



CDISC Operational Procedure COP-005 Education

1 Introduction

1.1 Purpose

This document describes the policies and processes related to the development, maintenance and ownership of authorized CDISC Education instructional materials, and the qualification of course developers and instructors.

1.2 Background

CDISC is committed to providing authoritative education to implementers and other stakeholders of the CDISC 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 VP, Education and by the CDISC President and CEO and should be used by CDISC staff, consultants, and volunteers for the development and maintenance of all CDISC Education instructional materials, and for the selection and management of course developers and instructors. The CDISC Education leadership and standards Technical Team Leads have primary responsibility for the implementation of this procedure 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 Related Documents

COP-001 Standards Development

CIP-017 Instructor Qualification and Re-qualification

CIP-021 Development and Maintenance of Instructional Materials

2 CDISC Education Instructional Materials Ownership and Licensing

1. Ownership of Instructional Materials and Intellectual Property
 - a. All instructional materials developed under this Procedure are owned by CDISC regardless of who participated in the development of said materials.
 - b. All previously developed materials that are contributed by external parties will be credited and no materials will be used without appropriate permissions.
 - c. Any instructional materials developed under this Procedure may not be used to develop unauthorized instructional materials.
 - d. All instructional 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 Education leadership.
2. Use of CDISC Instructional Materials

All instructor-led training using CDISC developed instructional materials will be

 - Used for teaching only by authorized CDISC instructors, and
 - Used only in teaching at authorized CDISC classroom or online events

Any instructional materials developed under this Procedure, whether classroom or online, may not be used to provide training outside of CDISC authorized training events.
3. Licensed Training
 - a. Companies that are CDISC members in good standing may license CDISC instructional materials to train their own staff.
 - b. Only authorized instructors may deliver licensed training.
 - c. CDISC will enter into annually renewable Licensed Training Agreements with organizations that wish to license CDISC training to teach their internal staff.
 - d. In the event a company does not renew membership, or withdraws their membership in CDISC, any instructional materials distributed to them under license must be promptly returned or destroyed. The Licensed Training Agreement will also be terminated on the day the membership ends.
 - e. CDISC Education will maintain a current list of companies that have licensed CDISC instructional materials.

3 Responsibilities of Technical Teams and Training Sub-teams

A training sub-team will be established and maintained by each Technical Team for the purpose of collaborating with CDISC Education to:

- a. Develop content for instructional materials
- b. Provide input to the development of or review of instructional content
- c. Notify CDISC Education when content updates are needed
- d. Collaborate with CDISC Education to identify, qualify and train new instructors
- e. Coordinate the availability of instructors who are on the sub-team
- f. Give final approval on the accuracy of instructional material content

4 Education Courses

1. CDISC Education leadership, authorized instructors and the Technical Team training sub-teams will have collaborative responsibility for ensuring that CDISC instructional materials are created for all published standards, and maintained in an accurate and current state.

2. CDISC Education staff will maintain the final approved versions of all course materials in an appropriately controlled environment that is available to the authorized instructors.

5 Course Developers and Instructors

1. CDISC Education leadership and the Training sub-teams will have collaborative responsibility for identifying and evaluating the qualifications of course developers and authorized instructors.
2. All course developers and authorized CDISC instructors must
 - a. Have documented experience for a minimum of three years implementing the CDISC standard in which they are training or for which they are developing materials, **and**
 - b. Be current, active, contributing members on the Technical Team of the standard for which they are training or developing instructional 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 which may be evaluated and qualified by the Technical Team and CDISC Education leadership.
3. All training sub-team members, course developers and authorized instructors 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 instructors for each training course, with documentation of each instructor's qualifications.

Authorization

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

Approved	Date
David R. Bobbitt, President and CEO	18 July 2017