Implementation of Risk Management Systems for Healthcare Products & Processes

About the Course

The best risk management strategy stays in step with recognized standards and guidance documents. For medical devices, this has meant following the Quality System Regulation authorized by the U.S. Food and Drug Administration (FDA) as well as the Medical Device Directives of the European Union (EU).

Both FDA and the EU have now accepted the new ISO 14971:2000 Standard: The Application of Risk Management to Medical Devices as a risk management model. ISO 14971 will become mandatory in the EU on April 1, 2004, and will be incorporated into Japanese Pharmaceutical Affairs Law in April 2005. As these dates approach, medical device manufacturers that wish to maintain a competitive edge must gear up to implement the new standard. Firms that structure their quality system to conform to the standard may benefit by streamlining audits and market approvals, and may also gain some protection from product liability suits. Full implementation may also result in savings on insurance coverage.

Our course parallels the contents of the ISO/IEC 14971 and includes all the basic principles of risk management applicable to medical devices. It focuses on risk acceptability, risk communication, risk control and effectiveness (RACE), and specifies the steps required to identify hazards, estimate and evaluate risk, and control risk. The course shows you how to include these assessments in your company’s risk management process, and provides you with the latest tools and techniques to close the loop of the total product life cycle through the use of hands-on practices using real life product examples.

Your Opportunity

Virginia Tech is hosting these TWO two-day international workshops in Carlsbad, California, to help you satisfy the requirements of ISO 14971:2000. With the guidance of experienced and knowledgeable instructors, attendees will learn by sharing example solutions and participating in practical workshop sessions.

Both programs begin at 8:30 am on Friday, October 31, and are completed by 3:00 pm on Saturday, November 1.

Part One: Risk Control and Effectiveness

Part Two: Risk Acceptability and Communication

Who Should Attend

Decision Makers, Risk Managers, Design and Quality Engineers, Regulatory Affairs Managers and Directors, Compliance Auditors, and others.

Why You Should Attend

To practice Risk Management within a team of risk managers on a practical step-by-step approach, which enables you to market your products successfully worldwide.

For More Information

For further information regarding ISO 14971 and the current development of the International Risk Management Standard: ISO 14971—The Application of Risk Management to Medical Devices please refer to the document found on the web-site at: www.conted.vt.edu/riskmngmnt/
About Your Coaches

Three or four of the following risk-management experts will be your coaches:

Tony C. Chan, MBA, MSQA, MRS, CQM, CQA, CQE, CRE, CQI
Quality Development Advisor
Guidant Corporation, USA

Oliver P. Christ, Dip.-Ing.
Risk-Management Expert
PROSYSTEM AG, Germany

Alfred M. Dolan, CCE, Ph.D.
Samuel Lunenfeld Professor of Clinical Engineering
University of Toronto, Canada

Tony Duarte, CQE, CQA-HACCP, CMI
Quality Engineer/Regulatory Compliance Auditor
Guidant Corporation, USA

George J. Flick, Jr., Ph.D.
University Distinguished Professor
Virginia Tech, USA

Juergen Stettin, M.D., Ph.D.
Professor for Medical Regulatory Affairs
University of Applied Science Hamburg, Germany

PROSYSTEM AG
Ulmenstrasse 29, 22299 Hamburg, Germany

To register for either program, go to the web-site at:
www.conted.vt.edu/riskmngmnt/

Location and Lodging
The workshops will be held at the Hotel Grand Pacific Palisades Resort and Hotel, 5805 Armada Drive, Carlsbad, CA, USA.

For more information, visit the web-site at:
www.grandpacificpalisades.com/