Laura Carolina Collada Ali

Mobile: +39 320 367 1224 Skype: laura.collada Email: laura.collada@teksema.com

Professional Summary:

Medical Writer and Translator with a track record of delivering multi-lingual medical writing and translation services for leading pharmaceutical companies, medical device companies, clinical research organisations, and private clinicians on an international scale. Key strengths include: authoring regulatory documents including clinical trial protocols & clinical investigations plans and related documentation, clinical evaluation reports, post-market surveillance reports, manuscripts and documentation for lay audiences (patient information leaflets, summaries of safety and clinical performance) through maintaining up-to-date knowledge on industry regulations; creating scientific content to support development of new medical products; enhancing medical communications through creating engaging content for pharmaceutical, medical device and private medical clients; analysing complex subject areas across multiple medical fields to create content to serve needs of diverse audiences.

Key Expertise:

- Medical / Scientific Writing & Translation
- Research protocols and Investigation Plans, CERs, PMS, SSCPs & PMCF Plans/Reports
- Manuscripts and Publications
- Regulatory Document Production
- Translation, Proofreading, Editing & Copy Review
- Writing for Patients and Lay Audiences
- Clinical Areas – Oncology, Orthopaedics, Urology, Metabolic Diseases, Haematology, Palliative Therapies, Cardiology
- Languages: Spanish, English & Italian
- EMWA & AITI Certified

Career Highlights:

- A multinational medical devices company in the field of orthopaedics needed support to produce clinical evaluation reports (CERs), Summaries of Safety and Clinical Performance (SSCPs), Post-Market Clinical Follow-up Plans (PMCF Plans) and related Clinical Investigation Plans (CIPs = study protocol) on their products. Engaged as medical writer to write these documents both according to MedDev 2.7/1 revision 4 and to the European MDR. Analysed client materials; researched the scientific literature; wrote clinical evaluations, SSCPs, PMCF Plans and CIPs (>45) in collaboration with the client for different devices; and supervised the drafting of additional CERs under MDD and MDR written by other suppliers. Succeeded in delivering accurate and quality reports in a timely manner.
- A Biotech developing a device in the field of vascular surgery needed support to produce MDR documentation including CER, SSCP, PSUR, PMS Plan on their product. Engaged as medical writer, Analysed client materials; wrote the said documents in collaboration with internal team. Delivered in a timely manner quality documents.
- A leading pharmaceutical company required support to be provided to clinicians involved in writing a literature review in the field of oncology (NSCLC). Researched the scientific literature; selected most appropriate publications; extracted most relevant data; reviewed and edited the manuscript following the instructions for authors. Succeeded in continuously

liaising with authors to produce a relevant review that fills a gap in the present scientific literature.

Career history:

Jan 2008 to Present: Teksema: Freelance Medical Writer & Translator

Freelance Writer and Translator offering a range of multi-lingual medical writing, content writing, proofreading, linguistic consulting services and translation services to clients across multiple sectors.

- Work with multiple clients in the medical sector, providing medical writing services including Clinical Evaluation Reports (in orthopaedics), SSCPs, PMCF Plans, Post-Market Surveillance reports, scientific manuscripts, research protocols, literature searches and documentation for lay audiences.
- Build and maintain relationships with international clients and agencies to define requirements and create materials that deliver scientific rigour whilst being aligned to style and form specifications.
- Provide strategic consultancy regarding clinical research to effectively adapt and translate clinical research documentation encompassing research protocol and medical documents.
- Coordinate a 20+ team of medical writers for a medical communications agency; managing all medical writing projects for the company.

