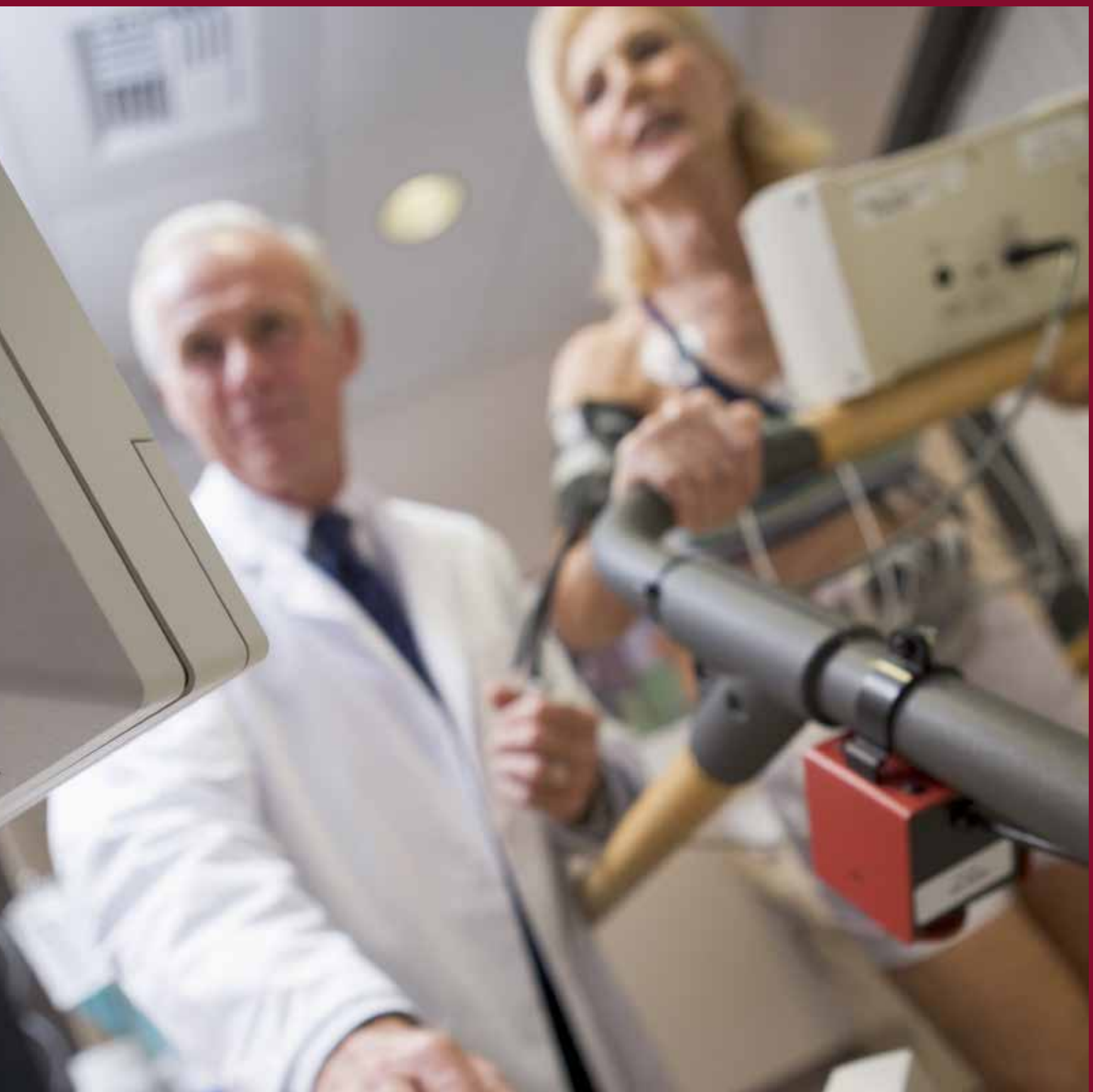
Life & Health

LIBRARY GUIDE:

Clinical Medical Device



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Overview:

Clinical Medical Device 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 Medical Device curriculum that focuses on the specialized knowledge needs of individual business functions for Medical Device 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 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 solution, which is available exclusively to UL's Life Science clients, provides the same level of preparedness and learning on which the FDA relies. The CRADA was recently extended 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 United States Food and Drug Administration (FDA) as a result of a CRADA between the FDA and UL.

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 is available in one or more foreign languages. Download Language Options for a Global Workforce for details.

Regular Content Updates

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

Driving Employee and External Partner Comprehension

UL's innovative technology-based solutions, deployed over the web, enable our customers to cost-effectively drive employee and external partner (e.g. investigators, Content Research Organizations (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 Medical Device Clinical Personnel

UL's innovative Knowledge Solution for clinical personnel is a technology-based solution deployed over the Web that enables our customers to cost effectively manage their expanding knowledge expectations of clinical research professionals.
The solution uses our validated and CFR 21 Part 11-compliant ComplianceWire® Platform to deliver, measure, document and track the online curriculum with content provided or reviewed by the FDA, as well as critical communications including protocols, amendments and Standard Operating Procedures (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 our customers to efficiently and effectively bridge the knowledge gap, thereby creating optimal performance and fewer compliance exposures. The end result is a more knowledgeable, productive and effective clinical team, which delivers bottom-line improvements through improved clinical quality and compliance with study and regulatory requirements.

