

Michelle Zakson

Oak Park, CA 91377
www.linkedin.com/in/mzakson

mzakson@gmail.com
(732) 421-6453

PHARMACEUTICAL EXPERIENCE

Baxter, Westlake Village, CA

10 month contract, 2013-2014

Medical Writer/Communications Specialist Global Biotherapeutics

Project management for HyQvia[®], Kiovig[®], SUBCUVIA[®], and the FLEXBUMIN[®] franchises. Development of MMN and Alpha-1 expansions. Employment of publications SOP, best practices, and meeting/journal style to document management and of all deliverables.

- Manage projects by establishing records that track milestones and maintain compliance in departmental database, enhancing compliance across development of project(s).
- Collaborate with team, biostatisticians, MORE personnel and authors (both internal and external) to produce publications that are accurate and reflect the authors' intent.
- Work with graphics support to develop and print posters, check documents for quality control and modify via Illustrator, whereby, increasing effective development of presentations.
- Partner with Grants Department for Investigator Initiated Research (IIR) studies, to develop process for reporting metrics to Senior Leadership Team (SLT).
- Develop slide sets for publication process presentations, to enhance both successful and compliant development of publications.

AMGEN, Thousand Oaks, CA

2008 – 2012

Medical Writing Manager Global Medical Writing Department

Project management for the development of manuscripts, abstracts, and meeting presentations for Oncology therapeutic area products/pipeline molecules including Nplate[®], Neulasta[®], Vectibix[®], Rilotumumab, Ganitumab, Conatumumab, and Dulenermin. Strategic management that employed Amgen SOP, best practices, and journal style to the development of all deliverables. Management of vendors and independent contractors for the development of outsourced publication projects.

- Ensured that clinical scientific statements were conveyed clearly in publications, by involvement in SA Cross-functional meetings.
- Maintained tracking records and indexed documents in departmental database, to aid in compliance of all publications developed.
- Encouraged collaboration with team, biostatisticians, authors, GHE personnel, and graphics support, to produce publications that are accurate, reflect the authors' intent, and sustain Amgen scientific goals.
- Participated in task forces, whereby improving processes within the department.
- Tailored and delivered publication SOP presentations to influence adoption by cross-functional departments, enhancing compliance across target audience.
- Assisted with departmental interviewing, development, and on-boarding of new hires.

- Participated in coordination of conference coverage, to ultimately provide an executive summary for the division to inform them of the meeting activities.
- Informed UCLA students about the job of a medical writer, by acting as a panel member for career week seminars.

MERCK RESEARCH LABORATORIES, Rahway, NJ

1993 – 2008

**Assistant Medical Writer/Publications Specialist
Department of Medical Communications**

(2003 – 2008)

Wrote, edited and managed the development of abstracts, slide/poster meeting presentations and manuscripts for the Respiratory and Metabolism/Endocrine/Atherosclerosis-Cardiology groups. Coordinated franchise activities for Singulair[®], Vytorin[®], Januvia[®], Janumet[®], Propecia[®], Proscar[®], proprietary, pipeline and/or INDs (Investigational New Drugs).

- Ensured that the clinical research was conveyed clearly in publications, by participation in publication writing teams.
- Collaborated on current and/or upcoming projects, and developed timelines and plans for publication.
- Built relationships with internal and external collaborators, enhancing successful development of publications.
- Participated in Clinical Study Report (CSR) writing courses, to increase understanding of the development of these documents.

Staff/Research Biologist

Department of Human/Animal Infectious Disease Research

(1993 – 2003)

Tested parasitic agents for flea control as part of a drug discovery process (developed assays, and HPLC analysis etc.). Developed animal models for human and animal health care products/pipeline drugs. Reviewer for The Journal of Medical Entomology.

- Designed and managed experiments, conducted both in vivo and in vitro research, and developed drugs, with the goal of NDA submissions.
- Wrote and edited manuscripts in the field of Entomology, informing scientific public about laboratory findings.
- Evaluated author submissions to The Journal of Medical Entomology, determining the value of submitted documents as potential publications.
- Mentored summer interns, enhancing their development as researchers.

