Human Factors Engineering Workshop

Innovation and Managing Risk with Medical Devices

October 28 - 29, 2008
Ann Arbor, Michigan

Instructors: John Gosbee, MD & Laura Lin Gosbee, MASc, Red Forest Consulting, LLC
Specialists in human factors engineering as it applies to healthcare
www.RedForestConsulting.com

Who Should Attend?

- Engineers, programmers, marketing, and managers involved in developing and refining medical devices
- Risk management, regulatory and clinical affairs personnel who address "use errors" with devices
- Government agency, academia, and legal personnel who seek better devices in the future

Why Attend?

- Gain a competitive advantage through easier-to-use and safer product design
- Survive FDA scrutiny and meet ISO guidelines on human factors engineering (HFE)
- Meet expectations of healthcare organizations (purchasers) who have an increased awareness of HFE

What are the Highlights?

- Learn how industry is using HFE to make products better and headaches go away
- In small group exercises, internalize how HFE helps innovation, risk management, and regulation
- Hands-on exercises allow you to apply HFE to the design of a product
- Mesh these ideas to innovation tools such as Six-Sigma and TRIZ

Industry Trends
"Over the next year, the term human factors must become very important to those who develop and market medical devices ...And many companies may need to alter their perception of human factors."
MD&DI, February 2008

Core Corporate Strategy
"Intellijject is a specialty pharmaceutical device company that is pioneering human factors engineering (HFE) applied to pharmaceutical products."
www.intellijject.com

FDA Guidance
"This FDA guidance describes how hazards related to medical device use should be addressed during device development ...use-related hazards are best identified and addressed using human factors engineering."
www.fda.gov/cdrh/humfac/1497.html

Who are the Instructors?

- Combined 25 years consulting experience with device industry and regulatory agencies
- Provided workshops to national audiences (e.g., AAMI) and for individual organizations
- Contributed to AAMI/ANSI & ISO guidelines (HE-74) and FDA practices (HFE, patient safety)
- Received AAMI medical device career achievement and ISMP medication safety awards

AGENDA

DAY ONE: October 28, 2008 (8AM - 4PM)

- Basics of human factors engineering (HFE)
  - HFE case studies of product development and applied risk management
  - Understanding HFE guidance from AAMI, ISO, IEC, and FDA
- Heuristic evaluation method (audit and checklist tool)
  - HFE analysis and redesign exercises
  - Application to and integration with clinical trials
  - Risk estimation in response to adverse events during clinical trials, alpha testing
- Usability testing method (gold standard of HFE)
  - Create test plans & execute tests
  - Apply results to risk management & new product development (invention)
  - Create designs for evaluation by another team (DAY TWO)

DAY TWO: October 29, 2008 (8AM - Noon)

- Introduction of TRIZ (inventive problem solving method)
  - HFE application of TRIZ
- Usability testing in action – bringing it all together
  - Developing test plan for another group's prototype
  - Perform usability test
  - Apply TRIZ principles to create innovation recommendations
- Prizes awarded for best design and best test plan

Details & Registration Info

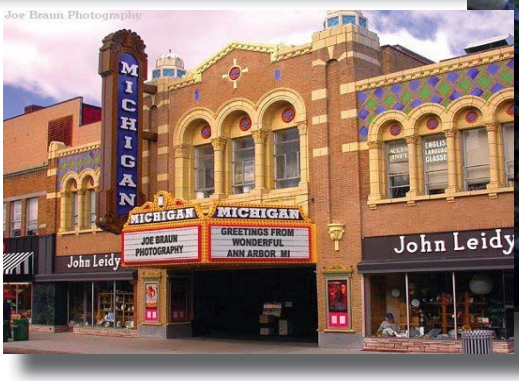
Date: October 28-29, 2008 **(1.5 days)**

Fee: $995 per person

Hotel: The Dahlmann Campus Inn • 615 E. Huron St. • Ann Arbor, MI 48104
800.666.8693 **www.campusinn.com**
Special $145/night workshop rate (until September 27, 2008)

Location: - In the heart of downtown Ann Arbor
- Only 30 minutes from Detroit Metro Airport
- Walking distance to over 30 international restaurants, numerous coffee shops and bookstores, 2 independent movie theaters, and campus of University of Michigan

Registration: Registration forms available at **www.redforestconsulting.com**



Downtown Ann Arbor