Clinical Trials Project Management

INSTRUCTORS

Kim Walker, MS, RAC (US & EU)
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Kim Walker, MS, RAC is an independent Global Regulatory Affairs and Quality Assurance Consultant. In her consulting practice, she assists clients with pre- and post-market regulatory and quality system issues. Her work experience includes environmental chemistry, veterinary science, blood banking, clinical laboratory science, infectious disease assay research, microbiology, surgical assistant, IVDs, biologics, pharmaceuticals, combination products, and medical devices in university, start-up company, and large company environments.

Kim has served on the Orange County Regulatory Affairs Discussion Group (OCRA) Program Committee since 2003. Additionally, she served on the OCRA Board of Directors 2004-2010 and was the 2008-2009 President. Kim participates on the CLSI Point of Care Testing, Quality Systems, EP9, and Process Improvement working groups. She has managed, presented at and/or moderated at several professional conferences and educational institutions on clinical, regulatory, and quality topics. She also has participated in the SDRAN Mentoring Program since 2009.

Currently, Kim is participating on the CSUPERB Advisory Committee and Development Team for the Project Management in Clinical Trials certificate program through the California State University system. She is the instructor for the Pre-Market Submission class and the co-instructor for the Regulatory Requirements for Medical Products class in the certificate program. Kim is also an instructor for the Medical Products Development certificate program at the University of California Irvine Extension.

She achieved both the US and EU RAPS Regulatory Affairs Certifications. Kim received the 2008 Leonard Stauffer Award from RAPS in recognition of her contributions to mentoring and furthering regulatory professional education development. She graduated from Auburn University with a Bachelor of Science degree in Bio-Medical Sciences and graduated with a Master of Science degree in Regulatory Affairs from San Diego State University.

Katie Smith, Ph.D.

Katie M. Smith, PhD is a Biotechnology Consultant with a focus on clinical research and regulatory affairs. Katie has 25 years’ experience in both the pharmaceutical and in vitro diagnostic device industries and has worked 20 of those years in the San Diego area.

Prior to consulting, Katie held the position of Associate Director, Clinical Operations at Biogen Idec Pharmaceuticals, San Diego. In this role, she led cross-functional teams to devise clinical development strategies and to execute clinical studies. Prior to this, Katie served as Sr. Director, Clinical Research and Regulatory Affairs at Prometheus Laboratories. In this role she developed a clinical research group and operating procedures from the ground up.

Other positions Katie has held were, Director of Clinical Research, Gen-Probe Incorporated San Diego for 5 years, and Director of Clinical and Regulatory Affairs at Hybritech Incorporated. Katie joined Hybritech as a Research Manager, managing a product development team in the laboratory, then transitioned to Clinical Research Manager and later served as Director, Clinical and Regulatory Affairs. Prior to Hybritech, Katie worked in Research and Development in the Boston area at Allied Instrumentation laboratory as a Research and Development Manager and in the Diagnostics Division of Abbott Laboratories, Chicago, Illinois.
Katie has a PhD in Biochemistry from the University of Arizona School of Medicine in Tucson, AZ. She has co-authored a number of peer-reviewed publications and has served on the Editorial Board of IVD Technology for the past 10 years.

**Peggy Pence, Ph.D**

Dr. Pence offers over 37 years of experience in the research and development of traditional pharmaceutical and biotechnology-derived products and medical devices, including in vitro diagnostics. Dr. Pence began her career at Eli Lilly and Company in 1970 in basic immunology research and later transitioned to clinical development and regulatory affairs.

She subsequently held key project and clinical management positions at several emerging-growth companies, namely the U.S. start-up of Serono Laboratories, Triton Biosciences (acquired by Berlex Laboratories, Inc.), and Amgen, Inc. In 1992, Dr. Pence founded a consulting firm that was incorporated in 1995 as Symbion Research International, a full-service contract research organization. She has been President and Chief Executive Officer since that time. Through her formation of strategic alliances, Dr. Pence has added centralized radiology imaging and European and South American regulatory and clinical development services to Symbion’s capabilities.

Dr. Pence earned her undergraduate degree in Microbiology from Louisiana Tech and her PhD in Toxicology from Indiana University. She is an active industry speaker and educator. Dr. Pence founded the Drug Information Association (DIA) Sub-group and Advisory Committee on Biotechnology and chaired 10 consecutive DIA workshops on biotechnology from 1991 through 2001. Dr. Pence holds the U.S. Regulatory Affairs Certification (RAC) designation and has served on the Regulatory Training Course Faculty, DIA. Dr. Pence is a RAPS (Regulatory Affairs Professionals Society) Fellow (FRAPS), a peerreviewed credential for which she was selected based on her experience, contributions, and leadership in the regulatory profession. She serves on the Board of Directors or Advisory Board for multiple organizations.