

## **SDRAN PROGRAM ANNOUNCEMENT**

### ***SDRAN Networking & Meeting Presentation: “Post Marketing Compliance & Government Scrutiny of Pharmaceutical Activities”***

**Date:** Wednesday, **September 23, 2009**

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

**Location:** Celgene Corporation (directions at end of this flier)  
4550 Towne Center Court  
San Diego, CA 92121  
(858) 795-4979

**Speaker:** Julia Feliciano  
V. P., Legal  
Amylin Pharmaceuticals

**Moderator:** Malcolm Lloyd Smith  
Cadence Pharmaceuticals

### ***“Post Marketing Compliance & Government Scrutiny of Pharmaceutical Activities”***

Many companies are keenly aware of the government scrutiny their commercial activities are under after successful market introduction. Julia Feliciano will share her over 20 year in-house pharmaceutical experience dealing with both the States and Federal government perspectives regarding the key areas of risk to be considered by a company to assure post marketing compliance. She will also summarize the recent Pfizer settlement and CIA as current examples. This presentation will outline several key strategic considerations along the path a regulatory professional would consider towards a successful commercial, post market surveillance program for their next drug or co-developed product.

### **Early Jobs Networking**

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 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](mailto: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](http://www.sdran.org).

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### **Speaker Biography**

Julia Feliciano has been a in-house pharmaceutical attorney for over 20 years. After private practice, she served as Deputy Chief Counsel, North America at Wyeth. She provided legal and business advice regarding strategies, budget and issues for all products in the neuroscience, cardiovascular, anti-infective and gastrointestinal therapeutic areas. She was the primary legal advisor regarding fraud & abuse, FDA regulatory matters, promotional programs, labeling, clinical study programs, contracting and responding to OIG subpoenas and congressional inquiries. Julia supervised outside counsel in the defense of product liability litigation and was the lead in-house attorney in the fen-phen mass tort litigation, working with outside counsel across the United States.

Next she served as Vice President, Legal, Therapeutic Markets at Elan Pharmaceuticals, responsible for legal review and support of all commercial marketing efforts for the company, as well as regulatory and product liability support for clinical development projects. Julia provided legal advice for labeling and the risk management plan to bring a multiple sclerosis drug back to market in the United States, following a voluntary market withdrawal for safety concerns, and to market in the European Union. In addition to MS, other therapeutic areas were Alzheimer's and Parkinson's research, anti-infectives and pain management. She was primary legal advisor on FDA matters, fraud & abuse, promotional programs, labeling, grants, clinical programs, contracting and government pricing. She assessed liability and compliance risk and helped develop company policies.

Currently Julia is Vice President, Legal at Amylin Pharmaceuticals and is primary legal advisor to the Sales, Marketing, Medical Affairs, Clinical Development, Quality, Safety and Regulatory Affairs departments, especially with regard to FDA regulatory matters, fraud & abuse, promotional programs, labeling, clinical study programs and government pricing for diabetes.

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## Registration Form

**Yes**, I will be attending the SDRAN program Sept. 23rd on:

***SDRAN Networking & Meeting Presentation:  
“Post Marketing Compliance & Government Scrutiny of Pharmaceutical  
Activities”***

Please make your reservation early. **Pre-registration due date –  
September 18, 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

**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](mailto:jodyuro@hotmail.com)

***Directions to Celgene:***

**From I-5**

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

Turn left onto Towne Center Drive

Turn left onto Towne Center Court

Celgene is on the right side (4550 Towne Center Court)

**From Interstate 805**

Exit on La Jolla Village Drive going west

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

Turn left onto Towne Center Court

Celgene is on the right side (4550 Towne Center Court)