

Helen Nicely, Ph.D.

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SKILLS

- ◆ In vivo & in vitro scientific research
- ◆ Data analysis
- ◆ Clinical evaluation
- ◆ Medical writing, editing, PowerPoint preparations, QC & review
- ◆ Abstracts, posters, manuscripts & medical information letters
- ◆ Publications in market research
- ◆ Review papers & case reports
- ◆ Grant writing
- ◆ Regulatory writing: Protocols, CSRs, IB
- ◆ MSL mentoring
- ◆ Recruiting personnel
- ◆ Business development
- ◆ Market research & analysis, competitive intelligence
- ◆ Publication management
- ◆ Word, Excel, PowerPoint, Adobe Acrobat, Foxit PDF, Abby FineReader, Adobe-InDesign, Datavision, EndNote, Reference Manager, Ovid, Sigma Plot, Veeva

WORK HISTORY HIGHLIGHTS

Sr. Medical Writer/ Sr. Market Research Analyst

Nicely Done Research, Daly City

Feb 2013 to present

- Writing and submitting manuscripts, abstracts, slide sets, and posters on 4 pain therapeutics (using Adobe In-Design/Excel) to journals and congresses.
- Writing and submitting manuscripts, abstracts, and posters, with graph plotting in Sigma Plot and Excel for rare diseases, autoimmune diseases (tabalumab for multiple myeloma), bone (Forteo®, teriparatide for osteoporosis), muscle, joint diseases, and diabetes (dulaglutide for Type 1 diabetes) for US, China and Japan.
- Data analysis, clinical evaluation, and legal brief editing.
- For HighTech Business Decisions or AGY*: Market research, competitive intelligence*, analysis and report writing for dozens of repeat biopharmaceutical clients, contract manufacturing clients, medical devices, and original equipment manufacturers (OEM) within the printed-circuit-board industry. Presentation of market research results to clients. Analyzing and understanding market trends in biotechnology, pharmaceutical sciences, and high technology industries.

Sr. Manager Global Scientific Communications & Publications

Raptor Pharmaceuticals Inc., Brisbane

January 2016 to January 2018

- Planning, producing, writing, revising and submitting manuscripts, standard response letters, abstracts, slide sets and posters on Procysbi® for nephropathic cystinosis, Quinsair® for Pseudomonas aeruginosa-related lung infection in cystic fibrosis, Teprotumumab® for thyroid-associated ophthalmopathy, Krystexxa® for refractory gout, Actimmune® for chronic granulomatous disease, Ravicti® for urea cycle disorders, and Rayos®, Duexis®, Vimovo® for pain.
- Congress planning at US and Ex-US conferences.
- Continuing Medical Education grant synopses prepared for upper management review.
- Working knowledge of GPP3, ICMJE, Datavision, EndNote, Veeva, Outlook, PowerPoint, Excel.

Sr. Medical Writer/ Sr. Market Research Analyst

Nicely Done Research, Daly City

February 2013 to present (see above)

Publication Project Manager/Sr. Medical Writer/EndNote Librarian

Ipsen Biopharmaceuticals, Inc., Brisbane (contractor pre-LLC)

February 2011 to February 2013

- Management of MSLS for development of medical communication documents including posters and manuscripts relating to Increlex® for IGF-1 deficiency, Somatuline® for acromegaly and neuroendocrine tumors, and Dysport® for cervical dystonia.
- Congress planning
- Writing medical information letters for neurological, off-label queries regarding Dysport® & phase 4 Dysport® protocols. eCTD training for the submissions process.
- Preparation of monthly publication summaries, executive summaries, and dashboards.

Communications Director

Pacific Beach Coalition, a 501(c)(3), Pacifica

January 2007 to January 2014

- Project management of communications, including grant writing, blogs, email messages, press releases, and articles relating to Pacifica and Daly City's coastal environmental protection strategies.

Regulatory Medical Writer

(Ad hoc Interim Manager)

Scios Inc./ a Johnson & Johnson company, Fremont

Clinical Department

May 2005 to August 2006

- Regulatory documents were written and edited according to ICH guidelines and J&J PRD guidelines.
- Documents included phase 1 and phase 3 protocols for subcutaneous delivery of Natrecor® and an outcomes trial, respectively, and two clinical study reports (CSR) in phase 2 and 4, as well as updates of the Natrecor® investigator's brochure. One CSR involved a trial on subjects with congestive heart failure undergoing coronary artery bypass graft and receiving Natrecor® during anesthesia (NAPA). Another CSR involved the renal protection and diuretic effect of Natrecor® compared to furosemide.
- QC and QA of CSRs were conducted in collaboration with J&J Global Support QA department.
- Worked with a team to create SOP, template and guidance for clinical study report preparation.
- Helped beta-test a new in-house electronic document system, RREDS, based on Documentum software and later trained on final version.

Supervisor & ad hoc Interim Manager of 5 contract medical writers

Founder of Medical Writing Department

Reviewer of applicant directors' and medical writers' writing exercises.

EDUCATION

Ph.D. Ear, Nose and Throat Pathology, University College London, UK

Thesis: Primary Tissue Culture of Human Laryngeal Carcinoma and Interaction with Native Lymphocytes

B.S. Microbiology (with honors), University of Surrey, UK

Internship: forensic science at the Metropolitan Police Forensic Lab, London, England.

Thesis: Staphylococcus aureus: A Study Related to its Potential Use in the Forensic Examination of Face Masks

U.C. Berkeley Extension Courses: completed & passed:

- Grammar, Mechanics, and Usage for Editors, 2011
- Protocol Development, 2006

American Medical Writers Association (AMWA)

- Core Curriculum Accreditation (with a specialty in writing and editing), 2012

AWARDS

Tom Whitaker Pacific Beach Coalition Outstanding Member Award, 2018

All-One-Ocean Award, 2016

Dove Press: Favored Author Program Status for Yang Y, **Nicely H et al**, 2015 paper: In-patient cost of treating osteoporotic fractures in mainland China. 1052 article reviews in the first 12 weeks of publication.

New York, New Jersey Society of Interventional Pain Physicians. Pain Medicine Symposium 2015: Evolving Pain Therapies. E-Poster (Vanita Spagnolo, et al) awarded one of 4 top abstracts submitted: Dosage-dependent effectiveness of treatment of breakthrough cancer pain with fentanyl pectin nasal spray.

State of California Earth Hero Award, 2014: Communication Director for Pacific Beach Coalition (PBC) and founder of Mussel Rock Stars, a volunteer beach cleanup group.

American Diabetes Association Congress 2013: Best poster awarded for Skrivanek Z *et al*, 2013 poster: Dose-finding results in an adaptive trial of dulaglutide combined with metformin in type 2 diabetes (AWARD-5).

BIBLIOGRAPHY

provided upon request