Using CITI Program Content: Good Clinical Practice (GCP)

CONTENT AUTHOR

- Jaime A. Arango, EdD, CIP
  CITI Program

INTRODUCTION

Like all CITI Program educational materials, the components of the GCP series can be customized to fit the specific needs of your organization’s learners. Taking advantage of this flexibility requires that you are familiar with the CITI Program’s GCP offerings and with the capabilities of the CITI Program’s web platform to deliver them. This module addresses the components of the GCP series. For general information on the CITI Program’s instructional capabilities, see Using CITI Program Content: An Introduction.

LEARNING OBJECTIVES

By the end of this module, you should be able to:

- Identify the structure of the CITI Program’s GCP series.
- Determine how to access the GCP series based on organization-wide or individual needs.
- Understand the recommended configuration for the GCP series in light of industry standards.
- Obtain additional information on the GCP series from the GCP Catalog, Help Desk Staff, and Sales Group.

GCP SERIES OVERVIEW

Basic Courses

CITI Program’s GCP series includes three basic courses, GCP for Clinical Trials with Investigational Drugs and Medical Devices - U.S. FDA Focus, GCP for Clinical Trials with Investigational Drugs and Biologics – ICH Focus, and GCP for Clinical Investigations of Devices. These courses have been constructed to meet the needs of varying organizations. The GCP for Clinical Trials with Investigational Drugs and Medical Devices - U.S. FDA Focus course is intended for research personnel involved in drug, device, or biologic studies and who would benefit from a more U.S. FDA focused training. The GCP for Clinical Trials with Investigational Drugs and Biologics – ICH Focus course is intended for investigators involved in drug and biologic studies where a more international focused training would
be meaningful. The GCP for Clinical Investigations of Devices is intended for research personnel involved in device studies. This course is more U.S. FDA focused (but includes International Organization for Standardization Guidelines ISO 14155:2011) and recognizes that the regulatory requirements for device studies have substantial differences in a number of areas from those related to drugs and biologics.

**Refresher Courses**

CITI Program’s GCP series includes three refresher courses, GCP ICH Refresher, GCP FDA Refresher, and GCP Device Refresher. The refresher courses are meant to reinforce the importance of concepts covered in the corresponding basic level courses.

**SUBSCRIPTION OPTIONS**

GCP series subscriptions are available to both organizations and independent learners. Review the information below to help determine which option best meets your current needs. To discuss these options in further detail, please contact sales@citiprogram.org.

**Organization Subscription**

GCP series access is included within the CITI Program base subscription fee. Organization access allows for unlimited learner use (per site), designated administrative oversight, and the flexibility to use the courses in a number of different ways as discussed in the next section.

**Independent Learner Subscription**

The GCP series is available to independent learners for $110/course. Independent learner access is intended for those not affiliated to an organization that subscribes to the CITI Program or whose organization does not offer the GCP courses.

**SELECTING MODULES FOR YOUR ORGANIZATION’S LEARNERS**

For the GCP series, the CITI Program offers the following options on how modules are presented to learners.

- **Required**: A module that must be taken by the learner in order to earn a Completion Report.
- **Elective**: A module that is associated with a set of other Elective modules. Learners select and complete a specified minimum number of electives from the set in order to earn a Completion Report. For example, if a learner group is required to complete three Elective modules, and five choices are presented, then completing any three of the five modules will allow the learner to move forward.
- **Supplemental**: A module that becomes available to the learner after completing any applicable Required and Elective modules. A learner may review Supplemental modules on a voluntary basis.
The selection of **Required**, **Elective**, and **Supplemental** is entirely at the discretion of organization. Although, there must be at least one **Required** module for each learner group.

It is important to note that organizations may also develop customized organization-specific content to supplement the training. Organizations then work with the CITI Program to develop modules that are included in learner groups for seamless delivery to learners.

Organizations may choose to create separate GCP learner groups containing only the GCP modules in any combination as noted above. Alternatively, organizations may add the GCP modules to existing learner groups. A combination of both a GCP-specific learner group and inclusion of GCP modules in existing learner groups is yet a third option for organizations.

In keeping with the options above, the CITI Program can assist administrators in creating courses (learner groups) that best meet their organizational needs, including utilizing modules from across the CITI Program. To discuss course recommendations that combine modules from different CITI Program offerings, please contact the Help Desk at support@citiprogram.org or (888) 529-5929.