Key Projects and Achievements:

- Appointed as member of the Executive Committee of EMWA (European Medical Writers Association) in 2022 to lead professional Development Committee.
- Appointed as Professional Development Committee Member of EMWA (European Medical Writers Association) in 2018 to lead professional education webinar and manage online learning programme.
- Selected as EMWA Expert Seminar Series Committee Member is 2018 to organise and deliver several seminars, among which, 'Where is Publishing Going to?' including coordinating a team of 4 expert delegates.
- A multinational orthopaedics medical devices company: produced CER according to up-to-date regulations, wrote clinical research protocols and white papers on their products.
- Relevant biotech in cardiovascular area: produced SSCP, PMS Plan, PSUR.
- Leading pharmaceutical companies: run literature researches, wrote manuscripts and liaised with authors for their publication.
- Italian pharmaceutical company: covered scientific board/consensus meetings on antibiotics access and stewardship as medical writer.
- Spanish Haematology Society: Led key medical writing assignments and provided guidance on clinical research delivery.
- Italian Clinical Research Independent Organization: Oversaw key registration of clinical trials data in the US NIH international open registry (ClinicalTrials.gov).
- Research organisation: Wrote and edited full protocols, patient information sheets, clinical study reports and manuscripts.
- Leading technical translation agency: Supervised the translation of materials and revised content for a university-level haematology course from English to Spanish.

Jul 2003 to Sep 2011: GIMEMA Foundation: Project Manager/Regulatory Affairs Coordinator

GIMEMA is an Italian non-profit organisation led by prof. Mandelli, that coordinates clinical research and establishes diagnostic and therapeutic protocols in the area of adult haematological malignancies.

- Initially engaged as Project Manager and later assumed the additional role of Regulatory Affairs Unit Coordinator; reporting directly to the organisation's Managing Director.
- As Regulatory Affairs Coordinator, oversaw and led the development of protocol review documentation and obtained approval from Italian regulatory agencies and Independent Review Boards.
- Assisted the Managing Director in the hiring, training and managing a team of 5 staff based in Rome dedicated to regulatory affairs.
- Worked closely with global pharmaceutical firms, including Sigma-Tau, Celgene, Pfizer, Novartis and Bristol-Meyers Squibb, among others, to negotiate study contracts and coordinate funding for multiple research clinical trials.
- Reported to the Quality Assurance Director to support Quality Assurance activities.

Key Achievements:

- Played a key role in coordinating the annual ISO certification yearly audit including review and documentation of standard operating processes and procedures.
- Instrumental in delivering several major translation projects of medical texts and abstracts from Italian to English and English to Italian.

Earlier Career

04/2001 to 04/2003: **European Organisation for Research & Treatment of Cancer**: Administrator of the Protocol Review Committee

Education & Memberships:

- Bachelor's degree in Translation & Interpreting from University of Alicante (Spain)
- Advanced & Foundation Certificate from the European Medical Writers Association (EMWA)
- Pharmacology essentials (HMS Pro Harvard Medical School)
- Drug Delivery Systems (HMS Pro Harvard Medical School)
- Medical Devices continuous professional education: 'Medical Device Software: Complying with the MDR & FDA Regulations' (Management Forum); 'Understanding Clinical Evaluations' (MDTI); 'Literature Reviews for Medical Devices' (EMWA); 'How to write a Clinical Evaluation Report from MDR Perspective' (LS Academy); 'Management of claims and post-market vigilance within the Medical Devices industry' (EMWA); as observer and supervisor 'Writing Clinical Investigation Plans' (EMWA); Symposium 'MedDevDay' (LS Academy); Symposium 'Medical Devices and Technologies – Emerging Opportunities for Medical Writers' (EMWA); 'Basics of Writing for Medical Devices' (EMWA); 'Device drug and drug device combination products in the EI under the Medical Devices Regulation' (LS Academy)

- Pharma continuous professional development: 'Manuscript Writing: from Good to Excellent'; 'From Clinical Study Report to Manuscript'; 'Clinical study reports – Mastering the Essential Skills'; 'Manuscript Writing'. (***Full List of Workshops and Seminars available on request***)
- Member of EMWA; Education Officer and member of the Executive Committee
- Member of EMWA's Medical Devices Special Interest Group
- Member of EMWA's Medical Communications Special Interest Group
- Member of Italian National Association of Translators & Interpreters (AITI)
- Member of International Association of Translators and Editors in Medicine and Applied Sciences (TREMEDICA)

Industry Recognition:

