

SDRAN PROGRAM ANNOUNCEMENT

SDRAN Networking & Meeting Presentation: “Communications and Strategy for Successful Regulatory Outcomes”

Date: Tuesday, August 25, 2009

Time: 5:00- 6:00 pm Early Jobs Networking & Snack
6:00 - 7:00 pm Presentation

Location: Amylin Pharmaceuticals, Inc.(directions at end of this flier)
9360 Towne Center Drive
San Diego, CA 92121

Panelists: Pratik Multani, MD
V.P., Clinical Development
Fate Therapeutics, Inc.

Natalie J. Kennel, RAC, ASQ CQE & CQ Mgr
Founder
NJK & Associates

Moderator: Lynne Eddy, RAC
President, SDRAN

“Communications and Strategy for Successful Regulatory Outcomes”

Panel members will share their extensive experience regarding pharmaceuticals, biologics, devices or IVDs to assure successful product approvals for commercialization. Participants will interact with the panelists to address what, when and how Regulatory Managers would approach and communicate with government personnel to meet mutually agreeable outcomes. Specifically, discussion will include small and emerging company regulatory strategies, safety concerns and the changes a regulatory professional may expect as we move forward in the 21st Century. The emphasis is on what kind of knowledge and experience should each of us have to facilitate and benefit through these encounters, what presentation skills, etc.

This is an audience participation event. Bring your questions!

Early Jobs Networking – Using LinkedIn to Further your Career

As part of our continuing effort to assist the San Diego regulatory community during these challenging economic and industry times, SDRAN will once again be starting its pre-program networking at 5:00pm to focus on networking for those hunting for jobs or wanting to improve their career prospects. We will be talking about ways to use the business-oriented networking site, LinkedIn, both to aid in finding new positions or to advance your career.

We will also be making announcements about job openings. Bring your job announcement to the program or email it to Joyce Williams, our President Elect, at jwilliams0628@sbcglobal.net. A brief summary of the discussion will be posted on the SDRAN LinkedIn site after the program. Remember that we also post jobs on the SDRAN website at www.sdran.org.

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Panelist Biographies

Pratik Multani, MD is currently Vice President, Clinical Development at Fate Therapeutics, which focuses on identifying small molecules and biologics that guide cell fate for therapeutic purposes. Prior to joining Fate Therapeutics, Dr. Multani held multiple executive level positions with several biotech companies in the San Diego area, working in the areas of oncology, hematology, pain, and metabolic disease. He began his biotech career at IDEC Pharmaceuticals. Where from 1999 to 2004, he led or provided strategic direction for multiple drug development programs in Phase 1 through Phase 4 clinical trials, including Zevalin® and Rituxan®.

Before his industrial career, Dr. Multani held academic and clinical positions at Harvard Medical School and at the Massachusetts General Hospital. His postdoctoral training included a fellowship in hematology and oncology at Dana-Farber/Partners and an internship and residency in Internal Medicine at Massachusetts General Hospital. Dr. Multani received his medical doctorate from Harvard Medical School and a Bachelors of Science in Chemistry and Biology from Yale University.

Natalie J. Kennel, RAC, ASQ CQE and CQ Mgr founded NJK Associates to bring her practical perspective to medical device quality and regulatory affairs. With more than 25 years in industry, most devoted to medical devices, she has hands-on experience with development and manufacturing as well as QA/RA and clinical roles in both major and start up medical device companies. In the last two years, Ms. Kennel has submitted sixteen 510(k)s and four Pre-IDE submissions. She has been published in RAPS regarding clinical trials for medical devices. Ms. Kennel has spoken on multiple regulatory, quality and clinical topics for SDRAN, ASQ and ACRP. She has taught the medical device submission section for the U.S. RAC Study Group for the last seven years and a seminar regularly for the USC regulatory affairs master’s program on software validation. Ms. Kennel holds a Bachelors of Science degree in Chemical Engineering from the University of Rochester.

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Registration Form

Yes, I will be attending the SDRAN program August 25th on:

***SDRAN Networking & Meeting Presentation:
“Communications and Strategy for Successful Regulatory Outcomes”***

Please make your reservation early. **Pre-registration due date – August 21, 2009**

Name: _____

Title: _____

Company: _____

Address: _____

Phone/FAX: _____

**e-mail
(required):** _____

My mailing address/contact information has changed.

If you want a receipt, check here.

Pre-registration: \$15.00 SDRAN member \$25.00 nonmember

On-site registration: \$20.00 SDRAN member \$30.00 nonmember

2009 SDRAN membership: \$40.00 (you can pay the lower meeting rate)

NOTE: SDRAN does not accept credit cards or PayPal (internet payments). No refunds. No Bill me.

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SEND YOUR REGISTRATION FORM AND PAYMENT TO:

Jody Surowiec, SDRAN
P.O. Box 927595
San Diego, CA 92192-7595
e-mail: jodyuro@hotmail.com

Directions to Amylin:

From I-5

Exit on La Jolla Village Drive and proceed east approximately 1.3 miles

Turn left onto Towne Center Drive

Turn left into Amylin parking lot

(9360 Towne Center Drive)

From Interstate 805

Exit on La Jolla Village Drive going west

Turn right at the first stoplight, which is Towne Center Drive

Turn left into Amylin parking lot

(9360 Towne Center Drive)