iJOBS Workshop: Regulatory Writing

Tuesday January-30th, 2018
5:30-8:30pm
Deans Conference Room 123, RWJMS Research Tower,
675 Hoes Lane West, Piscataway, NJ 08854.

Regulatory Writing Panelists

Arthur Gertel
Principal at MedSciCom, LLC
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Arthur Gertel is currently the principal at MedSciCom, LLC, an agency providing independent and collaborative strategic regulatory consulting and medical writing services, as well as Data Safety Monitoring Board (DSMB), SOP preparation, and Bioethics expertise. Arthur has more than thirty-five years of increasingly senior-level positions in the pharmaceutical industry, where he had an extensive history of overseeing preparation of large, complex corporate and regulatory documents, with particular expertise in developing strategic approaches to developing and registering new therapies at companies such as Schering-Plough, Hoffman-La Roche and Revlon. Arthur has held leadership positions in many professional organizations, including CDISC (Clinical Data Interchange Standards Consortium), ACRES (Alliance for Clinical Research Excellence and Safety), AMWA (American Medical Writers Association), GAPP (Global Alliance of Publication Professionals). He attended graduate school at NYU, New York Medical College and Temple University.

Diane Petrovich, PhD
Head of Medical Writing Infectious Diseases and Vaccines
Merck & Co.
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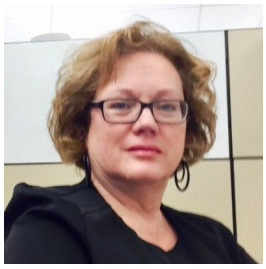

Diane Petrovich is currently Head of Medical Writing Infectious Diseases and Vaccines at Merck. In this role, Diane works with the global head of Medical Writing and has established a Medical Writing unit for the Infectious Diseases and Vaccines therapeutic area. She takes leadership responsibility for medical writing support of 100+ regulatory documents a year, including clinical study reports (CSRs), clinical summaries for registration dossiers, briefing books, and other clinical documentation. Before joining Merck, Diane had worked at PRA Health Sciences, Novo Nordisk, and Wyeth-Ayerst Research. Diane received her PhD

degree in Pathology from Temple University of Medicine at Philadelphia and completed her postdoctoral training in Biophysics at Albert Einstein College of Medicine in New York.

Ketna Volcy, PhD
Medical Writer Consultant
ketvolcy@gmail.com

Ketna Volcy is currently a medical writer providing medical writing deliverables for the development of clinical efficacy programs and for the management of product safety while working in cross-functional teams. Her responsibilities include development of module 2 summaries and product labeling to support new drug application (NDA) submissions. She had previously worked as a regulatory medical writer at Indivior, where she developed clinical study protocols and investigator's brochures according to ICH and GCP guidelines, and company SOPs. Ketna received her PhD degree in Microbiology from University of Rochester School of Medicine and Dentistry and completed her postdoctoral training at University of Pennsylvania School of Medicine.

Lecturer

Rupal Patel
Senior Manager, Regulatory Affairs
Chugai Pharm
rupalpatelhrc@gmail.com

Rupal Patel is a currently Senior Manager of Regulatory Affairs at Chugai Pharm. In this role, she supports and provides regulatory strategy input for multiple development projects in different therapeutic areas, facilitating phase transfers. Rupal is also an adjunct assistant professor at Rutgers in the Master of Science in Clinical Trials Sciences Program. She has 10 years of regulatory affairs experience and 20+ years of professional experience in pharmaceutical industry including Bayer Schering, Sanoi-Aventis, Celgene, Novo Nordisk. Rupal received her Bachelor of Science in Chemistry from Rutgers University and later obtained MBA in Finance from Fairleigh Dickinson University.

AMWA Speaker

Qing Zhou, PhD
President, AMWA Empire State – Metro New York Chapter (AMWA-NY)
qzhou.writer@gmail.com

Qing Zhou grew up in China and came to the United States for her PhD study in Molecular Pharmacology at Purdue University. Qing found her passion for scientific communication and joined Cook Research Incorporated, a medical device company, as a scientific communications scientist. She has written regulatory and scientific documents on a wide range of medical devices, and her current main responsibility is to plan and develop scientific publications arising from clinical studies of innovative endovascular therapies. Qing has been an AMWA member since 2006 and has volunteered in various positions at local chapters as well as at the national organization level. She currently serves as the president of AMWA-NY.

Moderator

Doreen Lechner, PhD
Program Director and Assistant Professor, Clinical Trial Sciences
BioPharma Educational Initiative, Rutgers University
lechnedw@shp.rutgers.edu

Doreen Lechner is the Program Director of the Master of Science in Clinical Trial Sciences Program at School of Health Professions (SHP), the Program Director of the Biopharma Educational Initiative, and an Assistant Professor in the Department of Health Informatics at Rutgers. She brings over 30 years of pharmaceutical industry experience in all areas of clinical trial, regulatory and drug safety to the program. Doreen holds the recognition as “One of the 100 Most Inspiring People in the Life-Sciences Industry” by PharmaVoice. She received her doctoral degree in Pharmacology from Rutgers University - Graduate School of Biomedical Sciences.