- Appointed as MedDevDay Conference Scientific Coordinator, in 2021, 2022 & 2023
- Appointed as Professional Development Committee Lead of EMWA (European Medical Writers Association) in January 2022 and member of EMWA's Executive Committee.
- Selected as EMWA Expert Seminar Series Committee Member is 2018 to organise and deliver the expert seminars, including coordinating a team of 4 expert delegates. Have organized 'Where is Publishing Going to?' in 2019 and presently organizing 'Real World Evidence in Publications'
- Editor of the Translation Section of EMWA's Journal, *Medical Writing*, January 2015 to 2020
- Elected to PR Officer of the Executive Committee of EMWA, May 2013
- Speaker at Pethema Annual Meeting on Italian Academic Research, May 2013
- Instructor at GIMEMA Foundation Workshop on Informed Consent, March 2012
- Instructor at GIMEMA Foundation Workshop on Clinical Research, June 2011
- Instructor at University of Rome for Paediatric Haematology Master's Program, 2007/2009
- Instructor at National Medicine Academy on Clinical Trials Closure Logistics, 2007
- Instructor at University of Rome for Paediatric Haematology Master's Program, 2006
- Instructor at University of Rome Department of Cellular Biotechnology & Haematology, 2005

Publications:

- Collada Ali, et al. Post-market clinical follow-up insights. Medical Writing. 2022;31(2):45-47.
- Collada Ali. Book review: Software as a Medical Device, Regulatory and Market Access Implications. RAPS. Written by Koen Cobbaert, Gert Bos, Gloria Hall (editor). Medical Writing Journal; 2022;31(1):
- Collada Ali L. et al. First experiences writing summaries of safety and clinical performance for medical devices. Medical Writing Journal. 2020; 29(4):62-65.
- Collada Ali L., et al. New Documents Required by the Medical Device Regulation. Medical Writing Journal. 2020;29(3):24-29
- Collada Ali L., Johnson J., Whereat A. When less is more: Medical writers as guardians of curated content. Medical Writing Journal. 2019;28(3):24-27.
- Collada Ali L, Milani M. Medical writing and medical translation – two crossing paths. Medical Writing Journal. 2019;28(1):42-44.
- Collada Ali L, Gómez Polledo P, Harmer C. Revision: Parameters and practices within the translation industry. Medical Writing Journal. 2018;27(3):21-24.

- Collada Ali, L., Paoloni, F. English to Italian translation: 17 biostatistical terms that we are using in Itanglish that could just be used in proper Italian! Medical Writing Journal. 2016;25(3):75-76
- Collada Ali, L., Peterson, F. Authoring medical translations - to MD or not to MD? Medical Writing Journal. 2016;25(1):65-69

(***Full List of Publications available on request***)

Recommendations: (from LinkedIn personal profile)

'I have been working with Laura for the last three months. We are both working as consultants to a medical device company, and we were working together to finalise the CER's for a group of products. This is quite intense work because there is a deadline and they are large documents. I worked on several documents that Laura had written and / or edited. I have found her to be very capable and professional, and very knowledgeable in her field. Laura has a pleasing personality and this comes across in her communications. I have very much enjoyed working with her, and I know that the company we are working for greatly value her professionalism. I can strongly endorse her capabilities in the fields of medical writing and medical device regulation.' **John Scott, MD, Independent Consultant in Medical Devices**

'Working with Laura is a pleasure. Laura's work is extremely accurate and efficient. Laura has a very nice approach in any circumstances with the different stakeholders. The project could be successfully achieved in a friendly setting. I highly recommend Laura for medical writing support,' **Estelle Cassoly, Dr. sc. Nat., Medical Affairs Oncology, Takeda, Switzerland**

'I had the good fortune to work with Laura for my first scientific publication project at Recordati. She is an experienced and passionate medical writer with a deep knowledge on clinical trials. I was impressed by Laura's ability to deal with difficult situations, staying calm, and solve problems before they even appear. She is an excellent team player and I'm looking forward to working with her on a new project' **Valentina André, Corporate Medical Affairs, Recordati S.p.A., Italy**

'Laura is a highly skilled medical writer in both Spanish, English and Italian. Having worked with her on numerous projects in both Spanish and English, I'm impressed with her understanding of medical information and ability to simply complex matters sufficiently for diverse audiences. Laura is collaborative, great at meeting demanding deadlines, and an overall pleasure to work with' **Ben Gallarda, Associate Director, Oncology Content Strategy, Aptus Health, US**