



 www.btechtranslations.com	 Via Antica Certosa 20, 14100 Asti, ITALY
 +39 340 6095295	 +39 0141 320266
 marialuisa@btechtranslations.com	 www.linkedin.com/in/italianmedicaltranslations
 VAT ID: IT01175640059	

Over 25 years of experience as a full-time **English-Italian** freelance translator. Ongoing cooperation with CROs, pharma-companies, medical-device manufacturers, and quality-conscious translation agencies worldwide.

Areas of Specialization

Medicine, Pharmacology and Medical Equipment Translations

- **Clinical Trials, Research** - Translation of study protocols, synopses, informed consent forms (ICFs), patient diaries and questionnaires, case report forms, safety reports (SAEs, SARs, SUSARs), 'Dear Doctor' letters, and correspondence with Ethics Committees and regulatory authorities. Special focus on Clinical Outcome Assessments (COA), including Patient-Reported Outcomes (PRO) and electronic formats (eCOA).
- **Pharmacology, Drug Safety** - Translation of summaries of product characteristics (SmPCs), package leaflets (PILs), labelling, regulatory approval dossiers, technical documentation, educational materials, manufacturing-related documents (GMPs), and Safety Data Sheets (SDSs).
- **Medical Devices and In Vitro Diagnostics (IVDs)** - Translation of MDR/IVDR-compliant IFUs, and technical documentation, Post-Market Clinical Follow-up (PMCF) and Periodic Safety Update Reports (PSURs), internal corporate materials, and video scripts. Localization of medical software and medical device manufacturers' websites.
- **Nutrition** - Translation of technical documentation, promotional materials, and educational content on products for targeted populations (e.g., celiac disease, diabetes, IBS, metabolic syndrome).

Linguistic Validation Services

Comprehensive Italian LV services for Clinical Outcome Assessments (COAs), including Patient-Reported Outcomes (PROs), Clinician-Reported Outcomes (ClinROs), Observer-Reported Outcomes (ObsROs), and Performance Outcomes (PerfOs). Services are performed in accordance with ISPOR guidelines to ensure the cultural and conceptual equivalence of instruments. Activities include:

- Translatability assessments
- Forward and back translation, reconciliation
- Clinician input coordination
- Cognitive debriefing interviews (patients, caregivers, clinicians, or general population)

Equipment

CAT Tools

- SDL Trados Studio 2024, STAR Transit NXT.

I can also use MemoQ, XTM, Phrase and Wordbee, if provided with a license.

Other Software

- Office 365, Adobe Acrobat 9.0 Professional, Xbench, QA Distiller 9.

Education

- 2025. **ART OF DIVERSITY**, Linguistic Validation Specialization Course.
- 2013-2014. Milan. **CTI, post-Degree Master course for Medicine and Pharmacology Translators and Interpreters**. Final mark: 100/100.
- 1992-1997. **University of Turin, Degree in Modern Languages** (English and German), specializing in translation. Graduated summa cum laude.
- 1996, Turin. **SETL, Scuola Europea di Traduzione Letteraria**. Diploma in literary translation from US English.

Memberships

- **ITI (Institute of Translation and Interpreting)** qualified member (MITI). Membership number: **00021318**.
- **AITI (Italian Association of Translators and Interpreters)** qualified member. Membership number: **990035**.
- **ITI Medical and Pharmaceutical Network** member.

Insurance

Professional liability insurance covering the risk of legal assessments caused by service or professional mistakes, including GDPR-related risks.

Hobbies and Interests

- Yoga (qualified Hatha Yoga Teacher, YTT300+), Nordic walking, hiking
 - Voluntary blood and plasma donor (AVIS)
-

