



PROGRAM ANNOUNCEMENT

Wednesday, 15 August 2018

Monthly Program

Companion Diagnostics: Building a Successful Regulatory Strategy

Program Speaker:

Brad Fox, BSME, MSML

Founder and President, Fox Consulting Network, LLC

Tom Stergar

Director of Partnerships, Greenlight Guru

Event Agenda:

Date: Wednesday, 15 August 2018

Time: 5:15 – 6:00 PM Registration, Snacks, & Speed Networking
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

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

Program Speakers: Brad Fox, BSME, MSML and Tom Stergar

Program Topic:

With the growth of Personalized Medicine and the rapid pace of targeted therapies, the drug development process often relies on a Companion Diagnostic (CoDx). The FDA defines a CoDx as an *in vitro* diagnostic medical device that provides information deemed essential for the safe and effective use of a corresponding drug or biological product. The CoDx helps health care professionals determine if a potential therapy's benefits outweigh the risks for an individual patient. Importantly, most new targeted therapies will not be approved by the FDA without a CoDx. Come learn key considerations for the development and regulatory approval of CoDx technologies.

Program Summary:

This talk will provide an overview of crucial CoDx product development and regulatory information to provide a systematic and successful approval process, including:

- Historical perspective of Companion Diagnostics
- Defining Companion and Complementary Diagnostics

- The importance of FDA's term "contemporaneous development"
- Understanding the FDA: Drug and Device Regulatory timelines
- Defining the right Regulatory strategy
- How to prepare for and leverage FDA meetings on CoDx
- The 3 most important take-aways for successful CoDx strategy

Speaker Biography:

Brad Fox: Brad Fox is an experienced and energetic consultant, manager and leadership professional with over 25 years experience in technology commercialization of life science related products. Mr. Fox is the Founder and President of Fox Consulting Network, LLC; a company dedicated to assisting companies and organizations set and meet Regulatory (FDA and CE) plans and objectives. Mr. Fox's expertise is primarily in medical devices and he has taken an industry leadership role in developing effective Regulatory strategies for Companion and Complementary Diagnostics. Mr. Fox has received a B.S. in Mechanical Engineering and a M.S. in Management and Leadership.

Tom Stergar: Tom Stergar is business development professional with more than 25 years experience connecting people with solutions in the technical and life science services. Early on, Tom started, grew and exited a virtual nutraceutical manufacturing company that served patients in diabetes, immune system enhancement and cholesterol. Using that experience, he grew territories for Safis Solutions as a Director and then Maetrics as a Vice President. Today, he serves as Director of Partnerships for Greenlight Guru. In this role he works with medical device consultants and service providers helping them incorporate the Greenlight Guru QMS software into their service offerings.

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, 13 August 2018. Credit Cards are accepted online only. Cash and Check are accepted at the door.

Online registration (through Monday 13 August 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