

# PROGRAM ANNOUNCEMENT

**Wednesday, 15 May 2019**

**Monthly Program**

**The Dos and Don'ts of Regulatory Consulting:
What to consider if you’re considering consulting**

Program Speakers:

**Mya Thomae, RAC**

Former VP of Regulatory, Clinical and Medical Affairs

Illumina and Myraqa

**Allison C. Komiyama, PhD, RAC**

President and Founder

AcKnowledge Regulatory Strategies, LLC

Moderated by:

**Frank Prokop**

Senior Director for RA/QA

Sotera Wireless

**Event Agenda:**

**Date:** **Wednesday, 15 May 2019**

**Time\*:** 5:15 – 6:00 PM Registration, Snacks, & 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:**

According to the US Bureau of Labor Statistics, the regulatory affairs field will continue to grow at an average rate of eight percent until 2026. With many professionals finding their career paths navigating towards regulatory affairs, and the emergence of a thriving “gig-economy” over the past decade, it’s no wonder that many new and experienced professionals are finding success in the consulting business. Whether you’re a veteran or novice in the regulatory world, or looking for part-time or full-time opportunities, this panel presentation will cover the pros & cons and the dos & don’ts of entering the consulting field.
Key topics covered will include:

* Best practices in setting up your consulting practice and pitfalls to avoid.
* Where to find guidance on building and maintaining your consulting business.
* How to market your services, as well as find and secure clients.
* How to manage your time appropriately and manage client expectations on deadlines.
* Whether and how to scale up when needed; best practices for hiring staff.
* Tips and tricks on making your clients happy all while keeping you sane!

**Speaker Biographies:**

**Mya Thomae, RAC,** has extensive experience in gaining regulatory approvals for novel in vitro diagnostic (IVD) devices in the United States and Europe. This work has included PMAs, 510(k)s and de novos in the US for both kit and lab-based products. In the EU, Mya has experience with working with Notified Bodies and Competent Authorities on List A, List B and self-certified products. Certified by the Regulatory Affairs Professional Society (RAPS) since 1994, Mya first worked as an RA Manager at Epitope and then Chiron Corp. She started Mya Thomae Consulting in 1999 and later founded Myraqa in 2008. Myraqa was a boutique regulatory consulting firm focused on IVD and companion diagnostic products. The company offered in-depth advice on development, regulatory guidance, and clinical validation of both IVD systems and laboratory developed tests (LTDs). Myraqa was acquired by Illumina in July 2014 at which time Mya became their VP of Regulatory, Clinical and Medical affairs, leading Illumina's interests in regulatory approvals. She stayed with Illumina for 3 years before moving back into self-employment, as both an artist and regulatory advisor.

**Allison Komiyama, PhD, RAC**, is a consultant who works on regulatory strategies and submissions for medical device and IVD manufacturers. Her work has focused mainly on US regulations, with a specialty in pre-submissions, 510(k) notifications, de novo applications, IDEs, and 513(g) submissions. After her education in molecular biology and neuroscience, Allison moved to DC to work at FDA as a reviewer in the Office of Device Evaluation (ODE). She acted as a lead reviewer for premarket submissions and was a consult for files evaluating the biocompatibility of patient-contacting devices. After her time at FDA, she worked as a project manager and regulatory affairs manager at an IVD company in Poway, CA, and then as a senior regulatory specialist at a consulting company in Del Mar. She started AcKnowledge Regulatory Strategies in 2014 in order to serve medical device manufacturers who need FDA approval. She was certified by RAPS in 2014 and works with a team of 7 people in Old Town, San Diego.

**Frank Pokrop** has worked in the medical device arena for more than 20 years, and is employed at Sotera Wireless in San Diego as the Senior Director for Regulatory Affairs and Quality Assurance. His prior experience covers manufacturing quality assurance for large and small volume parenteral drugs. Frank’s responsibilities cover: management of staff and budget, global submissions, worldwide regulatory intelligence, project management, auditing and compliance, recall management, and training. A long-standing supporter of training and personnel development, Frank has spent a considerable amount of time in volunteer positions including: MD&DI's Editorial Advisory Board, officer and volunteer with SDRAN, member of the “B” IRB at UCSD, and course instructor on medical devices at UCSD. Frank is a frequent contributor and speaker with ASQ and RAPS, both locally and at national meetings.

**Location:** Pfizer Inc.
10770 Science Center Drive (visitors center)

 Conference Room #1110
San Diego, CA 92121

**To register for the meeting, click** [**here**](#https://www.123signup.com/register?id=rjmvb) **to access the SDRAN registration system (123Signup) for this event.**

**\* Please make your reservation early. The pre-registration due date is *Monday, 13 May 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.***

**Online registration (through Monday 13 May 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 From the South**

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

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