



### **iJOBS Simulation: Regulatory Writing**

Wednesday December 4, 2019

6-9pm

Newark



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Aaron Bernstein is a consultant Medical Writer supporting the strategic development of all clinical regulatory documents. He has 30 years of experience in the pharmaceutical industry leading the planning and writing of new drug applications to global health authorities. Dr. Bernstein has led departments of Medical Writing, Project Management, Quality Control, Publishing, and Strategic Communication in several international pharmaceutical companies. Dr. Bernstein is a founding member and past president of the European Medical Writers Association. He is an active member of the American Medical Writers Association, where he frequently presents on topics of medical writing standards and processes, as well as, drug regulation and drug development. Dr. Bernstein is a primary contributor to the development of the CORE Reference tool and website, a detailed companion to the ICH E3 guideline on Clinical Study Reports. He has recent publications in peer reviewed journals on the topic of clinical trial transparency and the production of clinical study reports.



**Marjorie Winters**

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Marjorie Winters, a freelance medical writer and editor heads Winters Editorial Services. She received her BA from UCONN (1963) switching to a major in English from a mathematics major, having taken mathematics, statistics, and science courses. She went on to be a definer for a college dictionary and built her editing and writing skills through a series of editorial jobs that culminated in a full-

time position as a clinical writer for Hoffmann-la Roche. During her writing and editorial “training years” and subsequent positions, she worked as a medical writer for other big pharmas, CROs, and as a free-lance editor and writer of peer-reviewed medical articles and allied topics. Documents she wrote or edited included IBs, protocols, clinical Statistical Reports, regulatory agency responses, manuscripts, abstracts, medical professionals and salesforce communications. She joined the Empire State-New York Metropolitan (NY) Chapter of AMWA at the recommendation of her manager at Hoffmann-la Roche. Her volunteer history with AMWA includes serving on the Executive Board as secretary and on the Program Committee; co-chair of the programming committee, and other tasks. At the AMWA national level, Ms Winters served several times as Roundtable Leader, member of the Education Committee, and currently as a member of the “Communications Committee.” She was delighted to be honored to as an AMWA Fellow in 2018, and plans to continue her service to the AMWA community.