Course Descriptions:

Listed Alphabetically

Clinical Curriculum – Core Program:

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

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 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

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 so that you can recognize how the industry and the FDA have evolved. Review of ICH will also provide you with an understanding of its impact on the industry from a global perspective.

Topics include:

- Setting Standards
- Organizations
- Regulations and 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?

Clinical Curriculum – Core Program (continued):

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.

This course will provide you with some tools for conducting effective clinical trial audits. After completing this course, you will be able to identify FDA standards for conducting and reporting clinical site inspections, as well as recognize the FDA's system for classifying inspections and taking corrective action.

Topics include:

- Clinical Trial Audit
- FDA Inspection
- Noncompliance
- Challenge

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 the 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 our 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 (EU) 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 Medical Product (IMPs)
- Future Prospects

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

GxPs (PHDV61)

"GxP" is a collective term for the regulations known as Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs) and Good Manufacturing Practices (GMPs). Without these combined regulations, the safety and efficacy of the pharmaceutical and medical device products would be in question. After completing this course, you will understand how these practices relate to each step in the development and manufacture of new drugs, biologics and medical devices..

Topics include:

- GxPs
- GLPs
- GCPs
- GMPs

References:
This course references regulations that are found in the Code of Federal Regulations Title 21

Clinical Curriculum – Core Program (continued):

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 Iinformed 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 through the IC process.

References:
21 CFR Parts 50, 56 and 312
International Conference on Harmonization (ICH) Guidelines
World Medical Association Declaration of Helsinki
Nuremberg Code
Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report)

ISO 14155: Obligations of Sponsors and Monitors for Medical Device Trials (GCP20)

ISO 14155 is intended to be applied worldwide to clinical investigations of medical devices in order to fulfill the various national, regional and international regulatory requirements.

After completing this course, you will be able to identify the specific requirements of ISO 14155 Part I and Part II. You will also be able to recognize the roles and responsibilities of sponsors and monitors in clinical investigations.

Topics include:

- Ethics
- Certified IRB Professional (CIP)
- Investigator's Brochure
- Informed Consent
- Documents
- Sponsor
- Monitor

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 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

Medical Device Safety Reporting (GCP19)

This course will introduce the learner to the regulatory requirements in the medical device clinical trial and post-marketing environments, as well as explore device safety monitoring and reporting efforts in Europe.

Topics include:

- Definition
- Safety
- Adverse Events
- Pre-Market
- Marketed Devices
- Reports

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 its proposed labeling. The safety and efficacy of the product is approved via clinical trials in humans and by investigators who demonstrate 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, beginning with the "bench scientists" who discover the compounds or devices, 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
- GCPs
- Technical documents required to gain approval to market new drugs, biologics and devices
- Phases of clinical research that follow GCPs
- Timelines and costs
- Final stages in the clinical research process

Clinical Curriculum – Core Program (continued):

Protection of Human Subjects in Clinical Trials (PHA46)

FDA CRADA

This course provides the learner with a working knowledge of informed consent regulations, Institutional Review Board/ Independent Ethics Committee (IRB/IEC) responsibilities 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 recruitment and retention of patient volunteers within a clinical trial. Patient enrollment into active clinical trials has always been challenging. Recruiting a patient for 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:

- 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 Oanization (CRO) and other supportive contract service providers for the clinical stages of the investigation 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' effective communication with CROs

Role-Based Curriculum:

Administrative Roles of the Clinical Research Associate (GCP26)

This course examines the administrative roles and responsibilities of the Clinical Research Associate (CRA) specific to on-site monitor visits conducted at the principal investigative 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 (GCP) standards.

Topics include:

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

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

Role-Based Curriculum (continued):

GCP Obligations of Sponsors and Monitors (GCP04)

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

Topics include:

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

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

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 FDA regulations and 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 Good Clinical Practice (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 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

Obligations of Investigators in Conducting Medical Device Trials (GCP03)

This course addresses requirements for conducting clinical trials for investigational pre-market medical devices. It provides an overview of the clinical investigator's general and specific obligations to protect human subjects while providing valid data that sponsors may submit to regulatory authorities for approval. This course also introduces the investigator and staff to documentation and reporting requirements, the inspection process and the consequences for failure to comply with Good Clinical Practices (GCPs). It concludes with suggestions for improving compliance.

Topics include:

- Investigator obligations
- Protecting human subjects
- Protocol
- Reporting
- Documentation
- Inspections
- Noncompliance

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

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 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 Case Report Form (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 Study
- Visits During and After 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.

202 Carnegie Center
Suite 301
Princeton, NJ 08540
609.627.5300

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