



CDISC Operational Procedure CDISC-COP-005 Education Curriculum Development and Ownership, and Qualification of Course Developers and Trainers

1 Introduction

1.1 Purpose

This document describes the policies and processes related to the development and maintenance of the CDISC Education curriculum, ownership of CDISC Educational course materials, and qualification of trainers.

1.2 Background

CDISC is committed to providing authoritative education to the biopharmaceutical and medical device industry, regulators, and other implementers on the current CDISC production standards. This education will be provided through various public and private venues including conferences, classroom training, company workshops, webinars and tutorials.

1.3 Authority

This document is approved by the CDISC President and CEO and should be used by CDISC staff, consultants, volunteers and technical teams for the development and maintenance of all CDISC training materials, and for the selection and management of course developers and trainers. The CDISC Education leadership and staff have primary responsibility for the implementation of this policy and the related processes.

1.4 Definitions

Term	Definition
Technical Team	The team that is responsible for developing and maintaining a particular standard (e.g., SDS team)
Technical Team Lead	The person who is leading a particular standards or project team; usually the Technical Leadership Committee (TLC) representative for the standard

1.5 References and Related Documents

Licensed Training Agreement Template
Authorized Trainer Agreement Template
Private Training Agreement Template

2 CDISC Training Materials Ownership and Licensing

1. Ownership of Training Materials, Exercises and Intellectual Property
 - a. All training materials and exercises developed under this Procedure will be owned by CDISC regardless of who participated in the development of said materials.
 - b. Any training materials and exercises developed under this Procedure may not be used to provide training outside of CDISC authorized training events, or to develop unauthorized training materials.
 - c. All training materials developed under this COP are copyrighted by CDISC and may not be used for any purpose other than authorized CDISC training without the express written permission of CDISC.
2. All training using CDISC developed course materials will be
 - i. Provided by authorized CDISC trainers
 - ii. Delivered through authorized CDISC venues.
3. Licensed Training
 - a. Companies that are CDISC members in good standing may license CDISC education materials to train their own staff.
 - b. Only authorized trainers may deliver licensed training.
 - c. CDISC will enter into annually renewable Licensed Training Agreements with organizations.
 - d. In the event a company does not renew membership, or withdraws their membership in CDISC, any training materials distributed to them under license must be returned or destroyed.
 - e. CDISC Education will maintain a current list of companies that have licensed CDISC training materials.

3 Responsibilities of Technical Teams

A training sub-team will be established and maintained by each Technical Team for the purpose of:

- a. Providing authoritative input or review of the training content
- b. Notifying CDISC Education when content updates are needed
- c. Collaborating with CDISC Education to identify and qualify trainers
- d. Coordinating the availability of trainers who are on the sub-team

4 Education Courses

1. CDISC Education leadership, authorized trainers and the Technical Team training sub-teams will have collaborative responsibility for ensuring that CDISC training materials are created and maintained in an accurate and current state.
2. CDISC Education staff will maintain the final approved version of all course materials in an appropriately controlled environment that is available to the authorized trainers.

5 Course Developers and Instructors

1. CDISC Education leadership and the Technical Team Leads will have collaborative responsibility for identifying and evaluating the qualifications of course developers and authorized trainers.

2. All course developers and authorized CDISC trainers must
 - a. Have documented experience for a minimum of three years in the technical aspects of the CDISC standard in which they are training or developing materials, **and**
 - b. Be current, active, contributing members on the Technical Team of the standard for which they are training or developing training materials, **or**
 - c. If the standard is less than three years in publication, a person who is an active, contributing member of the Technical Team may be selected to do training contingent on the approval of the Technical Team Lead and CDISC Education leadership, **or**
 - d. A person with commensurate experience may be evaluated and qualified by the Technical Team and CDISC Education leadership.
3. All training sub-team members, course developers and authorized trainers must agree not to use CDISC course materials for any purpose that is not authorized by CDISC.
4. CDISC Education staff will maintain a list of authorized trainers for each training course, with documentation of each trainer's qualifications.

Authorization

This document has been approved and is in effect on this date:

Name	Rebecca Kush
Date	31 May 2012