Marisa C. Greenfield, M.S.

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SUMMARY

Over 15 years of experience in the pharmaceutical/biotechnology industry. Demonstrated ability in critical evaluation and interpretation of experimental data. Sound knowledge of preclinical and clinical R&D and the overall drug development process. In-depth understanding of FDA/ICH guidelines, medical terminology, AMA editorial style, and MS Word including use of styled formatting. Excellent written communication, interpersonal and negotiating skills. Able to handle multiple competing priorities while remaining attentive to details. Excellent organizational, problem-solving, project management, teamwork, and leadership skills. History of successful supervision and coordination of writing projects, involving writing, editing, documentation quality management, and information research. Writing experience includes projects in diagnostic imaging (ultrasound and nuclear medicine modalities), surgical adhesion prevention, cosmetic dermal correction, vascular surgery, and the following therapeutic areas: lysosomal storage disorders/enzyme replacement therapies, oncology, cardiovascular, orthopedics/osteoarthritis, and Parkinson's disease.

EXPERIENCE

Independent Medical Writing Consultant March 2010-present
Greenfield Medical Writing Greater Boston Area, MA

- Provided medical writing expertise to clients working in oncology and specialty biopharmaceutical products
- Planned, wrote, and edited clinical trial protocols, abbreviated and full CSRs, patient discontinuation and safety narratives, and IBs
- Assisting manager of medical writing department in developing processes

Associate Director, Medical Writing 2009-2010
Principal Medical Writer 2006-2008
Senior Medical Writer 2002-2006
Medical Writer 2001-2002
Genzyme Corporation, Biomedical Data Sciences and Informatics Cambridge, MA

- Worked on the following products: mipomersen (ISIS 301012), Aldurazyme (laronidase), Synvisc (hylan G-F 20), hylastan (hylan G-F 20), Seprafilm (chemically modified hyaluronic acid/carboxymethylcellulose [HA/CMC]), Seprafilm II (chemically modified HA/CMC and glycerol), Sepraspray (chemically modified HA/CMC), Thyrogen (thyrotropin alfa), Carticel (autologous chondrocytes), Neurocell PD (porcine fetal neuronal cells), DC Fusion/Electrofusion cancer vaccines for renal cell carcinoma and melanoma, Hylaform (hylan-B gel), and Saphlite (retractor system for vascular surgery)
- Planned, wrote, and edited clinical trial protocols and amendments (Phase 1, 2, 3, and 4), abbreviated and full CSRs, patient discontinuation narratives, IBs, summary documents for global regulatory submissions (e.g., ISS, ISE, Executive Summary, Overall Summary, etc. for IND, IDE, MAA, BLA); posters and abstracts for national industry meetings
- Reviewed and critiqued statistical analysis plans (SAPs) including shell tables, figures, and listings; CRFs; NDA periodic safety update reports (PSURs); and Data Monitoring Board charters
- Helped prepare regulatory briefing documents and pre-meeting packages as well as responses to regulatory authorities' (e.g., FDA, MHLW) questions following submissions
- Prepared and participated in multiple Investigator meetings and calls in the USA and Europe with clinical/medical/marketing to discuss preliminary study results
- Wrote and edited manuscripts, abstracts and posters based on clinical trials for the medical/scientific community and for peer-reviewed journals; participated in publication team meetings

- **Aldurazyme (laronidase) approval** in USA (BLA) and Europe (MAA) in partnership with BioMarin Pharmaceutical Company, Novato, CA. Co-author of ISS and ISE, clinical pharmacology, pharmacodynamics, and human pharmacokinetics and bioavailability sections. Wrote 120-day safety updates on 3 CSRs, the Expanded Access Program, and an accompanying executive summary. QC'ed the entire Aldurazyme BLA including the ISS, ISE, Part IV Q 2 (additional analyses), overall summary, executive summary, package insert, risk/benefit, and pharmacologic class sections. Edited the MPS I MAA for the lead writer.
- **Hylaform (hylan B gel) approval** in USA in partnership with Inamed Corp., Santa Barbara, CA
- **Synvisc-One (hylan G-F 20) approval** in Europe and USA
- **Thyrogen (thyrotopin alfa for injection) approval** for use in thyroid cancer ablation in USA
- Provided input to project teams to achieve overall goals for creation of documents and regulatory submissions.
- Provided writing, editing, and quality review support to peers and guided junior medical writers and contract writers/organizations.
- Assisted manager of medical writing department, including developing processes (e.g., developing standard operating procedures (SOPs), style guide, templates), managing cross-project planning and resource allocation, and coordinating writing activities for clinical development programs including negotiating timelines and responsibilities with project teams
- Earned Genzyme Management Fundamentals Certificate through a series of in-house classes

Medical Writer, Clinical Research 1999-2001
DuPont Pharmaceuticals Company, Medical Imaging Division North Billerica, MA

