

Douglas Fiebig, PhD

Employment in Medical Writing

- Sep. 2002 – present** **Trilogy Writing & Consulting GmbH**
Frankfurt am Main, Germany
Managing Director
Medical writing consultant and senior medical writer responsible for planning, coordinating and writing of documents required for compilation of submission dossiers seeking marketing approval in the US and Europe.
- Jan. 2002 – Aug. 2002** **Covidence GmbH (CRO spinoff from Aventis Pharma)**
Eschborn, Germany
Senior Medical Writer
Same experience and responsibilities as at Aventis Pharma (see below)
- Sep. 1996 – Dec. 2001** **Aventis Pharma Deutschland GmbH (formerly Hoechst AG)**
Frankfurt am Main, Germany
Lead Medical Writer
Responsibility for writing the entire spectrum of clinical documents used for regulatory submission. As Lead Medical Writer: writing and coordinating clinical documentation for submission dossiers.

Employment in Scientific Research

- Jun. 1988 – Aug. 1996** **River Research Station, Max Planck Institute of Limnology**
Schlitz, Germany
Research scientist with responsibility for a research program investigating microbiological aspects of carbon dynamics in running waters
- Jan. 1984 – Dec. 1984** **Max Planck Institute of Cell Biology**
Heidelberg, Germany
Scientific assistant with responsibility for screening novel rape seed variants for specific toxins.

Education

- Jan. 1985 – Jun. 1988** **University of Wales, Bangor, UK, and
Institute of Hydrology, Oxford, UK**
Ph.D. in microbiology, organic chemistry and hydrology of groundwater and river sediments.
- Sept. 1982 – Dec. 1983** **University of Wales, Bangor, UK**
Master of science (M.Sc.) in Ecology
- Oct. 1979 – Jul. 1982** **London Guildhall University (City of London Polytechnic)**
London, UK
Bachelor of science (B.Sc. Honors) in Biological Sciences, graded: 2.1.

Professional Experience – Medical Writing

- Participation in internal (company) study, clinical, and project teams, coordinating medical writing aspects of preparing clinical regulatory documentation.
- Planning, writing, compilation, and timely completion of clinical study protocols and reports (all development phases), and investigator's brochures.
- Planning, writing, compilation, and timely completion of clinical summary documentation for European (MAA) and US (NDA) submission dossiers (including simultaneous MAA and NDA submissions).
- Coordination of medical writing aspects of post-submission activities (MAA and NDA): responses to agency questions, preparations for EMEA oral explanations and FDA Advisory Committee hearings (briefing documents, presentation slides).
- Indications: anti-infectives, asthma, rheumatism, metabolism, cardiovascular, CNS.
- Implementation and refinement of company standards for the preparation of clinical documentation. Member of the Aventis integration team for standard table outputs.
- Regular attendance of internal (company) and external training courses. Topics include: international clinical development, clinical expert report, common technical document, summary of product characteristics, investigator's brochure, pharmacokinetics, pharmacoeconomics, project planning.
- Member of the European Medical Writer's Association (EMWA). Workshop leader: "Medical writing between dossier submission and drug approval".

Professional Experience – Scientific research

- Formulation and organization of research concepts, successful procurement of funding for research projects (Max Planck Society for Promotion of Science, German Research Foundation).
- Basic and applied research in aquatic ecology (microbiology, organic and inorganic chemistry, hydrology) and cell biology.
- Design, implementation and successful conclusion of field and laboratory-based research projects in aquatic microbiology at the University of Wales, Bangor (UK), the Institutes of Hydrology and Terrestrial Ecology (UK) in Oxford and mid-Wales, the Woods Hole Oceanographic Institution (USA) in Alaska, and the Max Planck Institute of Limnology (Germany).

Communication skills (in addition to medical writing)

- Mother tongue: English; foreign languages: fluent German, basic knowledge of French.
- Presentation of research data and concepts to national and international audiences (seminars, conferences, invited lectures, workshops). A list of presentations can be supplied on request.
- Publication of scientific research papers in peer-reviewed international journals. A list of publications can be supplied on request.
- Refereeing of scientific manuscripts for various peer-reviewed international journals. 1992 – 2000: member of the Editorial Board of the international journal *Freshwater Biology* (Blackwell Science).

Computing skills

- Word processing, spreadsheet calculation, graphical presentation, statistical analysis, electronic archiving.

Finance

- Cost analysis and budget planning for medical writing and scientific research projects.
- Justification of research budget proposals to internal (institute, company) and external (research financing agency, client) reviewers.

Management

- Managing Director of Trilogy Writing & Consulting GmbH, a specialist medical writing consultancy.
- Supervision and support of technical and secretarial staff, contractors, students, and trainees in a variety of settings.
- Attendance of Provaldis training course *Fundamentals of Management*.

Personal

Born in Kingston-upon-Thames (UK) on June 6, 1960.