

Human Factors Engineering & Medical Device Workshop

June 15 - 16, 2009 • 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 evaluation and design of a product
- Mesh HFE with innovation tools such as Six-Sigma and TRIZ

Who are the Instructors?

- Combined 25 yrs consulting & teaching experience with hospitals & medical device industry
- Provided workshops to national audiences and 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

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

“Intelliject is a specialty pharmaceutical device company that is pioneering human factors engineering (HFE) applied to pharmaceutical products.”
www.intelliject.com

FDA Guidance

“...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

AGENDA

DAY ONE: Monday June 15, 2009 (9AM - 5PM)

- Basics of human factors engineering (HFE)
- Heuristic evaluation method (audit and checklist tool)
 - HFE analysis and redesign exercises
- Usability testing method (gold standard of HFE)
 - Hands-on exercises to create test plans & execute tests

DAY TWO: Tuesday June 16, 2009 (8AM - 3PM)

- Usability testing in action – bringing it all together
 - Develop test plans for evaluating medical devices
 - Perform usability tests
- Introduction of TRIZ (inventive problem solving method)
 - HFE application of TRIZ

Details & Registration Info

Date: June 15-16, 2009

Fee: \$1095 per person

Hotel: The Dahlmann Campus Inn • 615 E. Huron St. • Ann Arbor, MI 48104

800.666.8693 www.campusinn.com

Special \$151/night workshop rate (until May 14, 2009)

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