EDUCATION

MS, Entomology, Ohio State University, Columbus

BS, Entomology, Texas Tech University, Lubbock

PROFESSIONAL ACTIVITIES

Yellow Belt Training Certification

Six Sigma Tools, Lean Techniques, and Variation Reduction to reduce quality waste

Entomological Society of America (ESA) Member

Animal Alternatives Committee (Merck Research Laboratories)

Amgen Women's Interactive Network (AWIN) Networking and Membership Committee Member
Speed networking presentations (2008 – 2012)

International Society of Medical Publication Professionals (ISMPP)

Certificate of Excellence – 2010 Best in Best Practice Award

Member, American Medical Writers Association (AMWA)

Core Curriculum Certificate - Editing/Writing specialty

Poster presentation of publications SOP

Roundtable discussion leader

Roundtable session co-coordinator for the 2011 and 2012 annual meetings

PATENT

Cordelia G. Rasa, Harold W. Heimbach, Wesley L. Shoop, **Michelle Zakson-Aiken**.
2004. Flea feeding apparatus. U.S. Patent 0069235 A1, filed September 29, 2003, and
issued April 15, 2004.

Merck 2004 Animal Alternatives Award.

PEER-REVIEWED MANUSCRIPTS**Acknowledged (partial list)**

1. A retrospective study of patients' out-of-pocket costs for granulocyte colony-stimulating factors. Karen Tomic*, Stacey Long, Xiaoyan Li, An-Chen Fu, Tzy-Chyi Yu, Richard Barron. Published online before print January 24, 2013, doi: 10.1177/1078155212473001
2. Pegfilgrastim prophylaxis is associated with a lower risk of hospitalization of cancer patients than filgrastim prophylaxis: a retrospective United States claims analysis of granulocyte colony-stimulating factors (G-CSF). Naeim A, Henk HJ, Becker L, Chia V, Badre S, Li X, Deeter R. *BMC Cancer*. 2013 Jan 8;13:11.
3. Evaluation of bleeding-related episodes in patients with immune thrombocytopenia (ITP) receiving romiplostim or medical standard of care. Stasi R, Murali M, Michel M, Viillard JF, Giagounidis A, Janssens A, Legg J, Deuson R, Danese MD. *Int J Hematol*. 2012 Jul;96(1):26-33. Epub 2012 May 5.
4. The burden of immune thrombocytopenia in adults: Evaluation of the thrombopoietin receptor agonist romiplostim. Deuson R, Danese M, Mathias SD, Schoonen M, Fryzek J. *J Med Econ*. 2012;15(5):956-76. Epub 2012 May 23.
5. A novel approach to the evaluation of bleeding-related episodes in patients with chronic immune thrombocytopenia. Weitz I, Sanz MA, Henry D, Schipperus M, Godeau B, Northridge K, Gleeson M, Danese M, Deuson R. *Curr Med Res Opin*. 2012 May;28(5):789-96. Epub 2012 Apr 25.
6. Health-related quality of life in nonsplenectomized immune thrombocytopenia patients receiving romiplostim or medical standard of care. Kuter DJ, Mathias SD, Rummel M, Mandanas R, Giagounidis AA, Wang X, Deuson RR. *Am J Hematol*. 2012 May;87(5):558-61. Epub 2012 Mar 28.
7. Romiplostim dose response in patients with immune thrombocytopenia. Perez-Ruixo JJ, Green B, Doshi S, Wang YM, Mould DR. *J Clin Pharmacol*. 2012 Oct;52(10):1540-51. Epub 2011 Dec 13.
8. Elicitation of utility scores in Canada for immune thrombocytopenia treated with romiplostim or watch and rescue. Iskedjian M, Tinmouth AT, Arnold DM, Deuson R, Isitt JJ, Mikhael J. *J Med Econ*. 2012;15(2):313-31. Epub 2012 Jan 3.
9. Pilot study of the effect of romiplostim on child health-related quality of life (HRQoL) and parental burden in immune thrombocytopenia (ITP). Klaassen RJ, Mathias SD, Buchanan G, Bussel J, Deuson R, Young NL, Collier A, Bomgaars L, Blanchette V. *Pediatr Blood Cancer*. 2012 Mar;58(3):395-8. Epub 2011 Sep 9.
10. A randomized, double-blind study of romiplostim to determine its safety and efficacy in children with immune thrombocytopenia. Bussel JB, Buchanan GR, Nugent DJ, Gnarra DJ, Bomgaars LR, Blanchette VS, Wang YM, Nie K, Jun S. *Blood*. 2011 Jul 7;118(1):28-36. Epub 2011 Apr 18.
11. Investigation of the pharmacokinetics of romiplostim in rodents with a focus on the clearance mechanism. Wang YM, Sloey B, Wong T, Khandelwal P, Melara R, Sun YN. *Pharm Res*. 2011 Aug;28(8):1931-8. Epub 2011 Apr 8.
12. Pharmacodynamics-mediated drug disposition (PDMDD) and precursor pool lifespan model for single dose of romiplostim in healthy subjects. Wang YM, Krzyzanski W, Doshi S, Xiao JJ, Pérez-Ruixo JJ, Chow AT. *AAPS J*. 2010 Dec;12(4):729-40. Epub 2010 Oct 21.
13. Subcutaneous or intravenous administration of romiplostim in thrombocytopenic patients with lower risk myelodysplastic syndromes. Sekeres MA, Kantarjian H, Fenaux P, Becker P, Boruchov A, Guerci-Bresler A, Hu K, Franklin J, Wang YM, Berger D. *Cancer*. 2011 Mar 1;117(5):992-1000. Epub 2010 Oct 13.

