directives are reflected in the content of this course.

Topics Include:

- Sponsor's role
- Research team
- Investigators
- Pre-Investigational Site Visit (PISV)
- The other types of visits sponsors/monitors conduct
- Monitor's responsibilities during the clinical trial

GCP/ICH Obligations of Sponsors, Monitors and Investigators (GCP01)

FDA CRADA

Drugs and biologics are tested extensively in clinical trials to assure their safety and efficacy before being made available to the public. This course addresses the obligations of sponsors, monitors, and investigators who participate in clinical research governed by US FDA regulations and International Conference on Harmonisation (ICH) guidelines. The course communicates how human subjects are protected, and provides a glossary of commonly used terms and definitions.

Sponsor obligations addressed include developing the protocol and investigator's brochure; selecting qualified investigators, sites and monitors; ensuring protocol adherence and adequate monitoring of the investigation; fulfilling reporting requirements; and investigational product accountability. The transfer of sponsor obligations to a contract research organization (CRO) is also discussed. Monitor obligations addressed include verifying protocol compliance; confirming investigators' compliance with GCP obligations; and auditing trial data to ensure its high quality and integrity. Monitor responsibilities during four different types of site visits and the importance of thorough documentation are also addressed.

Finally, the course discusses investigator obligations including adhering to the protocol and strictly following the investigational plan; abiding by the signed FDA-1572 Form; obtaining Institutional Review Board/Independent Ethics Committee (IRB/IEC) approval for the protocol, amendments, informed consent, and recruitment advertisements; accountability for the investigational product; and fulfilling reporting requirements.

Topics include:

- Responsibility for subject safety
- Obligations of a sponsor in conducting clinical research programs
- Responsibilities of a monitor in conducting clinical investigations
- Obligations of an investigator in conducting clinical investigations

Financial Disclosure by Clinical Investigators (GCP24)

This course discusses which financial arrangements must be disclosed, as well as investigator and sponsor responsibilities when disclosing financial information. The course also covers how the FDA evaluates financial information.

Topics include:

- Financial arrangements that must be disclosed
- The requirements for financial disclosure
- Who is responsible for disclosing financial information
- How the FDA evaluates the financial information that clinical investigators disclose

Obligations of Investigators in Conducting Drug and Biologic Trials (GCP02)

This course addresses how investigators comply with Good Clinical Practice (GCP) regulations when conducting clinical trials for investigational new drugs and biologics. It addresses the investigator's obligation to protect human subjects who participate in clinical trials, as well as the handling of safety data, drug accountability, clinical reporting requirements and compliance with FDA regulations and International Conference on Harmonisation (ICH) guidelines.

Upon completing this course, investigators, their staffs and all pharmaceutical personnel involved in overseeing clinical research will recognize what is involved in complying with GCPs, as well as their obligations in the following areas: Institutional Review Board/Independent Ethics Committee (IRB/IEC) approval, informed consent requirements, ethical conduct of clinical trials, Health Insurance Portability and Accountability Act (HIPAA) requirements, financial disclosure, and FDA and sponsor inspection visits. The course concludes with a discussion of the consequences of failure to comply with GCPs including FDA 483 observations, Warning Letters, investigator disqualification / restriction, and criminal prosecution.

Topics include:

- Research phases
- Obligations of a clinical investigator under GCP regulations
- Investigator's reporting and documentation requirements
- Investigator's obligation for product accountability
- Inspections the investigator should be prepared for
- How the investigator fulfills HIPAA requirements
- Consequences of failing to comply with GCP obligations and HIPAA in the United States

Responsibilities of Clinical Research Monitors (PHA57)

This course provides a detailed review of the regulatory and Good Clinical Practice (GCP) responsibilities of individuals assigned to monitor the conduct of clinical research studies. Such 'monitors' are usually referred to in the Pharmaceutical industry as Clinical Research Associates (CRAs) or Medical Research Associates (MRAs).

Topics include:

- Purpose of clinical trial monitoring
- Responsibilities of a clinical research monitor
- Criteria for the selection of monitors
- Personal characteristics and skills exhibited by successful monitors

Responsibilities of the Investigator in Drugs/Biologicals Clinical Trials (PHA56)

FDA CRADA

This course will familiarize potential investigators and interested clinical research personnel with federal and international regulations/requirements and the Good Clinical Practice guidelines on the investigator's responsibilities during the conduct of a clinical trial.

Topics include:

- Responsibilities
- Product Control
- Records
- Reports

The Role of the Clinical Research Associate (GCP17)

This course will explore the role of the Clinical Research Associate (CRA) in monitoring a clinical trial and acting as a liaison between the investigative site and the sponsor company. The course will introduce key CRA responsibilities widely recognized throughout the industry and globally applicable. The CRA's role during pre-study, initiation, interim and closure visits will be examined, as will the CRA's involvement in addressing noncompliance when observed. Finally, the course will conclude with a look at emerging trends affecting the industry's CRA resources.

Topics include:

- CRA Role
- Visits Before, During and After the Study
- Recruitment and Retention
- Informed Consent
- Source Documentation
- Case Report Forms
- Essential Documents
- Noncompliance

The Role of the Clinical Research Coordinator (GCP18)

This course will explore the role of the Clinical Research Coordinator (CRC) in executing a clinical trial and acting as a liaison to the investigator, sponsor and monitor. The course will introduce key CRC responsibilities at the site, including subject recruitment, informed consent, source document and CRF completion, and test article accountability. The CRC's role during site visits, including pre-study, initiation, interim and closure, will be examined.

Topics include:

- Role of the Clinical Research Coordinator
- Visits Before the Study
- Visits During and After the Study
- Recruitment and Retention
- Informed Consent
- Source Documentation
- Case Report Forms
- Essential Documents
- Noncompliance

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

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