PROGRAM ANNOUNCEMENT

Wednesday, 20 November 2019

Monthly Program

Regulatory Intelligence: Staying Current in an Increasingly Regulated Global Environment

Program Speaker:

Linda Bowen, MSc, RAC, FRAPS

Head of Regulatory Policy and Intelligence
Seattle Genetics, Bothell, WA.

Event Agenda:

Date: **Wednesday, 20 November 2019**

Time*:
5:15 – 6:00 PM Registration & Snacks
5:30 – 5:55 PM Speed Networking
6:00 – 6:05 PM Welcome and Announcements
6:05 – 7:05 PM Program Presentation
7:05 – 7:30 PM Q & A

*Times are approximate

Program Topic:

In this session Ms. Bowen will examine the fundamentals of global regulatory intelligence, including what it is and isn't, how it is conducted, the strategic value it brings to key stakeholders and how it is imperative to regulatory decision making throughout a development program and lifecycle management of a therapeutic product. Specifically, the presentation will focus on:

- Defining Regulatory Intelligence (RI) and its key components
- Understanding RI skills and competencies
- Outlining sources of regulatory information and why information ≠ intelligence
- Identifying regulatory trends
- Explaining the role of impact analysis

- Discussing the consultation procedure and how to communicate RI effectively within an organization
- Answering whether Regulatory Policy is the same as Regulatory Intelligence

Speaker Biography:

Linda Bowen, MSc, RAC, FRAPS : Linda has 36 years-experience in the BioPharma Industry, of which 26 years have been spent in regulatory affairs. She is Head of Regulatory Policy and Intelligence at Seattle Genetics and Assistant Professor in the Temple University RAQA graduate program for the last 20 years.

She attained Regulatory Affairs Certification (RAC) for the US, Canada and Europe and was an inductee to the 2011 Class of RAPS Fellows. Linda was honored with the Drug Information Association (DIA) 2012 and 2019 Excellence in Volunteer Leadership Awards.

She is a past two-term member of the RAPS Board of Directors and outgoing Chair of the NJ/NY RAPS Chapter. She chairs the DIA Regulatory Affairs Community and is founder of the DIA Regulatory Intelligence Working Group. She has sat on the planning committee for multiple DIA and RAPS Conferences and was Program Chair for the 2018 and 2019 RAPS Annual Convergence.

Location: Pfizer Inc.
10770 Science Center Drive (visitors center)
Conference Room #1110
San Diego, CA 92121

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

* **Please make your reservation early. The pre-registration due date is *Monday, 18 November 2019*. Advanced registration is appreciated to assist in event planning.**

** ***Space is limited for our monthly programs. Registration is capped at 85 participants. Register today to ensure your seat. Once our limit is reached, registration will close. Events with closed registration will not allow walk-ins.***

*** ***A photo ID is required to sign in at the venue.***

Online registration (through Monday, 18 November, 2019):

$15 SDRAN Member $25 Non-Member

Onsite Registration:

$25 SDRAN Member $35 Non-Member

For Questions Email: programs@SDRAN.org

Directions to Pfizer:

From the North

I-5 South toward San Diego
Take Exit 29, turn left into Genesee Ave
Turn right onto Science Center Dr
CB2 Visitors Center is located at the end of the cul-de-sac

From the South

I-5 North toward Downtown
Take Exit 29, turn right into Genesee Ave
Turn right onto Science Center Dr
CB2 Visitors Center is located at the end of the cul-de-sac