Biomedical Consulting International, Inc.
REGULATORY CENTER OF EXCELLENCE

FUNDAMENTALS OF MEDICAL AND REGULATORY WRITING

October 6 -7, 2010 | Doubletree Hotel, Skokie, Illinois

FACULTY

Durisala Desaiah, PhD
Eli Lilly and Company
Indianapolis, Indiana

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Biomedical Consulting International, Inc.
Skokie, Illinois

PROGRAM OVERVIEW

In the current competitive environment, effective communication of research findings is the key for any individual or company to be successful. This training program is aimed toward teaching participants how to develop their written and verbal communication skills. With combined industry and academic experience of 60 years, the three speakers will provide you with the tools to help you develop effective writing of medical, scientific and regulatory documents, including manuscripts, abstracts, posters, oral presentations and dossiers for regulatory authorities (e.g., FDA). The speakers will use teaching techniques (both oral presentations and hands-on workshops) that are easy to learn and implement in your own settings. This 2-day course is divided into two parts: Part 1 will cover an overview of medical and regulatory writing and various processes and Part 2 will be devoted to the "how to" of writing these documents. At the end of this comprehensive course, the participants will be able to effectively write publication-worthy documents as well as appreciate what it would take to write clear and concise regulatory documents; additionally, the workshop participants will be able to gain a range of relevant practical writing and verbal communication skills.

Day 1
Overview of Medical and Regulatory Writing
Publication process
Types of documents
Presentations at scientific congresses
Building a writing style
Getting started in medical writing
Hands-on writing exercises (optional to participants)
Organize data and thoughts
Convert data into graphics

Day 2
Scientific/Medical Writing
Manuscript (basic science, clinical trials, and reviews)
Congress abstract
Congress poster
Slide set
Oral presentation
Annotations
Peer review process and editing
E-submissions to journals and congresses
Response to reviewer comments
Verbal presentation skills
Hands-on writing exercises (optional for participants of web-based training)

Regulatory Writing
Cover Letter
Reviewer's Aid
Reviewer's Roadmap

Nonclinical Pharmacology-Toxicology
- Overview and Integrated Summary

Clinical
- Investigator Brochure
- Informed Consent
- Integrated summary of efficacy (ISE)
- Integrated summary of safety (ISS)
- Overview and Summary

go to www.biomedconsult.com for more details and registration information
or contact Yelena Sheftelevich at yelena.sheftelevich@biomedconsult.com or 847-972-6903

Durisala Desaiah, PhD

Dr. Desaiah is a highly skilled medical writer with over 35 years of experience. While at Eli Lilly & Company, he has been in positions of increasing responsibility, most recently as the Scientific Communications Consultant. His duties included planning, writing, and publication of manuscripts, abstracts, and scientific posters in osteoporosis, neuroscience, and oncology; advising Lilly affiliates in the development of clinical studies and disclosures; and, planning and developing study slide sets, manuscript slide kits, and providing know-how for global slide kits. He provides training in medical writing to contract medical writers and to medical personnel at different Lilly affiliates.

Prior to joining Eli Lilly, Dr. Desaiah was a Regulatory Affairs Specialist at ProEd Communications, a CRO. In this role, he was responsible for writing clinical study reports, updating annual reports, writing commercialization documents and advising pharmaceutical clients in the preparation of FDA advisory committee presentations; expertise in pre-clinical studies of pharmaceuticals, especially the recombinant products; and, reviewing and evaluating non-clinical (pharmacology and toxicology) study reports, scientific and technical documents.

While at Baxter Healthcare Corporation as Manager of Global Regulatory Affairs, Dr. Desaiah conducted safety evaluation and risk assessment of major components of pharmaceutical formulations, develop documents for IND and BLA submissions of biologics in CTD format, and developed knowledge of ICH, FDA and CTD guidelines in the preparation of IND and BLA submissions.

