

DAIDS GCLP Training Related FAQs

1) What are the GCLP training requirements for U.S. laboratories?

CLIA requirements overlap to a large extent with GCLP; therefore, the DAIDS GCLP training is not required for clinical laboratory personnel in the United States (U.S.) that are CLIA certified.

For U.S. personnel in specimen processing laboratories and endpoints laboratories, the comprehensive GCLP training eLearning course (10 modules, approximately 14 hours) on the DAIDS Learning Portal (DLP) is highly recommended (<https://daidslearningportal.niaid.nih.gov/>). Click on the Course Catalog link. Type “GCLP” into the Search by Keyword field.

Networks/non-Networks may have more stringent requirements that laboratory personnel are expected to follow.

2) What are the GCLP training requirements for non-U.S. laboratories?

For non-U.S. laboratories, all clinical laboratory personnel involved in specimen processing and testing must take the GCLP training available on the DLP.

a. What are the GCLP training requirements for study nurses, physicians, or non-laboratory personnel **who only collect and/or transport specimens?**

The GCLP training requirement does not apply to study nurses, physicians, or non-laboratory personnel **who only collect and/or transport specimens.**

b. What are the GCLP training requirements for study nurses, physicians, or other non-laboratory personnel **who perform specimen processing and/or testing?**

Fulfillment of GCLP training by study nurses, physicians, or other non-laboratory personnel **who perform specimen processing and/or testing** can be accomplished using one of the options noted below:

- Documentation of training on a set of abbreviated GCLP Primer eLearning courses (approximately 1.5-2 hrs.). Available on the DLP (<https://daidslearningportal.niaid.nih.gov/>).
- Documentation of participation in a DAIDS-sponsored instructor-led (on-site or remote) focused-GCLP training session (led by DAIDS GCLP audit contractors). Prior approval to determine the availability of training will be required from DCLOT to participate in the training.
- Documentation of training records attesting to the review and understanding of GCLP training guidelines version 4.1 (<https://www.niaid.nih.gov/sites/default/files/gclpstandards.pdf>)
- Documentation of participation in a DAIDS GCLP training session provided by a qualified staff member who completed the latest comprehensive DAIDS GCLP training and is approved as a trainer by the lab manager, director, or designee with DCLOT and network/non-network concurrence.

3) How do sites submit a request for the DAIDS-sponsored instructor-led (on-site or remote) focused-GCLP training session?

The request for the DAIDS-sponsored instructor-led (on-site or remote) focused-GCLP training session requires DCLOT approval considerations including, logistic feasibility

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and funding availability. Therefore, the instructor-led training request must be submitted three to six months in advance. The timeline for approval may take up to 12 months; hence this option should be the least preferred. Site or Network/non-Network should send training request to DCLOT (NIAIDDCLOT@niaid.nih.gov).

4) Are sites allowed to use other third-party training platforms to satisfy DAIDS GCLP training requirements?

The comprehensive and primer DAIDS GCLP training eLearning courses, available on the DLP, are based on DAIDS GCLP Guidelines version 4.1 and include specific requirements for laboratories participating in DAIDS-Supported and/or Sponsored Clinical Trials. **Therefore, the CITI portal or any other third-party GCLP training will not be permitted.**

5) Can the GCLP Primer eLearning course be used as a “refresher” GCLP course after someone has completed the comprehensive GCLP course?

The Primer course is specifically targeted for study nurses, physicians, and other non-laboratory staff at **non-U.S. sites**, who perform specimen processing and/or testing for DAIDS studies. These primer modules only address basic principles of GCLP.

6) Is it possible to get retrained in GCLP?

Yes, it is possible to get retrained in GCLP every year. The training material will only be updated when the GCLP manual is updated, so the course material may not be updated annually. The staff must visit the DLP (<https://daidslearningportal.niaid.nih.gov/>) and click on the Course Catalog link. Type “GCLP Recertification” into the Search by Keyword field and then click on the current year’s recertification offering. The staff will then enroll, and once completed may choose to print their certificate. Annual recertification is not required. However, the recertification option is available as a refresher on the current GCLP version.

Note: the certification course for the current year consists of the same training material as the main GCLP training course that the relevant staff are required to take as described in (1) and (2).

7) How frequently should staff train in GCLP?

Laboratory management should ensure that training frequency is sufficient to ensure that personnel remain familiar with the GCLP requirements applicable to them.

- Laboratory staff must train in GCLP within six months of release when a new version of the GCLP guidelines is published and training materials updated.
- Laboratory staff must train in GCLP prior to conducting any study-specific tasks and retraining as needed or per relevant updates.
- Laboratory staff must comply with organization or Networks / non-Networks training requirements.

8) Is GCLP training available in languages other than English?

The latest version of the comprehensive GCLP eLearning and the GCLP Primer eLearning courses are available in Portuguese and Spanish.