**Note:** Courses intended to present the principles of GCP must include all of the GCP modules within one of the CITI Program’s GCP offerings.

**GCP for Clinical Trials with Investigational Drugs and Medical Devices – U.S. FDA Focus**

Listed below are the available modules within the **GCP for Clinical Trials with Investigational Drugs and Medical Devices – U.S. FDA Focus** course. The typical recommendation is to designate the modules listed below as being **Required**. Some organizations will make several modules **Supplemental**, particularly when they provide organization-specific training on the topic.

- The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices
- Overview of New Drug Development
- Overview of ICH GCP
- ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations
- Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
- Investigator Obligations in FDA-Regulated Clinical Research
- Managing Investigational Agents According to GCP Requirements
- Overview of U.S. FDA Regulations for Medical Devices
- Informed Consent in Clinical Trials of Drugs, Biologics, and Devices
- Detecting and Evaluating Adverse Events
- Reporting Serious Adverse Events
- Monitoring of Clinical Trials by Industry Sponsors
- Audits and Inspections of Clinical Trials
- Completing the CITI GCP Course
The following **Supplemental** modules may be beneficial to this GCP course:

- Humanitarian Use Devices (HUDs)
- Phase I Research: Understanding Phase I Research
- Phase I Research: Protecting Phase I Subjects
- Overview of the Clinical Trial Agreement (CTA)
- Understanding the Terms of the Clinical Trial Agreement (CTA)
- Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)
- Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites

**GCP for Clinical Trials with Investigational Drugs and Biologics – ICH Focus**

Listed below are the available modules within the *GCP for Clinical Trials with Investigational Drugs and Biologics – ICH Focus* course. The typical recommendation is to designate most of the modules listed below as being **Required**. Some organizations will make several modules **Supplemental**, particularly when they provide organization-specific training on the topic.

- The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Biologics
- Overview of New Drug Development
- Overview of ICH GCP
- ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations
- Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
- Investigator Obligations in FDA-Regulated Research
- Managing Investigational Agents According to GCP Requirements
- Informed Consent in Clinical Trials of Drugs and Biologics
- Monitoring Clinical Trials of Drugs by Industry Sponsors
- Audits and Inspections of Clinical Trials of Drugs and Biologics
- Detecting and Evaluating Adverse Events
- Reporting Serious Adverse Events in Investigations of Drugs and Biologics
- Completing the CITI GCP Course

The following **Supplemental** modules may be beneficial to this GCP course:

- Humanitarian Use Devices (HUDs)
- Phase I Research: Understanding Phase I Research
- Phase I Research: Protecting Phase I Subjects
- Overview of the Clinical Trial Agreement (CTA)
- Understanding the Terms of the Clinical Trial Agreement (CTA)
- Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)
- Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites
GCP for Clinical Investigations of Devices
Listed below are the available modules within the GCP for Clinical Investigations of Devices course. The typical recommendation is to designate most of the modules listed below as being Required. Some organizations will make several modules Supplemental, particularly when they provide organization-specific training on the topic.

- The CITI Good Clinical Practice Course for Clinical Investigations of Devices
- Overview of U.S. FDA Regulations for Investigational Devices
- Investigator Obligations in FDA-Regulated Clinical Investigations of Devices
- Conducting Investigator-Initiated Clinical Investigations of Devices
- Managing Investigational Devices According to GCP Requirements
- Informed Consent in Clinical Investigations of Devices
- Monitoring Clinical Investigations of Devices
- Audits and Inspections of Clinical Investigations of Devices
- Reporting Requirements for Clinical Investigations of Devices
- Completing the CITI Program's GCP Course for Clinical Investigations of Devices

The following Supplemental modules may be beneficial to this GCP course:

- Humanitarian Use Devices (HUDs)
- Overview of the Clinical Trial Agreement (CTA)
- Understanding the Terms of the Clinical Trial Agreement (CTA)
- Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)
- Clinical Trial Agreement (CTA) Negotiation for researcher and Sites

GCP ICH Refresher

Listed below are the available modules within the GCP ICH Refresher course. The typical recommendation is to designate most of the modules listed below as being Required. Some organizations will make several modules Supplemental, particularly when they provide organization-specific training on the topic.

