



GOOD CLINICAL PRACTICE (ICH-GCP)

PROFESSIONAL DEVELOPMENT COURSE

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INVESTIGATOR AND SITE PERSONNEL GOOD CLINICAL PRACTICE (ICH GCP)

Introduction

Welcome to the Investigator and Site Personnel Good Clinical Practice (ICH GCP) online training program.

The intent of this training program is to define the Minimum Criteria for Good Clinical Practice (GCP) training of investigators and site personnel (based upon ICH E6 R2) to enable the mutual recognition of GCP training within the clinical research industry.

To satisfy these Minimum Criteria, the training includes an overview of GCP, the principles of ICH-GCP, and investigator responsibilities.

Course Overview

The Investigator and Site Personnel Good Clinical Practice (ICH GCP) online training program is a free, online, self-paced learning course consisting of two (2) lessons. Each lesson is organised into a series of topics, with 16 topics in total.

Each topic consists of one page of learning materials. Written content is accompanied by short videos, summary tables, and diagrams (including our own purpose-made infographics). References and recommended readings are listed at the end of each topic.

A GCP course assessment quiz will become accessible upon completion of the two lessons. A passing grade of at least 80% is required to pass the course and receive a certificate of completion.

The course and certificate are compliant with the [TransCelerate Site Qualification and Training \(SQT\) Initiative](#), reflecting professional recognition for ICH E6 Good Clinical Practice (GCP) Training targeted to investigator site personnel. The certificate is valid for a period of 3 years.

The course takes approximately 2 - 4 hours to complete.

Learning Objectives

There are a total of 16 course topics covering the following learning objectives:

- ◆ 1. Introduction to Clinical Trials
- ◆ 2. Good Clinical Practice – An Overview
- ◆ 3. The Australian Regulatory Environment
- ◆ 4. Roles and Responsibilities
- ◆ 5. Investigator Qualifications and Agreements
- ◆ 6. Resourcing
- ◆ 7. Medical Care of Trial Participants
- ◆ 8. Communication with HREC
- ◆ 9. Compliance with Protocol
- ◆ 10. Investigational Products
- ◆ 11. Randomization Procedures and Unblinding
- ◆ 12. Informed Consent of Trial Participants
- ◆ 13. Records and Reports
- ◆ 14. Progress Reporting and Final Reports
- ◆ 15. Safety Reporting
- ◆ 16. Premature Termination or Suspension of Trial

Instructions

Please read the instructions below before starting the course. Following these instructions will ensure that your progress is updated correctly and that your certificate displays the correct information.

If you are experiencing any issues with the course, please refer to the [Frequently Asked Questions](#) before contacting us.

Course Content

The course consists of **2** lessons. Each lesson contains several **topics**. Each topic consists of one page of learning material. A list of References and Resources is provided for each unit.

Some topics contain embedded short **videos** that we recommend you take the time to watch.

Course Progression

At the end of each topic, you must click on the **“Mark Complete”** button to confirm your progress and move on to the next topic. This includes the GCP Course Assessment lesson page.



Mark Complete ✓

Once you have completed all topics within a lesson, you must click on **“Back to Lesson”** and then click on the **“Mark Complete”** button before moving on to the next lesson.

You can revisit topics at any time by clicking on the course title or the unit title above the progress bar located on the top of any course page.

Assessment Quiz

The final lesson contains the assessment quiz. The quiz consists of 20 randomised questions, including single choice (only 1 correct answer) and multiple choice (more than 1 correct answer possible) items. The type of question is indicated in parentheses ()'s underneath the question.

You will need to correctly answer at least **16 of the 20** questions (**a score of at least 80%**) to pass each unit.

There is no time limit. You may attempt the quiz as many times as you need to.

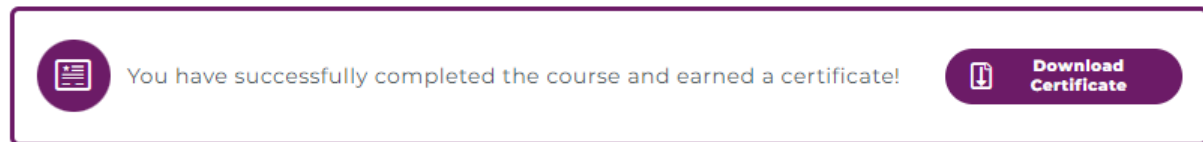
A results page will load upon finishing the quiz. To review your answers, click on the View Questions button. Correctly answered questions are highlighted green. Incorrectly answered questions are displayed with a red border, with the correct answers displayed in a green border.

Course Certificate



Once you have completed all lessons and topics and received a passing grade on the assessment quiz, a personalised course certificate will be generated.

To download your certificate, return to the main course (overview) page to find a certificate download button as shown.



You can also download your certificate from the [Student Account](#) page.

NOTE: Before you can download your certificate, you must mark each course topic and lesson as complete.