

## 2013 PDA Human Factors and Human Error Reduction Workshop

### Speaker Biographies

As of March 22, 2013

#### Bill Blunt

Amgen, Inc.

Bill Blunt has dedicated his career to the development of human performance programs in high reliability organizations. His approaches to managing human errors in nuclear plants contributed to nuclear industry best practices, and the outcomes of this work were documented in *Managing the Unexpected*, by Weick and Sutcliffe. As a business consultant, he adapted these methods to improve human performance across the automotive manufacturing sector. Bill is currently applying his techniques in the biotechnology manufacturing arena, as the Director, Operations Human Performance for Amgen, Inc. He has also been an adjunct professor in the Boise State University College of Engineering, teaching Human Performance Fundamentals. Bill is an active member of the BioPhorum Operations Group Human Error Reduction team, the International Society for Performance Improvement, and the Human Factors and Ergonomics Society.



#### Christina Mendat, PhD

Radius Product Development

Christina is the Director of Research and Human Factors at Radius Product Development where her primary role is to provide technical oversight to the research and HF teams and champion the integration of human factors in the product development process. Christina has contributed technical expertise to a number of projects ranging from large scale medical devices and systems to consumer goods. She is an expert at translating research findings such as user needs, requirements, product strengths and product weaknesses into compelling design directions and solutions. At the heart of Christina's skill set are human factors and ergonomics where she has carried out numerous User-Centered Risk Analyses, HF/E Evaluations and Competitive Benchmarks while taking great pride in maintaining the integrity of sound HF/E guidelines and standards throughout the development process. She has presented papers to the Human Factors and Ergonomics Society and the American Psychology Society and has been providing lectures on navigating the latest standard, HE75 and human factors integration in quality management systems. Christina has a doctorate in experimental psychology and ergonomics from North Carolina State University and is a member of the Human Factors and Ergonomics Society and the Association for the Advancement of Medical Instrumentation.

#### Najmedin Meshkati, PhD

University of Southern California

Dr. Najmedin (Najm) Meshkati, Ph.D., CPE is a (tenured, full) Professor of Civil/Environmental Engineering and a Professor of Industrial and Systems Engineering at the Viterbi School of Engineering, University of Southern California (USC). He was a Jefferson Science Fellow, and a Senior Science and Engineering Advisor, Office of Science and Technology Adviser to the Secretary of State (2009-2010), Washington, DC. He is a member of the Global Advisory Council of the Civilian Research and Development Foundation (CRDF) Global, chaired by Ambassador Thomas Pickering. For the past 25 years, he has been teaching and conducting research on risk reduction and reliability enhancement of complex technological systems, including nuclear power, aviation, and petrochemical and transportation industries. In June 2012, it was announced that he was selected as a member of the National Academy of Sciences/National Research Council committee to conduct a congressionally mandated study entitled "Lessons Learned from the Fukushima Nuclear Accident for Improving Safety and Security of U.S. Nuclear Plants". [This study is requested by the U.S. Congress and is being sponsored by the U.S. Nuclear Regulatory Commission.] He was a member of the National Academy of Engineering/National Research Council's Committee on the



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Analysis of Causes of the Deepwater Horizon Explosion, Fire, and Oil Spill to Identify Measures to Prevent Similar Accidents in the Future (2010-2011) which produced the *Macondo Well Deepwater Horizon Blowout: Lessons Learned for Improving Offshore Drilling Safety* (published by the National Academies Press, 2012).

#### **Miguel Nogueras, PhD**

Abbott Medical Optics

Dr. Miguel Nogueras is currently the global manager of Quality Assurance-Microbiology for the division of ophthalmic products for Abbott Laboratories (Abbott Medical Optics). Miguel Nogueras served in the capacity of the director of the division of microbiological and virology testing at BioReliance® after serving in the capacity of lead microbiologist at AMGEN and Genentech (Tanox, Inc). Miguel has extensive experience in the clinical pharmaceutical/biotech industry, specifically in the creation and implementation of microbiological, diagnostics and quality systems in support of production of parenteral drugs, medical devices, clinical and product development. He is very knowledgeable of areas such as: Aseptic processing, Final Sterilization, Clinical Diagnostics, Viral pathology, Microbial Identification, Environmental Controls, Start Up of New Laboratories & Production Facilities. In addition Miguel has vast experience in the areas of assay development and final product testing within the areas of Virology, Bacteriology, Mycoplasma and Sterility testing. He has provided support to different institutions including but not limited to: development, improvement and implementation of cGCP, cGTP, cGLP and cGMP; quality systems; cGMP and cGLP improvements plans, preparation of manufacturing sites for regulatory, health agencies and notified body inspections. As a member of the quality and compliance organization Dr. Nogueras has aided in leading investigations, BPDRs and MDRs for root cause analysis and implementation of CAPA programs and Compliance, in addition to field actions.



#### **Rebeca Rodriguez**

Food and Drug Administration

Rebeca Rodríguez is a National Drug Expert Investigator from the Office of Medical Products and Tobacco Program Operations, Office of Regulatory Affairs, FDA, Rockville, MD. Ms. Rodríguez has served in several positions since she joined FDA in 1989: Chemist, Investigator, Drug Specialist Investigator, and National Drug Expert Investigator. She also worked as a Chemist for a pharmaceutical company before joining FDA. She received her BS in Chemistry from the University of Puerto Rico and is certified as a Quality Engineer by the American Society for Quality (ASQ). She has been a member of FDA's Foreign Inspection Cadre since 1993, and has conducted inspections of pharmaceutical, biotech, APIs and medical device manufacturers in several countries of Europe, South America, Australia and Asia. She is certified as member of FDA's Pharmaceutical Inspectorate. She has participated in numerous conferences and training to the pharmaceutical and medical device industries and to regulators, both in the US and internationally. Her current responsibilities include conducting inspections and training FDA staff.



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**Kathy White**

Amgen, Inc.

Kathy White has extensive experience in small and large molecule production, new product introductions, and managing global learning organizations. Kathy is on the Board of Advocates of the International Society for Performance Improvement and frequent speaker at American Society for Training and Development. Kathy's organization recently received the ISPI Award of Excellence for Performance Intervention.

