SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

PROGRAM ANNOUNCEMENT

Wednesday, 19 September 2018

Monthly Program

What Does ICH E6 (R2) Mean for Risk-Based Monitoring and Clinical Trials?

Program Speakers:
Neil Vivian, MSc.
Sr. Director of Business Solutions
OmniComm Systems, Inc.
and
Gregory M. Hockel, PhD.
Regulatory Affairs Consultant
TFS International

Event Agenda:

Date: Wednesday, 19 September 2018

Time:
5:15 – 6:00 PM Registration & Snacks
6:00 – 6:05 PM Welcome and Announcements
6:05 – 7:05 PM Program Presentation
7:05 – 7:30 PM Q & A

LOCATION: BD (former CareFusion) (directions on last page of this flyer)
3770 Torrey View Court
San Diego, CA 92130

Program Speakers: Neil Vivian MSc. & Gregory M. Hockel, PhD.

Program Topic:

The International Council for Harmonisation (ICH) Integrated Addendum to the Guideline for Good Clinical Practice (E6 (R2)) are intended to encourage implementation of improved approaches to clinical trials design, conduct, oversight and recording/reporting. The guidelines are meant to ensure reliable trial results and patient safety.

Program Summary:

This program will focus on how your organizational structure and processes will be affected by the ICH E6 (R2) addendum.

The program will include:

- Evaluating ICH E6 (R2) and learn how it affects your Risk-Based Monitoring (RBM) strategy
- Discuss ICH guidelines versus FDA guidelines
- Understanding ICH guidelines from a regulatory perspective
- SDVs impact on data quality

Speaker Biography:

Neil Vivian- Mr. Vivian joined OmniComm in 2009 as a senior director of Business Solutions and product manager. He is responsible for providing technical support to the Business Development group's strategy of positioning OmniComm applications and services to potential and existing clients. As product manager, his responsibilities include providing guidance and insights about high-level business requirements for new product features. His role at OmniComm is based on his industry experience and understanding of new regulatory guidance related to risk-based monitoring, eSource, and other areas. Prior to joining OmniComm, he was vice president of Technology Solutions at ERT, where he assisted in the development of ERT's long-term architecture and product integration strategy. Mr. Vivian has worked closely with the sales & marketing group and developers to build a solid line of integrated products, using his technical background and understanding of the pharmaceutical industry in the area of drug development. He has more than 38 years of experience in the software industry, including 24 years focused on the life sciences, built from a solid foundation in the defense industry. He has a BSc in Physics and Engineering Science and MSc in Information Technology.

Gregory M. Hockel, PhD.- Dr. Hockel has more than 35 years of experience in the pharmaceutical industry (large pharma, biotech companies, and contract research organizations), including both drug discovery and development. He has supervised the planning, submission, and maintenance of numerous INDs and NDAs/BLAs to both CDER and CBER, and has organized and conducted well over 100 meetings with the Food and Drug Administration and Health Canada. From a submissions perspective, he has submitted and maintained more than 200 INDs, involving all therapeutic divisions with CDER and CBER, and provided strategic input into the complication of more than 50 NDAs/BLAs, more recently in the Common Technical Document format. Dr. Hockel has provided input into Fast Track applications, Special Protocol Assessment submissions, and has written and submitted numerous Orphan Drug Applications, "gap analyses," due diligence, and portfolio review. During Dr. Hockel's career, he has also been responsible for regulatory operations, drug safety and pharmacovigilance, clinical trial supply management, quality assurance, and medical writing. Over the course of his career, he has established a large network of associates capable of addressing all facets of product development. Dr. Hockel has presented at numerous symposia and DIA meetings on a variety of regulatory issues and holds a PhD. degree in renal physiology from Indiana University School of Medicine and an MBA degree from Rensselaer Polytechnic University.

To register for the meeting, click here to access the SDRAN registration system (123Signup) for this event.

Please make your reservation early. The online registration due date is Monday, 17 September 2018. Credit Cards are accepted online only. Cash and Check are accepted at the door.

Online registration (through Monday 17 September 2018):

$15 SDRAN Member $25 Non-Member

Onsite Registration:

$25 SDRAN Member $35 Non-Member

For Questions Email: programs@sdran.org

Directions to BD (former CareFusion):

From the North 5:

I-5 South toward San Diego
Exit toward Carmel Mountain Rd Left onto Carmel Mountain Rd Left onto Torrey View Court Facility is on the right

From the South 5:

I-5 North toward Del Mar
Merge onto I-5 local Bypass
Take Carmel Mountain Rd exit (32)
Turn right onto Carmel Mountain Rd
Turn left onto Torrey View Court
Facility is on the right