PROGRAM ANNOUNCEMENT

Wednesday, 21 October 2020

Monthly Program event co-organized by SDRAN and OCRA

GCP COMPLIANCE and FDA BIMO INSPECTION READINESS

Program Speakers:

Tommi Papson

Former FDA Investigator and President and Co-founder of Regulatory Consultants Group

& Jacqueline Bushong

Sr. Director, Head of GCP Quality Assurance at Kiniksa Pharmaceuticals in La Jolla, CA

Event Agenda:

DATE: **Wednesday**, **21 October 2020**

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

LOCATION: Virtual platform-this is an ONLINE event

Click here to register for this event.

Program Topic:

No matter if your company is a Sponsor or Clinical Research Organization, large or small, brick and mortar or virtual, we all need to be ready for regulatory inspections. Ideally, quality is built into the culture and processes where you work, & getting ready for an inspection is fairly easy.

But with competing priorities, external competition, rushing to meet corporate deadlines, and a need for speed even a Quality Culture can suffer some setbacks from cutting corners, too much work, and too few resources. Compliance is challenging and getting ready for inspection can be fraught with stress and worry. Take a deep breath and learn how to simplify your activities, manage timelines, and have everything ready for that BIMO inspection of a recent regulatory submission.

Speaker Biography:

Tommi Papson, former FDA investigator and *Jacqueline Bushong*, Sponsor Representative, have experience preparing companies for and participating in regulatory inspections (albeit from opposite perspectives).

Jacqueline Bushong is the Sr. Director, Head of GCP Quality Assurance at Kiniksa Pharmaceuticals in La Jolla, CA. She has 20+ years of experience in the pharmaceutical / biotech industry at various companies, both large and small. Jackie has experience in large and small molecule therapies, including T-Cell immunotherapies.

Her experience includes directing CQA department activities, managing Clinical and Pre-clinical QA staff and compliance programs, performing risk assessments, planning and executing inspection readiness activities, and conducting routine and for-cause audits of clinical investigator sites, internal systems, and a wide variety of service providers. She also serves as President of Pacific Regional Chapter of Society of Quality Assurance (PRCSQA).

Jackie graduated from Upsala College in East Orange, NJ with a Bachelor of Science degree in Chemistry. She lives in Southern California with her spouse, 3 chinchillas, and her 2 SPOOS (standard poodles), Gabriel and Mercedes.

Tommi Papson is the President and Co-founder of Regulatory Consultants Group. As a former FDA Investigator, Tommi, known for the "Knock Knock, the FDA is Here" training and experiences of do's and don'ts with the Regulator shares the fun and excitement of getting a "483" and warning letter. Over two decades of experience in the BIMO, Medical Device and Pharma regulatory environment, International Cadre, and Recall Coordinator, now provides support to companies regulated by FDA and global regulatory bodies.

Tommi is President Elect of Orange County Regulatory Affairs (OCRA) Worked with DOJ, FBI and Office of Criminal Investigations on investigations and prosecution of recalcitrant firms, and now help firms not to be on Breaking News. Tommi enjoys painting, traveling with a spouse that loves to hear "back up did you see that", as the Photographer captures another cloud, or barn, or flower along the journeys of life.

Registration Information:

Online registration ends Tuesday, 20 October 2020.

$10.00 SDRAN Member $10.00 Non-Member

For Questions Email: Programs.committee@sdran.org