Authored

1. Discovery of the development candidate N-tert-butyl nodulisporamide: a safe and efficacious once monthly oral agent for the control of fleas and ticks on companion animals. Meinke PT, Colletti SL, Fisher MH, Wyvratt MJ, Shih TL, Ayer MB, Li C, Lim J, Ok D, Salva S, Warmke LM, **Zakson M**, Michael BF, Demontigny P, Ostlind DA, Fink D, Drag M, Schmatz DM, Shoop WL. *J Med Chem*. 2009 Jun 11;52(11):3505-15.
2. Efficacy and safety of ezetimibe/simvastatin versus simvastatin monotherapy in hypercholesterolemic patients with metabolic syndrome. Feldman T, Ose L, Shah A, **Zakson M**, Meehan A, Johnson-Levonas AO, Maccubbin D, Tribble DL, Veltri E, Mitchel Y. *Metab Syndr Relat Disord*. 2007 Spring;5(1):13-21.
3. Efficacy and safety of ezetimibe/simvastatin co-administered with fenofibrate in mixed hyperlipidemic patients with metabolic syndrome. Gil-Extremera B, Mendez G, **Zakson M**, Meehan A, Shah A, Lin J, Mitchel Y. *Metab Syndr Relat Disord*. 2007 Dec;5(4):305-14.
4. Comparison of the lipid-modifying efficacy and safety profiles of ezetimibe coadministered with simvastatin in older versus younger patients with primary hypercholesterolemia: a post Hoc analysis of subpopulations from three pooled clinical trials. Feldman T, Davidson M, Shah A, Maccubbin D, Meehan A, **Zakson M**, Tribble D, Veltri E, Mitchel Y. *Clin Ther*. 2006 Jun;28(6):849-59.
5. Nodulisporic acid side-chain modifications: access to the 2", 3", 4", and 6" registers. Chakravarty PK, Shih TL, Colletti SL, Ayer MB, Snedden C, Kuo H, Tyagarajan S, Gregory L, **Zakson-Aiken M**, Shoop WL, Schmatz DM, Wyvratt M, Fisher MH, Meinke PT. *Bioorg Med Chem Lett*. 2003 Jan 6;13(1):147-50.
6. Nodulisporic acid B, B1, and B2: a series of 1'-deoxy-nodulisporic acids from *Nodulisporium* sp. Ondeyka JG, Dahl-Roshak AM, Tkacz JS, Zink DL, **Zakson-Aiken M**, Shoop WL, Goetz MA, Singh SB. *Bioorg Med Chem Lett*. 2002 Oct 21;12(20):2941-4.
7. Side-chain homologation of nodulisporic acid: synthesis of potent new dienyl derivatives. Ok D, Li C, Shih TL, Salva S, Ayer MB, Colletti SL, Chakravarty PK, Wyvratt MJ, Fisher MH, Gregory L, **Zakson-Aiken M**, Shoop WL, Schmatz DM, Meinke PT. *Bioorg Med Chem Lett*. 2002 Jul 8;12(13):1751-4.
8. Development of a mouse model to determine the systemic activity of potential flea-control compounds. Santora KA, **Zakson-Aiken M**, Rasa C, Shoop W. *Vet Parasitol*. 2002 Mar 20;104(3):257-64.
