

## **SDRAN PROGRAM ANNOUNCEMENT**

### ***SDRAN Networking & Meeting Presentation: “Pre-Approval Inspections: taking the long view”***

**Date:** Wednesday, April 22, 2009

**Time:** 5:00- 5:30 pm Early Jobs Networking & Resume Review 5:30 –  
6:00 pm 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:** Richard Gill  
RCG Consulting Inc.

**Moderator:** Malcolm Lloyd-Smith  
Cadence Pharmaceuticals

### ***“Pre-Approval Inspections: taking the long view”***

**What attributes/processes are absolutely necessary to be in place for a successful Pre-Approval Inspection? Richard Gill, PhD will share his extensive experience preparing for and completing such audits. Specifically, members will learn that Success is in the details!**

### **Early Jobs Networking and Resume Review**

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 extending its pre-program networking time. We invite paid program attendees who are seeking jobs, as well as those who can provide job hunting advice and those who have jobs available, to join us at our April meeting at 5:00 rather than at 5:30 p.m.

We provide a facilitator for this discussion, which will cover several subtopics including a special focus on resume review. Paid attendees at the April program can have their resume

reviewed by an experienced regulatory professional who will provide one-on-one feedback on polishing your resume. Bring your resume to the program or email it to Joyce Williams, our President Elect, at [jwilliams0628@sbcglobal.net](mailto:jwilliams0628@sbcglobal.net). We will assign someone who will follow up with you later to provide one-on-one suggestions for improving your resume. This is only open to paid attendees at the April program.

If you are a regulatory affairs veteran and are interested in helping SDRAN with the resume review process, please let us know.

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 [sdran.org](http://sdran.org).

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### **Speaker Biographies**

**Richard Gill, PhD, our presenter** graduated in Biochemistry and Physiology (1978) from the University of London, earning his PhD there in Experimental Surgery (1983). After two years at May & Baker Pharmaceuticals, Richard founded and led a UK-based CRO, Campbell Charles Associates (CCA). From 1988-1999, CCA provided clinical development services to major pharmaceutical companies in 18 therapeutic areas. After relocating to the USA in 1999, Richard worked for Quintiles Transnational as General Manager of their global analytical laboratory, then as head of the Global Quality Management Group. In 2002, he followed his growing interest in quality issues to Elan Pharmaceuticals as VP and Global head of Quality and Process, and was a member of Elan's Tysabri® launch team. Richard joined Chiron Corporation in 2005 as VP of Compliance and Process Improvement. Since 2007, Richard has been drawing on his 21 years of biopharmaceutical experience to help biotech and pharmaceutical companies improve their development, compliance and management processes.

**Malcolm Lloyd-Smith, Moderator** holds a Bachelors honors degree in Pharmacology from the University of Leeds, and a Masters in Pharmacological Biochemistry from Hatfield Polytechnic, both in the UK. He has had a long and varied career working in pharmaceutical regulatory affairs, based both in Europe and the United States. His career started with Bayer in the UK and then led to a position in Germany in a 3 person regulatory team with DuPont Pharmaceuticals as they were establishing their international business. This led on to 7 years with DuPont in Geneva, Switzerland where he headed up the Regulatory Affairs/QA organization in Europe. He then moved to Delaware starting a Corporate International Regulatory function for the larger DuPont-Merck organization, before being appointed VP European Regulatory Affairs based in the UK. With the sale of DuPont's pharmaceutical business to BMS, Malcolm joined Elan Pharmaceuticals in the UK in 2002 as their VP International Regulatory Affairs before becoming, in 2003, VP & Head Global Regulatory Affairs for Elan in San Diego and then San Francisco. He is now SVP Regulatory Affairs & QA for Cadence Pharmaceuticals in San Diego.

During his career Malcolm has recruited regulatory teams in the US and across Europe and has worked across many therapeutic areas with both small and large molecules, including infectious disease, cardiovascular, CNS, autoimmune disease and radiopharmaceuticals. He has filed multiple IND's and IMPD's and has filed and obtained approval for 1 major biologic in the US and more than 9 MAA's in Europe.