SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

PROGRAM ANNOUNCEMENT

Saturday, 6 April 2019

Making sense of FDA Land in Submissions (510(k)s, De Novos and PMAs) - Training Workshop

By

Mark DuVal, J.D., FRAPS, President & CEO, DuVal & Associates, P.A.

Lisa Pritchard, BSEEE, Regulatory, Quality & Compliance Consultant

Event Agenda:

Date: Saturday, 06 April 2019

Time:

8:30 - 9:00 AM	Registration
9:00 - 9:10 AM	Welcome and Introduction
9:10 - 12:00 PM	Training Session
12:00 - 12:45 PM	Lunch
12:45 - 2:15 PM	Training Session
2:15 - 3:45 PM	Q&A

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

Training Workshop Summary:

This workshop will take the beginning regulatory affairs professional and the veteran through the basics of medical device submissions to FDA. The speakers Mark Duval and Lisa Pritchard will share with the audience insights as to how their firm DuVal & Associates makes submissions that are designed to succeed and avoid wasting time and making common mistakes. The speakers have hundreds of submissions under their belt and are at the FDA physically about three times per month representing clients in pre-sub, 510(k), de novo and PMA negotiations. Their relationships with FDA and the knack for persuading FDA to their clients' position are their stocks-in-trade.

This interactive session will cover the following topics:

9:10-9:20—Seven Quick Tips for 510(k) Success

9:20-9:45—Withstanding RTA Review

9:45-10:00—Choosing the Proper Predicate

10:00-10:30—Choosing the Intended Use

10:30-11:00—Addressing Sameness in Technological Characteristics

11:00-11:30—Addressing Whether You Raise Different Questions of S&E

11:30-12:00—FDA Data Requests in a 510(k)

12:45-1:15—De Novo Submissions

1:15-2:15—PMA Submissions

Speaker Biography:

Mark DuVal, J.D., is President of DuVal & Associates, P.A., a law firm dedicated to counseling companies in the medical device, pharmaceutical, biotech, food, and nutritional supplement industries.

His practice includes providing strategic regulatory advice, developing compliance programs, designing and implementing sophisticated marketing programs, counseling on reimbursement matters, conducting sales training and interfacing extensively on behalf of companies with the FDA with relation to product approvals and clearances, clinical trial negotiations, approvals, policy arguments, appeals, etc.

Prior to founding the firm, Mark was general counsel for 3M Pharmaceuticals and Drug Delivery Systems working both domestically and internationally.

Mark earned his Juris Doctor from the William Mitchell College of Law where he served as executive editor on the law review, and his Bachelor of Arts in Public Administration from St. Cloud State University.

Mark is a frequent national speaker and writer on issues relating to product approvals/clearances; combination products, product advertising and promotion, Anti-kickback and False Claims Act (reimbursement) matters.

Lisa Pritchard, BSEEE, is a Regulatory, Quality & Compliance Consultant at DuVal & Associates, P.A., a law firm dedicated to counseling companies in the medical device, pharmaceutical, biotech, food, and nutritional supplement industries. She focuses on advising clients on Regulatory, Quality and Compliance topics.

Lisa works extensively with assisting clients with worldwide regulatory strategies, marketing submissions and applications (FDA submissions including pre-submissions, 510(k)s, de novos, PMAs, advisory panel meeting preparation, etc.; European Design Dossiers and Technical Files, Canadian license applications, Australian listing applications, etc.); quality system strategies and compliance topics. Lisa brings over 25 years of experience in working with industry.

Prior to joining DuVal & Associates, she executed successful Regulatory, Quality and Compliance strategies at a variety of device companies including American Medical Systems, Medtronic, UroMedica, and EnteroMedics.

Lisa earned her Bachelor of Science, Electrical and Electronics Engineering, from North Dakota State University.

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 *Wednesday, 03 April 2019*. Advanced registration is appreciated to assist in event planning.**

** ***Registration is capped at 85 participants. Register today to ensure your seat. Once our limit is reached, registration will close. There will be no onsite registration for this event.***

Online registration (through Wednesday, 03 April 2019):

$30 SDRAN Member $50 Non-Member

Onsite Registration:

No Onsite Registration

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

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 c
the cul-de-sac