9. Synthesis of nodulisporic acid 2' '-oxazoles and 2' '-thiazoles. Berger R, Shoop WL, Pivnichny JV, Warmke LM, **Zakson-Aiken M**, Owens KA, deMontigny P, Schmatz DM, Wyvratt MJ, Fisher MH, Meinke PT, Colletti SL. *Org Lett*. 2001 Nov 15;3(23):3715-8.
10. Systemic efficacy of nodulisporamides against fleas on dogs. Shoop WL, **Zakson-Aiken M**, Gregory LM, Michael BF, Pivnichny J, Meinke PT, Fisher MH, Wyvratt MJ, Pikounis B, Schmatz DM. *J Parasitol*. 2001 Oct;87(5):1150-4.
11. Systemic activity of the avermectins against the cat flea (Siphonaptera: Pulicidae). **Zakson-Aiken M**, Gregory LM, Meinke PT, Shoop WL. *J Med Entomol*. 2001 Jul;38(4):576-80.
12. Systemic efficacy of nodulisporic acid against fleas on dogs. Shoop WL, Gregory LM, **Zakson-Aiken M**, Michael BF, Haines HW, Ondeyka JG, Meinke PT, Schmatz DM. *J Parasitol*. 2001 Apr;87(2):419-23.
13. Chemical modification of nodulisporic acid A: preliminary structure-activity relationships. Meinke PT, Ayer MB, Colletti SL, Li C, Lim J, Ok D, Salva S, Schmatz DM, Shih TL, Shoop WL, Warmke LM, Wyvratt MJ, **Zakson-Aiken M**, Fisher MH. *Bioorg Med Chem Lett*. 2000 Oct 16;10(20):2371-4.
14. Development of an assay for the screening of compounds against larvae of the cat flea (Siphonaptera: Pulicidae). **Zakson-Aiken M**, Gregory LM, Shoop WL. *J Med Entomol*. 2000 Jul;37(4):571-7.

15. Reproductive strategies of the cat flea (Siphonaptera:Pulicidae): parthenogenesis and autogeny? **Zakson-Aiken M**, Gregory LM, Shoop WL. J Med Entomol. 1996 May;33(3):395-7.
16. Effect of combing time on cat flea (*Ctenocephalides felis*) recovery from dogs. **Zakson M**, Gregory LM, Endris RG, Shoop WL. Vet Parasitol. 1995 Nov;60(1-2):149-53.
17. A further comparison of the thumb-counting and comb-counting techniques used to determine *Ctenocephalides felis* infestation levels on dogs. Gregory LM, **Zakson M**, Endris RG, Shoop WL. Vet Parasitol. 1995 Feb;56(4):349-52.
18. Evaluation of a single oral dose of lufenuron to control flea infestations in dogs. Hink WF, **Zakson M**, Barnett S. Am J Vet Res. 1994 Jun;55(6):822-4.
19. Fate of the benzoylphenyl urea CGA-184699 in the cat flea *Ctenocephalides felis* **Zakson, M.**, Hink, W. F. and MacKichan, J. J. Pestic. Sci. 1992 May;35: 117–123.