PROGRAM ANNOUNCEMENT

Wednesday, 15 July 2020

Monthly Program

Emergency Use Authorizations – Tales from the Trenches

Program Speaker:

Kim Walker

Kim Walker Consulting

Event Agenda:

DATE: **Wednesday, 15 July 2020**

TIME:
6:00 – 6:05 PM Welcome and Announcements (ONLINE)
6:05 – 7:05 PM Program Presentation (ONLINE)
7:05 – 7:30 PM Q & A (ONLINE)

LOCATION: Not applicable - This is an ONLINE event

Click here to register for this event.

Program Topic:

Please join us for an overview of what Emergency Use Authorizations (EUAs) are, how to submit one, and recent experiences from those who have filed COVID-19 related EUAs.

Speaker Biography:

Kim Walker, MS, RAC, FRAPS is an independent Global Regulatory Affairs, Quality Assurance, and Clinical Affairs Consultant and owner of Kim Walker Consulting since 2006. In her consulting practice, she assists clients with pre- and post-market regulatory, clinical, and quality system needs. 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 (BOD) 2004-2010 and 2019 and was the 2008-2009 President. Kim participated on the CLSI Point of Care Testing, Quality Systems, EP9, and Process Improvement working groups and was listed as one of the authors for CLSI GP22-A3. Quality Management System: Continual Improvement. 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. Kim participated on the CSUPERB Advisory Committee and Development Team for the Project Management in Clinical Trials certificate program through California State University, Fullerton (CSUF). She was the instructor for the "Pre-Market Submission" course and co-instructor for the "Regulatory Requirements for Medical Products" course in the certificate program. Kim was also an instructor for the "Regulatory Requirements for Pharmaceutical Products" course and a co-instructor for the "Technical Writing for the Medical Product Industry" course at the University of California Irvine Extension. She also re-developed and currently teaches the "Medical Device Regulations" course for the SDSU Master of Science in Regulatory Affairs program. Kim developed and has taught since 2016 an undergraduate "Medical Product Regulations: Bench to Bedside" course at CSUF with a focus on stem cell therapies. She achieved both the US and EU RAPS Regulatory Affairs Certifications and has been accepted as a RAPS Fellow in recognition of her contributions and leadership in advancing the regulatory profession. Additionally, Kim received the 2008 Leonard Stauffer Award from RAPS in recognition of her contributions to mentoring and furthering regulatory professional education development. She has a Bachelor of Science degree in Biomedical Sciences and a Master of Science degree in Regulatory Affairs.

Registration Information:

Online registration ends Tuesday, 14 July 2020.

$10.00 SDRAN Member $10.00 Non-Member

For Questions Email: Programs.committee@sdran.org