- Worked on the following products: Definity® (perflutren lipid microspheres) and DMP 444 (glycoprotein IIb/IIIa platelet inhibitor)
- Wrote and edited Phase 2 and 3 protocols and amendments, CSRs, and an IB.
- Co-wrote and edited MAA and CPMP (Committee for Proprietary Medicinal Products of the EMEA) responses (DMP 115) with team members
- Provided writing, editing, leadership, and project management skills to ensure that all documents were accurate, clear, concise, and completed within established timelines. Guided documents through clinical, medical, regulatory, preclinical, pharmacovigilance, statistics, and marketing departments. Led team review meetings to ensure documents received critical and scientific review. Ensured high quality of reports through quality assurance reviews, and through resolution of comments.
- Edited documents to regulatory and company standards. Recommended design and format of clinical data displays. Interacted daily with project team members, discussing interpretation and presentation of efficacy and safety data.
- Trained for position of Clinical Research Associate and monitored clinical research sites – Yale (CT), U. Mass Medical Center (MA), Thomas Jefferson University Hospital (PA)
- Attended ultrasound imaging training, multiple clinical, writing, and regulatory affairs-related industry courses (Barnett/Parexel, PERI, DIA), and American Institute of Ultrasound in Medicine and Radiological Society of North America National Meetings

Staff Scientist, Discovery Research 1997-1999
Scientist, Discovery Research 1995-1997
DuPont Pharmaceuticals Company, Medical Imaging Division North Billerica, MA

- Synthesized and characterized novel therapeutic and diagnostic nuclear medicine imaging agents in support of pharmacology and biochemistry studies
- Published in peer-reviewed journals.
- Worked as lead LC-MS analyst for Inorganic Chemistry group. Proficient in HPLC, GC, GC-MS, FTIR, UV-VIS, AA, graphite furnace and ICP analytical techniques, repair and maintenance of HPLCs and LC-MS
- Trained new personnel, purchased supplies and capital equipment, organized workflow
- Safely handled radioactive materials
- Performed formulation development

- Attended relevant training courses (ACS Short Courses, Quincy College, Hewlett Packard, Perkin Elmer), Harvard Medical School Workshop in Clinical Nuclear Medicine
- Familiar with GLPs and applicable Codes of Federal Regulations
- Wrote pre-clinical experimental protocols and SOPs, quarterly report contributions, and OSHA documentation
- Acted as a clinical site liaison in USA and Switzerland
- Designed and implemented literature search strategies, reviewed/selected relevant articles for journal club

Chemist 1993-1995
Analytical Laboratory Technician 1992-1993
MTL-ACTS, Consumer Products Services Division of Bureau Veritas Brockton, MA
(formerly Merchandise Testing Laboratories, Inc.)

- Designed and established an analytical laboratory under the guidance of a senior chemist
- Conducted performance and quality testing of consumer products in compliance with applicable Codes of Federal Regulations, AOAC, ASTM, EPA and USP standard test methods. Products tested included hardlines (e.g., toys, furniture, tableware), softlines (textiles), and OTC pharmaceuticals and nutriceuticals.

Science Library Assistant 1991-1992
College of the Holy Cross Worcester, MA

- Assisted faculty, students and staff in performing literature searches and obtaining reference materials. Maintained an online database of library holdings. Performed administrative tasks.

EDUCATION

M.S. Chemistry, Honors, *cum laude* 2001
Northeastern University, College of Arts and Sciences Boston, MA

- Graduate level technical writing classes: Writing for the Professions: Science Writing, Scientific and Technical Editing, Managing Technical Publications

B.A. Chemistry 1993
College of the Holy Cross Worcester, MA

- Undergraduate MIT Child of Staff Scholarship (4 years), Immaculate Conception Parish Scholarship (1 year), Clark University Study in Luxembourg Grant (1 summer)

RELEVANT SKILLS

- Proficient speaking, reading and writing ability in Spanish and German
- Software experience includes: Microsoft Word, Excel, PowerPoint, Documentum and Livelink (document archiving systems), Adobe Distiller, FrontPage, FileMaker Pro (database design and maintenance), Canvas, HP ChemStation (instrument and data handling), DryLab, ChemDraw

AWARDS

- 30 BRAVO awards for significant contributions to the success of DuPont Pharmaceuticals Medical Imaging, including: reformulation support; formulation bioequivalence study; external parametric study; design, equip, and write SOPs for new isotope laboratory; training new employees; and supporting European Agency for the Evaluation of Medicinal Products (EMEA) Responses
- Genzyme Biomedical and Regulatory Affairs (BMRA) Vice President's Award; American Express Award from Biosurgery-Synvisc hip OVATION team; award in recognition for outstanding contributions to the MPS I Program; award in recognition of outstanding effort in bringing Hylaform to the U.S. market

MEMBERSHIPS

- American Medical Writers Association (AMWA) (Core Curriculum Certificate), College of the Holy Cross Career Advisors Network

Publications and references available upon request