- GCP Refresher - International Conference on Harmonisation (ICH): GCP Requirements
- GCP Refresher - Investigator’s Responsibilities and GCP
- GCP Refresher - Informed Consent
- GCP Refresher - Safety Management
- GCP Refresher - Investigational Product (Drug) Management
- GCP Refresher - Audits, Inspection, and Monitoring of Research Studies
- GCP Refresher - Sponsor Responsibilities and GCP
GCP FDA Refresher

Listed below are the available modules within the GCP FDA Refresher course. The typical recommendation is to designate most of the modules listed below as being Required. Some organizations will make several modules Supplemental, particularly when they provide organization-specific training on the topic.

- GCP Refresher - International Conference on Harmonisation (ICH): GCP Requirements
- GCP Refresher - Investigator’s Responsibilities and GCP
- GCP Refresher - Informed Consent
- GCP Refresher - Safety Management
- GCP Refresher - Investigational Product (Drug) Management
- GCP Refresher - Audits, Inspection, and Monitoring of Research Studies
- GCP Refresher - Sponsor Responsibilities and GCP
- GCP Refresher - Conducting Clinical Investigations of Devices
- GCP Refresher - Review of U.S. FDA Regulations for Investigational
- GCP Refresher - Additional GCP Standards for International Clinical Investigations of Devices
- GCP Refresher - Informed Consent and Exceptions to the Requirement for Obtaining Consent for Clinical Investigations of Devices
- GCP Refresher - Oversight of Clinical Investigations of Devices
- GCP Refresher - Reporting Requirements for Clinical Investigations of Devices

GCP Device Refresher

Listed below are the available modules within the GCP Device Refresher course. The typical recommendation is to designate most of the modules listed below as being Required. Some organizations will make several modules Supplemental, particularly when they provide organization-specific training on the topic.

- GCP Refresher - Conducting Clinical Investigations of Devices
- GCP Refresher - Review of U.S. FDA Regulations for Investigational
- GCP Refresher - Additional GCP Standards for International Clinical Investigations of Devices
- GCP Refresher - Informed Consent and Exceptions to the Requirement for Obtaining Consent for Clinical Investigations of Devices
- GCP Refresher - Oversight of Clinical Investigations of Devices
- GCP Refresher - Reporting Requirements for Clinical Investigations of Devices

RETRAINING FREQUENCY

There is not one uniform standard regarding how frequently GCP training should occur. However, it has been our experience that most organizations select a three-year period of retraining. The
organization could request that the designated refresher course or the same basic course be presented to learners again within a given period.

INDEPENDENT LEARNERS

For a listing of GCP courses available to independent learners, see the Independent Learner Course Guide.

TRAINING METHODS

There is not one uniform standard regarding the methods and format used for GCP training. CITI Program content is designed to be a component of an overall foundation of training for an organization’s affiliates. We recommend that organizations build frameworks of training that combine CITI Program content with face-to-face training, one-on-one mentoring, and other types of learning opportunities, as appropriate to the particular topics and their organizational cultures.

LANGUAGE AVAILABILITY

At the present time, the CITI Program’s entire GCP series is available in English. A select number of modules are also available in Spanish, Portuguese, Korean, Chinese, Thai, French, Khmer, and Vietnamese. See the GCP Catalog for more details regarding language availability.

CONTINUING EDUCATION (CE) CREDITS

Detailed information regarding CMEs/CEUs is available in the GCP Catalog or at the CITI Program website. For more information on how to ensure CE availability for your organization’s learners contact support@citiprogram.org or (888) 529-5929.

MUTUAL RECOGNITION

The ICH E6 GCP Investigator Site Training (noted below) 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.

- GCP for Clinical Trials with Investigational Drugs and Medical Devices - U.S. FDA Focus
- GCP for Clinical Trials with Investigational Drugs and Biologics – ICH Focus
- GCP FDA Refresher
- GCP ICH Refresher

Organizations and learners that wish to utilize these mutually recognized GCP courses in keeping with the minimum criteria must designate all available modules as “Required.”

SUMMARY

The GCP series is highly customizable and commonly used to help meet organizational training requirements. Many organizational administrators have found it helpful to visit the CITI Program’s
website at least annually to review current content offerings and to consider these in light of the organization’s previously selected options. The CITI Program’s Help Desk is experienced with all of its curricular series, including GCP, and can assist you in configuring content for your learners. Contact the Help Desk at support@citiprogram.org or (888) 529-5929.

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