SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

PROGRAM ANNOUNCEMENT

Wednesday, May 3, 2017

Monthly Program:

510(k) Lessons Learned & What's New in 2017

Program Speaker:

Rob Packard

President, Medical Device Academy, Inc.

Chester, VT

Event Agenda:

Date:	Wednesday, May 3, 2017	
Time:	5:15 – 6:00 PM	Registration & Snacks
	6:00 – 6:05 PM	Welcome and Announcements
	6:05 – 7:00 PM	Program Presentation
	7:00 – 7:30 PM	Q & A
NEW LOCATION:	BD (former CareFusion) (directions on last page of this flyer) 6055 Lusk Blvd San Diego, CA 92121	
Program Speaker:	Rob Packard	

Program Topic:

The FDA recently made redacted, full 510(k) submissions available on-demand through the FDA website. This database gives you a lot more information and examples to work from when you are creating your next 510(k) submission. May's speaker shows you how to navigate this database quickly and make the most of it. He will also share his own experiences with the FDA, and his mistakes from more than a dozen submissions in 2016, so you can get your next device submission cleared as quickly as possible.

Program Summary:

Biopharmaceutical and Contract Research Organizations (CROs) bring a wide array of medical products to market in ever more sophisticated and innovative ways. The increase in specificity and complexity of modern clinical development continuously challenges our ability to enable it. This is exemplified by the fact that 60% of clinical trials have protocol amendments, nearly 80% of trials are delayed by enrollment, patient dropout remains very high, and almost half of trial sites are not able to reach enrollment targets.

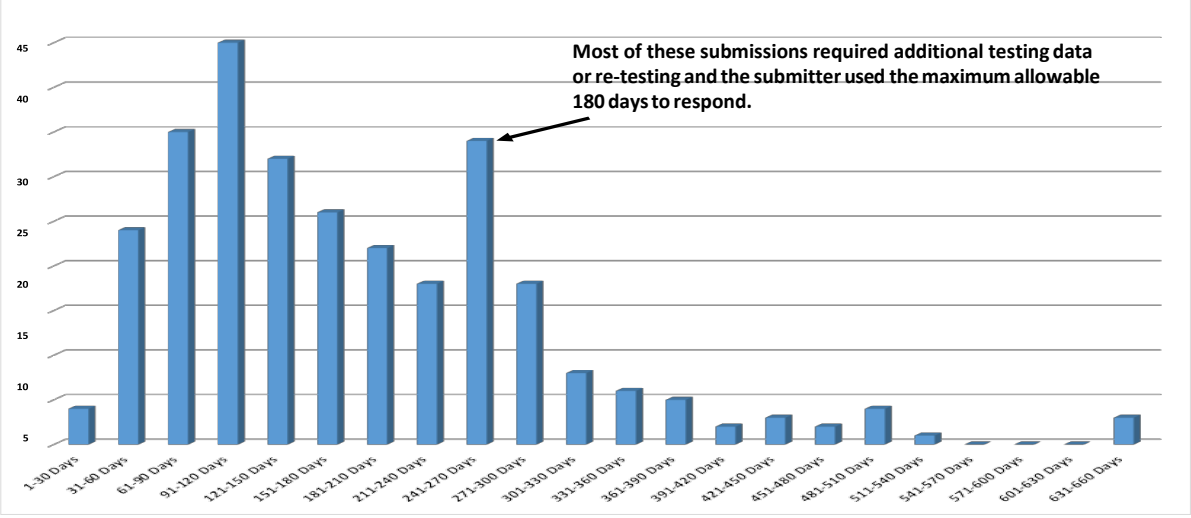
New and innovative clinical development offerings are now emerging at a rapid rate that leverage Real World Data on a global scale to better understand the risks and influence clinical program decisions, predict success, and identify avenues to control time and cost. Enabling and embracing the complex world of healthcare data creates opportunities to bring new insights to improve a traditional clinical development and operations process that still heavily relies on Key Opinion Leaders (KOLs), historical experience, and assumptions. Applications of real world data can be used to validate or refute these assumptions with real evidence about patient journeys, standards of care, disease progression, and drug access that can bolster understanding and reduce risk that protocols emerge with inherent flaws.

