

SDRAN PROGRAM ANNOUNCEMENT

SDRAN Networking & Meeting Presentation:

“Co-development of a Drug and a Companion Diagnostic: Key Strategic Considerations toward the Goal of Personalized Medicine”

Date: Thursday, **July 23, 2009**

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

Location: Celgene Corporation
4550 Towne Center Court
San Diego, CA 92121 (858) 795-4979

Speaker: Katie M. Smith, PhD
Katie Smith Consulting

Moderator: Radine Ganz Pobuda, RAC
V. P. Programs, SDRAN

“Co-development of a Drug and a Companion Diagnostic: Key Strategic Considerations Towards the Goal of Personalized Medicine”

Many pharmaceutical companies are keenly interested to deliver on the promise of personalized medicine. They are intent on developing a biomarker that may select a particular patient population that will benefit or not benefit from treatment with the company's drug, or, perhaps a biomarker that will be a prognosticator of a patient's outcome. The benefit of this strategy is that a higher portion of patients treated with the drug going forward will benefit, and fewer patients will be treated and realize little to no benefit. There is a particular interest in such co-development programs in the field of oncology, and other disease areas. This presentation will outline several key strategic considerations along the path towards the successful co-development of a drug and a diagnostic.

Early Jobs Networking – Structuring a Job Search by Taking a Project Management Approach

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. At this networking session Rachel Hernandez, a long-time member and project management consultant, will lead the discussion and offer ideas for using project management tools in your job search.

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 by July 17. A 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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Speaker Biography

Katie M. Smith, PhD, is a Biotechnology Consultant with a focus on clinical research and regulatory affairs. Katie has 25 years experience in both the pharmaceutical and in vitro diagnostic device industries and has worked 20 of those years in the San Diego area.

Prior to consulting, Katie held the position of Associate Director, Clinical Operations at Biogen Idec Pharmaceuticals, San Diego. In this role, she led cross-functional teams to devise clinical development strategies and to execute on clinical studies. In addition she helped to develop a cross-functional strategic approach for the co-development of a companion diagnostic and a new oncology drug. Prior to this, Katie served as Sr. Director, Clinical Research and Regulatory Affairs at Prometheus Laboratories. In this role she developed the first clinical research group and operating procedures to deliver clinical trial results to support newly developed diagnostics and existing therapeutic products.

Other positions Katie has held were Director of Clinical Research, Gen-Probe Incorporated, San Diego for 5 years, and Director of Clinical and Regulatory Affairs at Hybritech Incorporated. Katie joined Hybritech as a Research Manager, managing a research-based product development team, after which she transitioned to the role of Clinical Research Manager and later served as Director, Clinical and Regulatory Affairs. Prior to Hybritech, Katie worked in Research and Development in the Boston area at Allied Instrumentation Laboratory as a Research and Development Manager and in the Diagnostics Division of Abbott Laboratories, Chicago, Illinois.

Katie has a PhD in Biochemistry from the University of Arizona School of Medicine in Tucson, AZ. She has co-authored a number of peer-reviewed publications and has served on the Editorial Board of *IVD Technology* for the past 10 years.

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