SDRAN
SAN DIEGO REGULATORY AFFAIRS NETWORK

PROGRAM ANNOUNCEMENT

Wednesday, November 15, 2017

Speed Networking
AND
Monthly Program:

Everything You Need to Know About eCTD Before It's Too Late

Program Speaker:

Antoinette Azevedo

President

e-SubmissionsSolutions.com

Event Agenda:

Date:	Wednesday, November 15, 2017
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 – 7:30 PM Program Presentation
Location:	BD (former CareFusion) (directions on last page of this flyer) **3770 Torrey View Court** San Diego, CA 92130
Program Speaker:	Antoinette Azevedo

Program Topic:

FDA will require all IND and Drug Master File (DMF) submissions to be submitted in electronic common technical document (eCTD) format by May 5, 2018. FDA has required eCTD format for all abbreviated new drug applications (ANDAs), NDAs, and BLAs since May 5, 2017. National competent authorities (NCAs) across the globe have provided a standardized eCTD format for marketing applications – some with aggressive timelines such as China FDA planning to go live beginning 2018. The window is rapidly closing in which sponsors can submit paper or hybrid electronic submission formats.

Program Summary:

FDA and other NCAs have been receiving eCTD-formatted submissions since 2004. The eCTD format is technically challenging and potentially costly to implement if not commenced well in advance of the submission deadline. All NCAs validate the eCTDs they receive for compliance with a variety of standards. Failure to pass this validation can result in Refuse to Receive (RTR) or Refuse to File (RTF). Sponsors must resort to costly remediation if their submission receives an RTR or RTF, as the validation issues must be corrected and the eCTD pass validation before the NCA initiates the review timeline.

Antoinette will present best practices for successfully transition from legacy submission formats to the eCTD. This includes:

- The use of MS Word and templates to author documents that comply with NCA specifications for PDF files.
- The use of Adobe Acrobat to review & remediate noncompliant PDF files.
- The need for RFPs and contracts with consultants, medical writers, Contract Manufacturing Organizations (CMOs) and Contract Research Organizations (CROs) to stipulate that deliverables be compliant with NCA specifications for PDF files.
- The need to inspect for compliance during the draft review stage and the linking of payment to outside vendors based on delivery of compliant PDF files.
- Electronic datasets requirements looming on IND-phase sponsors.
- The role of electronic document management in an eCTD project.
- The options for in-house eCTD publishing vs outsourcing.

Speaker Biography:

Antoinette Azevedo founded e-SubmissionsSolutions.com (a California corporation) in 2000 to advise all sizes of biotechnology and pharmaceutical companies on the use of technology to manage regulatory documents and publish electronic submissions. Antoinette offers both consulting and training services. She has a cloud-based publishing system that has been in place since 2005 to provide electronic document management, PDF conversion & remediation, eCTD publishing and validation, and submission through FDA, CESG, and EMA Electronic Submission portals.

Ms. Azevedo purchased Sage Submissions in 2007 in order to acquire the Sage Templates for CTD/eCTD submissions. She provides MS Word templates for eCTD with Module 1 for multiple NCAs. Ms. Azevedo co-founded RegDocs365 in 2012, a private cloud-based electronic document management system (EDMS) for Regulatory Submissions and for electronic Trial Master File (eTMF).

Ms. Azevedo was director of West Coast Operations for Liquent from 1997 to 2000, and was principal consultant in the CSC Consulting life sciences practice as technical lead for regulatory submission publishing from 1994 to 1997, working with pharmaceutical clients in North American and Western Europe.

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=hjqgf

Please make your reservation early. The online registration due date is Monday November 13, 2017. Credit Cards are accepted online only. Cash and Check are accepted at the door.

Online registration (through Monday November 13, 2017):

$15 SDRAN Member $25 Non-Member

Onsite Registration:

$25 SDRAN Member $35 Non-Member

Directions to BD (former CareFusion):

From the North I-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 I-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