



16th Annual INCOSE Region II Fall Mini-Conference

**DATE: Saturday, November 19, 2011
8:00am to 4:00pm**

**LOCATION: National University's La Jolla Facility
11355 N. Torrey Pines Road
San Diego, CA 92037**



Theme: System Engineering: The Bridge between the Aerospace and Medical Industries

Attend this day of stimulating thought and discussion centered around the questions: How is classical Systems Engineering applied to the aerospace and medical industries (e.g., design requirements, verification, validation). Do these industries have similar or different approaches to SE and what can they learn from each other. The medical industry and FDA have recently come under fire for allowing unsafe products on the market – can SE help improve the safety, efficacy and quality of medical products? All are welcome.

KEYNOTE SPEAKER: Daniel P. Olivier

Dan is an acknowledged quality systems expert that has provided consulting services for over 200 medical device and pharmaceutical companies in design controls, software validation, and safety risk management practices. He has been contracted by FDA to train investigators and to provide inputs to software validation guidelines. Speaker at over 50 American Society for Quality (ASQ) and other professional conferences. Author and presenter of over 50 seminars on Computer System Validation, Safety Risk Management, and Part 11 requirements to meet FDA and ISO Guidelines. RAB certified ISO 13485:2003 lead auditor with experience from over 100 audits of medical device and pharmaceutical companies. Reviewer for International Organization for Standardization (ISO) WG10 defining software process assessment standards. Ten years experience as a software engineering instructor at undergraduate and graduate levels including UCSD Extension program and National University.

REGISTRATION:

Registration Fees	Online or On-Site (On-Site by check or cash only)
INCOSE Member	\$60
Non-member	\$70
Student	\$50

FEE: \$20 of any non-member fee can be applied toward INCOSE membership for those who join at this conference. Speakers and Panelists admitted free. On-site registration by cash or check only, no credit cards please! If registering on-site, please RSVP to Katy Campbell at katy_campbell89@yahoo.com by Thursday, November 17, 2011. Admission fee includes coffee and donuts, buffet lunch and soft drinks.

LUNCH: Buffet and soft drinks will be provided. Please state vegetarian preferences with your registration.

SCHEDULE: Please see next page

SCHEDULE: 0800 – 0900 Registration, Coffee & Donuts
0900 – 0915 Introductions & Welcome
0915 – 1000 Keynote Address by Daniel P. Olivier
1000 – 1045 Technical Presentation: “A Brief History of Systems Engineering” by Mark Halverson
1045 – 1100 Break
1100 – 1145 Technical Presentation: “Intended Use Validation of Rational DOORS for Use in a
FDA Regulated Environment” by Deric Merino
1145 – 1200 Vendor Introductions
1200 – 1315 Lunch & Vendor Exhibits
1315 – 1345 Technical Presentation: “Enterprise Architecture of Emergent Complex Adaptive
Systems” by Claudia Rose
1345 – 1415 Technical Presentation: “Information Modeling for Systems Integration” by Kim Idol,
Claudia Rose, and Alan Brenner
1415 – 1445 Technical Presentation: “Regulatory Affairs Arguments” by Alan Brenner
1445 – 1545 Panel Discussion
1545 – 1600 Wrap-Up

Questions? Email Katy Campbell at katy_campbell89@yahoo.com.