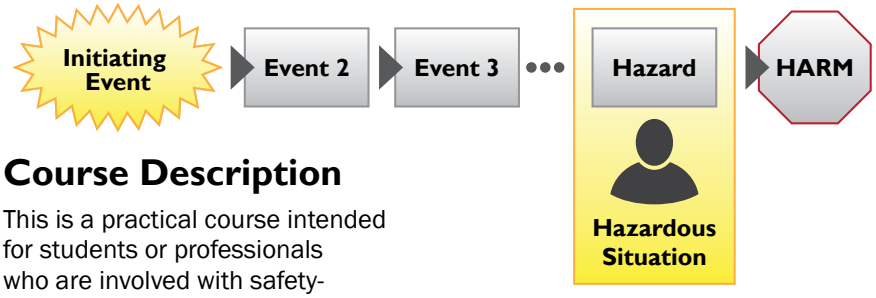
A-P-T RESEARCH, INC.

RISK MANAGEMENT FOR SAFETY-CRITICAL MEDICAL SYSTEMS

Training offered by A-P-T Research, Inc.

Introduction

The concept of Risk Management (RM) is becoming a progressively more prominent topic in the medical device industry. RM is a disciplined systematic approach to risk analysis, estimation, evaluation, and control. Application of formal RM techniques can predict and prevent harm to patients, and serious losses to business, particularly those involved in safety-critical systems. Safety-critical systems are those whose failure can result in injury or damage to human health, property or the environment.



Course Description

This is a practical course intended for students or professionals who are involved with safety-critical systems e.g., in the fields of biomedical engineering, and medical device development. This course is ideally suited for those involved in medical device development: systems engineers, design engineers, regulatory and quality assurance. Participants will learn principles of risk management, how to do risk analysis, risk estimation, risk evaluation and risk controls. An example medical device will be utilized as a test bed for teaching purposes. Students will work in small teams to practice RM techniques in class. In addition, students will learn tips and tricks to efficiently perform risk management work. To build mastery of the learned materials, a class project will be provided in which students will perform the RM process on a second example device.

Learning Objectives

- Basic principles of risk management
- Language and vocabulary of risk management
- Risk management in product development life-cycle
- International standard on risk management: ISO 14971: 2007 and 2012
- Preliminary Hazard Analysis
- Techniques of risk analysis
  - Fault Tree Analysis
  - Failure Modes and Effects Analysis
  - Use/Misuse Analysis
- Bringing it together: The System Hazard Analysis
- Residual Risk Estimation
- Risk/Benefit Analysis
- Post market feedback into the RM process

Course Duration and Format

The course is 32 hours over four days. Each day consists of about six hours of lecture and workshops, followed by two hours of teamwork on the class project. Attendees of this course will be credited with 3.2 Continuing Education Units (CEU) upon completion of the course. Class size is limited to 16 students. A laptop is required; it is recommended that it be equipped with Microsoft Excel & Powerpoint, a graphical application (such as Visio) and FreeMind (a free application available for download).

Bijan Elahi, Instructor

Bijan Elahi has worked as a risk manager for class II and III medical devices both in the USA and Europe for over 22 years. In addition to working at the largest medical device companies in the world,Bijan also teaches risk management at Eindhoven University of Technology to doctoral students in engineering.

Where

The A-P-T Research, Inc., Safety Engineering and Analysis Center in Huntsville, AL

Course Fee

$1995

Registration Information

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Other Courses Available

- Explosives Safety
- System Safety
- System Safety for Decision Makers
- Safety for Test Personnel