

GreenTree Medical Writing, LLC

Leslie Charles, Medical Writer

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Education

B.S. (chemistry) University of Wisconsin-River Falls, River Falls, WI

M.S. (organic chemistry) University of Maryland-College Park, College Park, MD

Medical Writing Skills

- Experienced with writing pharmaceutical regulatory documents (eg, clinical study reports, protocols, informed consent forms (ICFs), investigator brochures, safety and efficacy summaries for NDA and CTD filings, clinical overviews, IND annual reports, 4-month safety updates, Development Safety Update Reports [DSURs], and regulatory deficiency responses).
- Experienced in preparing/submitting manuscripts, abstracts, posters, and slide sets for oral communications, publication planning.
- Experienced with ICH E3, ICH M4, GCP, AMA style, MS Office, Documentum, Coredossier.
- American Medical Writer's Association (AMWA) core curriculum certificate in Pharmaceutical writing.
- Six-sigma trained/ Green Belt certified.
- Comfortable working with international clients and under the strict regulations required by the pharmaceutical industry.
- Strong team leader and independent writer

Work Experience

April 2013- Current

Owner, GreenTree Medical Writing, LLC

- Produced many CSRs in therapeutic areas including oncology (including skin cancer s), cardiovascular, neuromodulation, pain, inflammation, metabolic disorders, malaria, spinal fusion, and fertility. I have also prepared manuscripts, literature reviews, and regulatory safety documents for devices including those for spinal surgery applications, intrathecal drug delivery, and deep brain stimulation. Other extensive project experience has included a mix of manuscripts, posters, and white papers for clinical reporting.

June 2012-March 2013 Senior Medical Writer (PAREXEL Intl.)

- Prepared regulatory documents such as protocols, ICFs, and benefit-risk evaluations for Periodic Safety Update Reports.
- Worked with many different client companies and met various quality and process standards in a challenging and dynamic environment.

May 2003-2007

Senior Medical Writer (3M Pharmaceuticals).

- Worked with cross-functional and global teams to prepare documents for the FDA and international regulatory agencies such as EMEA and the TGA (clinical study reports, clinical sections of annual reports, NDA clinical safety and efficacy summaries, CTD safety and efficacy summaries, and deficiency responses);
- Worked with internal and external authors to prepare and submit abstracts and posters for presentation at scientific conferences.
- Was the lead writer for 3M's Basal Cell Carcinoma program -required to track writer progress on various projects, keep writer's informed of program direction and decisions made by the clinical research project team (CRPT) , to update the CRPT with information relating to publications/strategy and writer timeline and resource issues

- Led 3M's clinical publication planning team which consisted of writers, clinical team members, and marketing. This team proactively planned and tracked the publication timing and strategy for 2 primary programs as well as several smaller ones with less mature clinical programs.
- Worked extensively with 3M colleagues around the world using communication tools such as netmeeting.
- Led a six-sigma greenbelt team to optimize our process for preparing the clinical sections of annual reports. Included drafting the new SOP and training the clinical group on the SOP.
- Led 3M Pharmaceuticals' process for posting clinical study results to clinicalstudyresults.org.

Jun 2000-May 2003	Advanced Medical Writer (3M Pharmaceuticals/Medical Operations Department).
Mar 1997-Jun 2000	Advanced Research Chemist (3M Pharmaceuticals/Drug Discovery).
Dec 1993-Jan 1997	Assistant Scientist (Pfizer/ New Leads Drug Discovery Department).
Dec 1991-1993	Masters thesis research toward the synthesis of macrocyclic lactones through carbon-carbon bond formation using TMS-Mn(CO) ₅ .
Sep 1991-May 1993	Graduate school teaching assistant for general chemistry and organic chemistry university students at the University of Maryland.

Authored Presentations

- **“Ethics and the Medical Writing Freelancer”** Leslie Charles. Orally presented at the North Central AMWA Chapter Fall Event Panel Discussion; University of St. Thomas, St. Paul, MN, September 24, 2008
- **“It’s Not Just for Manufacturing Anymore: Six Sigma Applications for Medical Writing”** Leslie Charles, Rhonda Dick, Anne Roush. Poster at AMWA 2004 Annual Conference
- **“New Selective IRM’s”** Leslie Charles, Phil Heppner; Poster at 3M 1999 Pharmaceutical Annual Lab review
- **“Combinatorial Chemistry Comes to Life in Drug Discovery”** Leslie Charles, Steve Crooks, Phil Heppner; Poster at 3M life Sciences Tech forum event
- **“Combinatorial Chemistry: 5-LO and PDE-IV Projects”** Steve Crooks, Leslie Charles, Phil Heppner, Peter Maye, Poster at 3M 1997 Pharmaceutical Annual Lab Review
- **“The High Speed Pursuit of EGFR-Inhibitors”** Leslie Meerdink (Charles), Beth Cooper, Lee Arnold, Cathy Diorio, Jim Moyer, Jim Hauske. Poster at Pfizer Drug Discovery technical event.