In this presentation, we will look at areas where the applications of real world data coupled with experiential data can change the nature of clinical development. We will also discuss the regulatory applications and landscape for big data and real world data as it applies to the legal standard for drug reviews and the requirements for adequate and well controlled studies. We look to big data frameworks to build the concept of the learning healthcare system and how this information can be used to streamline clinical trials, satisfy post marketing commitments and requirements, and support applications of drugs into new indications.

Great lessons are usually learned the hard way–by making mistakes. If you want to avoid mistakes and obtain 510(k) clearance faster, learn from the mistakes of others. You can also learn by analyzing trends for 510(k) issuances. Here are examples of things you can learn at the SDRAN meeting in May:

- Do you know if the FDA will accept an abbreviated type 510(k) submission for your device?
- Does your software change require a 510(k) submission or a letter to file?
- Do you need biocompatibility testing reports on the finished device or will test reports from the materials supplier be sufficient?
- What's the best way to manage your 510(k) project to keep it on track?
- How do you remove hidden system folders from your FDA eCopy?
- Can the FDA issue two RTA Hold letters in a row for your submission?
- Should you request a pre-submission meeting in-person, via teleconference or email?

The graph below is a Pareto analysis of 510(k) submissions reviewed by the general and plastic surgery panel in the Office of Device of Evaluations. There were 690 submissions received between January 1, 2015 and August 10, 2016. Unfortunately, the "average" review time is not helpful in answering the question of how long should your submission take to review. The data does not have a statistically normal distribution, and therefore an average is misleading. Figure 5-1 below shows why 91-120 days is the best estimate of how long a traditional 510(k) review will require.



Speaker Biography:

Rob Packard is President of Medical Device Academy, Inc., a regulatory consulting firm. He also started a new business called FDA eCopy to help companies with printing and shipping 510(k) submissions. He writes weekly blogs and records webinars to teach quality and regulatory managers how to comply with US, European and Canadian device regulations.

Rob has 25 years of experience in the medical device, pharmaceutical and biotechnology industries. From 2009-2012, he was a lead auditor and instructor for BSI. Rob's specialty is regulatory submissions for high-risk devices, such as implants. The most favorite part of his job is training others. Rob received his BS in Chemical Engineering from University of Connecticut.

To register for the meeting, click on the link below to access the SDRAN registration system (123Signup) for this event:
https://www.123signup.com/register?id=nkqxv

The above registration link can also be accessed on the SDRAN website, Events and Seminars page at: http://www.sdran.org/eventsandseminars

Please make your reservation early. The pre-registration due date is Monday May 1, 2017. Credit Cards are accepted on-line only. Cash and Check are accepted at the door.

On-line Pre-registration (through Monday May 1, 2017):

$15 SDRAN Member $30 Non-Member

Late Online Registration (Tuesday May 2, 2017):

$25 SDRAN Member $40 Non-Member

On-site Registration:

$25 SDRAN Member $40 Non-Member

For Questions Email: jodysuro@hotmail.com

Directions to BD (former CareFusion):

❖ NOTE – NEW LOCATION UNTIL FURTHER NOTICE

From the North 5:

- I-5 South toward San Diego
- Keep left and continue on I-805 South
- Take exit 27 toward Mira Mesa Blvd
- Take Mira Mesa Blvd to Lusk Blvd
- Turn left on to Sorrento Valley Road
- Stay on the road until it turns into Mira Mesa Blvd
- Move to the left-hand lane
- At the light - On the left (notice Holiday Inn Express & Chili's)
- Turn left on to Lusk Blvd
- Turn at the first right hand
- Turn at the first left hand (opposite Chili's)
- BD, Bldg. "C" is straight ahead

From the South 5

- I-5 North
- From the right hand lane, take Exit 27A for Mira Mesa Blvd
- From the right hand lanes, turn right on to Mira Mesa Blvd
- Move to the left-hand lane
- At the light - On the left you will notice:
    - Holiday Inn Express / Chili's
- Turn left on to Lusk Blvd
- Turn at the first right hand
- Turn at the first left hand (opposite Chili's)
- BD, Bldg. "C" is straight ahead