

CERTIFICATE OF ACCOMPLISHMENT




ART OF DIVERSITY

This certifies that

Commit Global

has successfully completed the linguistic validation training for service implementation



Nur Ferrante Morales

Linguistic Validation Expert

October 20, 2023

Date

ART OF DIVERSITY

Medical Sciences and Humanities Linguistic Validation & Translation | Healing Words
www.artofdiversity.org

PROGRAM

Linguistic Validation Training for Service Implementation at Commit Global fully compliant with international regulatory authorities. ISPOR, PRO Consortium, and FDA guidelines.

DESIGN & METHODOLOGY

- This LV Course is paced according to the timelines set by the LV Service Development & Implementation Project
- It consists of the following:
 - On-line group training
 - 40 Group training sessions of 2 hours maximum. (Supported by Power Point presentations as required)
 - Compulsory and suggested readings and videos
 - Tests for each module
 - Final practice and evaluation
 - A 30 min one-to-one mentoring session after the end of each module and a closing evaluation session with the trainer after successfully completing the on-line training
 - Duration of the course:
 - Dedication time: 100 hours (80 hours of sessions and 20 hours of self-study)
 - Estimated time for completion: 2-3 months

PROGRAM

- This LV training course is structured into 5 main modules with units:
- **Module 1: Introduction**
 - Unit 1: COAs and other measures – What are we working with?
 - Unit 2: Linguistic validation – Translation & cultural adaptation at a glance
 - Unit 3: LV Process - A snapshot
 - Unit 4: A first glance of the role of the key performer in the LV process, the linguistic validation consultant (LVC)/in-country consultant/in-country team leader/cognitive debriefer and on the LV in-house members' roles
 - Unit 5: Implementing the LV service – Staples
 - Test for module 1 & recap session
- **Module 2: LV Concept**
 - Unit 1: COAs, types, and other measures
 - Unit 2: Linguistic validation: the concept
 - Unit 3: LV Service team roles
 - Unit 4: Human resources: vendors (the LVC's role and other service providers)
 - Unit 5: Technical resources
 - Unit 6: Quality control
 - Unit 7: Marketing and service positioning
 - Unit 8: Speaking with clients about the LV service
 - Test for module 2 & recap session
 - 30 min one-to-one sessions

Module 3: LV Project Methodology

- Unit 1: Preparation
 - Pre-launching
 - Budget and costs calculation for the commercial proposal to the client
 - Launching
 - Project timeline planification
 - Source file preparation for use in CAT tool (segmentation, task assignment, etc.)
 - Vendor recruitment
 - Recruitment of in-country linguistic validation consultants (LVCs), translators, reviewers, clinicians, cognitive debriefing outsourcing (if necessary)
 - Budget & PO preparation for vendors
 - LV process file preparation for each stage and instructions
 - Translatability assessment
 - Concept elaboration
 - Recap session and Q&A
 - Unit 2: LV Process
 - Forward Translation (FT) & reconciliation
 - Backward translation (BT) & BT analysis - Harmonisation
 - Cognitive debriefing & interviews
 - Clinician review
 - Review & final check
 - Recap session and Q&A
 - Unit 3: Finalisation
 - Final report & certification
 - Internal assessment report
 - Unit 4: Migration & electronic implementation of eCOAs
 - Test for module 3 & recap session
 - 30 min one-to-one sessions
- **Module 4: LV Project Workflow**
 - Unit 1: Stage 1 - Preparation: workflow for each team member and vendors. Tasks and deliverables
 - Unit 2: Stage 2 - LV Process: workflow for each team member and vendors. Tasks and deliverables
 - Unit 3: Stage 3 - Finalisation: workflow for each team member and vendors. Tasks and deliverables
 - Unit 4: Human & technical resources
 - Unit 5: Quality control
 - Unit 6: Marketing and service positioning
 - Test for module 4 & recap session
 - 30 min one-to-one sessions
- **Module 5: Practice and final evaluation**
 - Practice exercise and final exam with a simulated project
- **Final one-to-one mentoring session with the trainer**
 - A session with each team member individually in order to clarify his/her specific role and tasks and ensure comprehensibility of the training material and linguistic validation concept, process, and workflow as a whole

ART OF DIVERSITY

Medical Sciences and Humanities Linguistic Validation & Translation | Healing Words

www.artofdiversity.org