Authored Publications

- Charles L, Reidenbach F. Publication planners and medical writers: a natural alliance. *AMWA Journal* 2011;26:8-11.
- Charles LJ. AMWA Annual Meeting Open Session Review: How to Evaluate a Medical Writing Contract. *AMWA Journal* 2006;21:150-151.
- Crooks SL, Charles LJ. Overview of Combinatorial Chemistry. *Current Protocols in Pharmacology* (2000) 9.3.1-9.3.16 (supplement 10).

Drafted Publications (acknowledgement/writing assistance provided)

- Foley P, Merlin K, Cumming S, Campbell J, Crouch R, Harrison S, Cahill J. A comparison of cryotherapy and imiquimod for treatment of actinic keratosis: lesion clearance, safety, and skin quality outcomes. *J Drugs Dermatol* 2011;10:1432-1438.
- Zarutskie PW, Phillips JA. A meta-analysis of the route of administration of luteal phase support in assisted reproductive technology: vaginal versus intramuscular progesterone. *Fertil Steril* 2009; 92:163-169.
- Gollnick H, Barona CG, Frank RG, Ruzicka T, Megahed M, Maus J, Munzel U. Recurrence rate of superficial basal cell carcinoma following treatment with imiquimod 5% cream: conclusion of a 5-year long-term follow-up study in Europe. *Eur J Dermatol* 2008;18(6):677-82.

- Geisse J, Caro I, Lindholm J, et al. Imiquimod 5% cream in the treatment of superficial basal cell carcinoma: results from two phase III randomized, vehicle-controlled studies. *J Am Acad Dermatol* 2004;50:722-733.
- Sterry W, Ruzicka T, Herrera E, Takwale A, Bichel J, Andres K, Ding L, Thissen MRT. Imiquimod 5% cream for the treatment of superficial and nodular basal cell carcinoma: randomized studies comparing low-frequency dosing with and without occlusion. *Br J Dermatol* 2002;147:1227-1236.
- Shumack S, Robinson J, Kossard S, Golitz L, Greenway H, Schroeter A, Andres K, Amies M, Owens M. Efficacy of Topical Imiquimod Cream for the Treatment of Nodular Basal Cell Carcinoma: Comparison of Dosing Regimens. *Arch Dermatol* 2002;138:1165-1171.

Patents

- US 6,664,260 Heterocyclic Ether Substituted Imidazoquinolines. Issued Dec. 16, 2003
- US 6,670,372 Aryl Ether Substituted Imidazoquinolines. Issued Dec. 30, 2003
- US 6,677,348 Aryl Ether Substituted Imidazoquinolines. Issued Jan 13, 2004
- US 6,989,389 Aryl Ether Substituted Imidazoquinolines. Issued Jan 24, 2006

Scholarships and Awards

- 3M Pharmaceuticals IRM award-2005
- 3M Technical Circle of Excellence Award nominee-2003
- 3M Pharmaceuticals Recognition Award for Contributions to the Scientific Literature-2001
- 3M Language Society Student of the Year-2000
- 3M Research Scholarship-1990
- U.F.E. Inc. Scholarship-1989

Committees and Professional Organizations

- Editor, *Paws for Thought* newsletter, St. Croix Animal Friends (2014-current)
- Editorial Board Member-AMWA Journal (2010)
- Council of Science Editors (member 2009-2010)
- The International Publication Planning Association (member since 2009)
- American Medical Writers Association (member since 2000)
- American Medical Writers Association (AMWA) North Central Chapter Co-treasurer (2007)
- 3M IRM Award Selection Committee Officer (2006)
- AMWA North Central Chapter Treasurer (2005-2007)
- AMWA North Central Chapter Secretary (2001-2005)
- Technical Circle of Excellence Selection Committee (3M Pharmaceuticals, 1999)