TARGETED REGULATORY WRITING

Dr. Sigrun Niemitz

Phone +49 (0)4542 90 64 408
Mobile +49 (0) 174 37 39 497

Stecknitzweg 13
23879 Mölln, Germany

sigrun.niemitz@gmx.de
www.regtarget.com

CURRICULUM VITAE

Sigrun Niemitz, PhD

SUMMARY OF EXPERIENCE:
Experience in writing and editing miscellaneous documents within Medical Writing and coordinating large narrative projects (2 years at PAREXEL Int GmbH). Experienced in design and compilation of regulatory documents, (2.5 years at PAREXEL Int. GmbH). Several years of leadership of the department Quality Management with responsibility for the appropriateness of processes and the reliability and completeness of data. Project leader for Phase I and IIa trials with special focus on regulatory requirements (4 years at PAREXEL Int. GmbH).

PROFESSIONAL EXPERIENCE:

Freelance Regulatory and Medical Writer
- Writing of CSRs (all phases), IMPDs, IBs, SmPCs, PILs, safety narratives, study protocols and amendments and PSURs
- Editing/proofreading including source data verification of miscellaneous documents
- Regulatory compliance services

Associate Manager Medical Writing Services, PAREXEL International GmbH; Berlin, Germany
- Writing and editing of miscellaneous documents within Medical Writing
- Serve as primary contact for standalone MWS programs
- Coordinator and Lead MW for narrative projects
- Monitor project timelines and budget

Director Project Quality Management, PAREXEL International GmbH
- Daily management of the Quality Management Group as well as formulating and executing the long-term strategy of the mentioned group and aligning this to the overall Clinical Pharmacology Unit strategy.
- Verification of the fitness of the systems and processes to generate reliable, accurate and complete data and protect the wellbeing of trial subjects during the conduct of phase I/II/III clinical trials.

Regulatory Consultant, PAREXEL International GmbH
- Design and compilation of regulatory documents (e.g. IMPD) under limited supervision
- Design and completion of strategic regulatory development plans
- Review of key technical documents
- Preparation, review, and compilation of regulatory applications including investigational and marketing applications
- Management of project team, timelines and budgets
- Presentation of regulatory/technical information at meetings

Project Manager PAREXEL International GmbH
- Management of phase I and IIa clinical trials with regard to study conduct, timelines, regulatory issues and budgets

Medical writer (freelancer), Phytopharm Consulting, Berlin, Germany
- Writing of expert opinions and summary of product characteristics for herbal drugs

Medical writer (freelancer), Blackwell for Science, Berlin and Brockhaus, Mannheim, Germany

- Editing / proofreading of scientific publications
- Translation of manuals from English into German

Assistant of Science, Humboldt-Universität, Department of Oncology, Berlin, Germany

- Cloning of plasmide and viral vectors
- Transfection of human cells
- Establishing of primary cell lines

EDUCATION:

Free University of Berlin, Germany, December 1993 - May 1996, Doctorate in Biology, *Summa cum Laude*

Study of Biology, College Free University of Berlin, Germany; April1987 - December 1993; Master's Thesis in Biology

High school, Silbermann Abendgymnasium, Berlin, Germany; Leaving Exam, academic standard required for university entrance, 1983 – 1986

FURTHER PROFESSIONAL EDUCATION

Certificate of Accomplishment: Medical Writing. APPOLLON Hochschule der Gesundheitswirtsachaft

Certificate of Accomplishment: Clinical Research and Regulatory Affairs: Deutsche Universität für Weiterbildung

Member of the European Medical Writer Association (EMWA)

During employment with PAREXEL(July 2000 – March 2016) yearly participation in GCP and AMG training

Regular specific Medical Writing training from Nov 2013 – March 2016 at PAREXEL.

LANGUAGE SKILLS:

German:	Mother tongue
English:	Writing, reading and speaking fluently

PUBLICATIONS:

Ebert O., 1997. Lymphocyte apoptosis: induction by gene transfer techniques, Gene Therapy (England), 4(4) p296-302

Finke S., 1998. Increase of proliferation rate and enhancement of antitumor cytotoxicity of expanded human CD3+ CD56+ immunologic effector cells by receptor-mediated transfection with the interleukin-7 gene., Gene Therapy (England), 5(1) p31-9

Finke S., 1997. Increase of cytotoxic sensitivity of primary human melanoma cells transfected with the interleukin-7 gene to autologous and allogeneic immunologic effector cells, Cancer Gene Therapy (United States), 4(4) p260-8

Schmidt-Wolf I.G.,1999. Phase I clinical study applying autologous immunological effector cells transfected with the interleukin-2 gene in patients with metastatic renal cancer, colorectal cancer and lymphoma, British Journal of Cancer (Scotland), 81(6) p1009-16

Niemitz C, Niemitz S (Editors), 1999. Genforschung und Gentechnik – Ängste und Hoffnungen, Springer Verlag

Zoll B., 1998. Generation of cytokine-induced killer cells using exogenous interleukin-2, -7 or –12, Cancer Immunology Immunotherapy (Germany), 47(4) p221-6