Dr. Desaiah was a tenured professor at the University of Mississippi Medical Center before retiring in 2001. During his time there, he led research programs that included designing and conduct of toxicology studies *in vitro* and *in vivo* in regard to mechanisms of action, kinetics, ADME and other end points in mammalian species; developed and followed laboratory protocols in compliance with the guidelines of NIH and EPA; and had twenty-five years of hands on experience in conducting the toxicology, molecular and biochemical studies on the mechanisms of action of drugs and chemicals, and neurodegeneration with particular emphasis on second messengers including calcium and nitric oxide. He has published 192 full-length papers in peer reviewed scientific journals and 320 abstracts that were presented as posters and oral presentations at scientific meetings, and he has received numerous honors and awards, and has been an invited speaker for many symposia and seminars. In 1999, he was elected as fellow in the Academy of Toxicological Sciences.

Dr. Desaiah received his B.S. in Biology, M.S. in Zoology (Entomology) and his Ph.D. in Zoology (Toxicology) at Osmania University, Hyderabad. Dr. Desaiah did his post-doctoral research at the University of Minnesota, Mississippi State University, and University of Mississippi Medical Center.

Satish Tripathi, PhD

Dr. Tripathi is the founder and president of Biomedical Consulting International, Inc. As a board certified regulatory affairs professional with a doctorate in the cardiovascular area, Dr. Tripathi has extensive Global R&D experience spanning 26 years. He has over 19 years of regulatory experience with both development and marketed products. Dr. Tripathi has extensive ICH experience, as well as worldwide labeling and promotion experience.

Additionally, Dr. Tripathi has extensive experience in global regulatory strategy and in the review and evaluation of regulatory documents, both in U.S. as well as internationally. Dr. Tripathi has pre-clinical and clinical experience, including that which is related to writing and regulatory review. He has extensive GCP, GMP and GLP experience. Dr. Tripathi has reviewed and evaluated safety and efficacy aspects of acquisition/licensing candidates and participated in due diligence of CRO companies identified for acquisition.

Dr. Tripathi has experience in regulatory review and evaluation of First-in-man candidates, and experience in the review of electronic document management systems (EDMS).

Prior to establishing BCI, Dr. Tripathi was the Vice-President of Global Regulatory Affairs and Quality at Kendle International. There, he provided regulatory leadership to the department of Regulatory, Quality and Safety.

Dr. Tripathi worked at Pfizer as Director of Worldwide Regulatory Strategy. While in New York, he was the Global Regulatory Leader for Endocrinology and a member of numerous committees, including the Global Steering Committee and Medical R&D Committee. At the Kalamazoo, MI office, Dr. Tripathi led global regulatory development of a portfolio of over 30 biologics and drugs.

Before joining Pfizer, Dr. Tripathi was Director of Global Regulatory Affairs at Baxter Healthcare Corporation. He was responsible for all aspects of global regulatory submissions, including Pre-IND, IND/CTX/CTA in U.S., Canada, Europe, and Japan. He was also responsible for performing a detailed review of EDMS systems for use by R&D, Regulatory, and Clinical Affairs. Dr. Tripathi represented Regulatory Affairs (Bio-Science Division) on corporate-level committees, such as Business to Consumer and e-commerce; he also chaired the Regulatory and Quality (CMC) Committee.

Previously, Dr. Tripathi was a Senior Manager of Clinical Regulatory Affairs at Bracco Diagnostics, where he developed and implemented strategies for preclinical and clinical development of drugs with Bracco's upper management and FDA. He also provided regulatory advice as well as reviewed and prepared regulatory submissions. Dr. Tripathi was also responsible for evaluating safety of new drug candidates for First-in-Man determination.

Dr. Tripathi was Reviewer of Pharmacology and Toxicology at USFDA. During this time, he reviewed IND, NDA, and DMF as well as related Amendments and Supplements. Dr. Tripathi represented the FDA in various meetings with Industry, and gained further experience on numerous committees, such as Inter-Center Working Group on Tissue Engineering.

Dr. Tripathi received his PhD from the University of Glasgow, Scotland, UK and conducted postdoctoral research at the Massachusetts Institute of Technology, Emory University Medical School and Medical College of Wisconsin. He has also taken on roles in public policy, such as Congressional Liaison Committee District Coordinator.