Clinical Pathways

Good Clinical Practice Training (GCP): Refresher

Course Description

Using industry case scenarios to support application and critical thinking, this Good Clinical Practice (GCP) Refresher course reviews the major requirements of GCP for clinical trials according to the global ICH E6(R2) guideline.

Recommended for clinical research professionals with 5 or more years' experience with GCP at sponsor, CRO, and/or clinical site.

Learning Objectives

1. Review major GCP requirements and Identify practical applications of the Guideline, including identifying methods to assess quality systems and documentation.
2. Relate GCP concepts during interactive activities to support application during a clinical trial.
3. Reflect on challenges and opportunities in the current state of the industry for implementing the GCP Guideline.

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Length: 35 minutes run time plus additional time to complete application exercises, activities, and post assessment

This ICH E6 (R2) GCP Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

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1. GCP Overview
    a. Purposes of GCP
    b. Thirteen Principles of GCP
    c. Elements in a Protocol
    d. Protocol Amendments vs Deviations
    e. Protocol Changes
    f. Investigator's Brochure
    g. GCP Resources
2. Stakeholders' Roles and Responsibilities
    a. How GCP Stakeholders Interact
    b. Responsibilities During the Study Conduct
    c. Risk Based Approach Guidance
    d. The Sponsor's Representative: The Monitor
    e. Monitoring Plan
    f. Quality Management
    g. Implementation of a Quality System
    h. General Qualifications for Investigator
    i. Guidance for Investigator Responsibilities
    j. Adequate Supervision of Trials
    k. Examples of Inappropriate Delegation
    l. Common Challenges
    m. IRB/EC Responsibilities
3. Challenges and Opportunities in Implementing GCP
    a. Essential Documents
    b. Electronic Records & Computerized Systems
    c. Trial Master Files (TMFs)
    d. Sponsor & Investigator Regulatory Binders/TMF
    e. Informed Consent Process
    f. Vulnerable Subjects
    g. Elements of Consent
    h. Informed Consent Stakeholder Responsibilities
    i. Common Informed Consent Deficiencies
    j. Safety Reporting
    k. Good Documentation Practices
    l. Certified Copies
    m. ALCOA-C
    n. Managing Non-compliance
    o. Managing Significant GCP Issues
4. 10 Question Post Assessment

Meet the Subject Matter Expert

Sam Sather
MS, BSN, CCRC, CCRA

Sam Sather's current focus of consulting is to promote clinical quality systems for Sponsors/CROs and Investigators/Research Institutions. She has over 35 years of clinical experience, has a Bachelor of Science degree in Nursing and a Master of Science degree in Education with a Specialization in Training and Performance Improvement. Sam has been dual certified by the Association for Clinical Research Professionals (ACRP) for over 15 years as a CCRA and CCRC. She is a current ACRP Fellow, which is awarded to individuals who have made substantial contributions to the Association and the industry at large.

Sam is a frequent speaker at industry conferences and has authored dozens of courses for clinical research training programs in various functional areas. She has multiple training, monitoring, and project management experiences of diverse size and objectives with a variety of global clients.

About Clinical Pathways

Clinical Pathways, LLC is a one-of-a-kind consulting and training firm whose purpose is to deliver affordable, customized, high quality clinical research services in an efficient, amiable, and professional manner. Understanding how to focus on what is essential and truly matters to promote better clinical quality systems for our clients is the key to our approach. Our agile consulting services adapt to the client's unique needs. Whether it is vendor management, SOP development, inspection readiness, RBQM, or an impact and gap analysis, Clinical Pathways has you covered.