



Implementation of  
**Risk Management  
Systems Course**

*for Healthcare Products & Processes*

[www.conted.vt.edu/riskmngmnt/](http://www.conted.vt.edu/riskmngmnt/)

**February 20-21, 2004**

**Carlsbad, California**

*Grand Pacific Palisades Resort and Hotel*

***A step-by-step approach on how to fulfill  
ISO 14971 Risk Management for  
Medical Devices. The curriculum focuses  
on the applications of total product life  
cycle, risk acceptability, communication,  
control, and effectiveness.***

### ● **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 who 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 (RAC<sup>2</sup>E), 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 and several partner companies and individuals are hosting these two-day international courses 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.

The course begins at 8:00 am on both days (see agenda) and is completed by 5:00 pm each day. For a detailed schedule, please check the web site at [www.conted.vt.edu/riskmngmnt/](http://www.conted.vt.edu/riskmngmnt/).

### ● **Who Should Attend**

Decision Makers, Risk Managers, Design and Quality Engineers, Regulatory Affairs Managers and Directors, Compliance Auditors, Hospital Executives (Risk Management, Human Resource, and Quality Assurance Directors/Executives), Medical Device Company Executives, 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. The curriculum focuses on the applications of total product life cycle, risk acceptability, communication, control, and effectiveness.

### ● **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/](http://www.conted.vt.edu/riskmngmnt/)

## Agenda

Hotel Conference Room  
7:30–8:00 Registration, Continental Breakfast

### Friday, February 20 *Total Product Life Cycle, Risk Acceptability and Communication*

- 8:00–12:30 Morning Session**  
Welcome and Introduction to Workshop  
Student Introduction  
Course Synopsis  
Executive Summary  
ISO 14971 Requirements and *RAC<sup>2</sup>E* Overview  
Total Product Life Cycle and Risk Management  
**Break**  
Introduction to Example Device and Exercise  
Intended Use and Exercise  
Functional Analysis and Exercise
- 12:30–1:30 Complimentary Lunch**
- 1:30–5:30 Afternoon Session**  
Adverse Effects, Hazard Identification and Exercise  
Fault Tree Analysis and Failure Mode and Effect Analysis and Exercise  
**Break**  
Hazard Analysis and Critical Control Point and Exercise  
Risk Chart Definitions and Exercise  
Risk Acceptability Criteria and Exercise
- 6:30–9:00 Evening Session including Reception and Dinner**  
Case Study Presentation (Tentative)

### Saturday, February 21 *Risk Control and Effectiveness*

- 8:00–12:00 Morning Session**  
Recap Day 1  
Option Analysis and Risk Control and Exercise  
Exercise  
Managing Risks at Product Design and Development  
Accepting Overall Residual Risk  
**Break**  
**Complete all exercises**
- 12:00–1:00 Complimentary Lunch**
- 1:00–5:00 Afternoon Session**  
Managing Post-Development Risk I  
Managing Post-Development Risk II  
Student Presentations  
Verifying Effectiveness  
Total Product Life Cycle and Risk Management Summary  
Conclusion  
Student Feedback
- 5:00 Adjourn**

### *Check out these other programs on Risk Management*

International Symposium on Risk Management  
June 15-16, 2004 • Hamburg, Germany

International Symposium on Risk Management  
September 13-15, 2004 • Washington DC

## 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  
Professor  
Virginia Tech, USA

**Oliver P. Christ**, Dipl.-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

**Thomas Storch**, Dipl.-Phys.  
Siemens Medical  
Forchheim, Germany

**PROSYSTEM AG**  
Ulmenstrasse 29\22299 Hamburg, Germany

*Speakers and topics subject to change.  
Please check the web-site for updates.*

To register, go to the web site at:  
[www.conted.vt.edu/riskmngmnt/](http://www.conted.vt.edu/riskmngmnt/)

## Location and Lodging

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

To make your lodging reservation at a special group rate or to contact the hotel, please call (800) 725-4723 or (760) 827-3200, or e-mail [GPPReservations@GrandPacificResorts.com](mailto:GPPReservations@GrandPacificResorts.com). Make sure you mention the Risk Management Program when making your reservations.

For more information, visit the web site at:  
[www.grandpacificpalisades.com/](http://www.grandpacificpalisades.com/)



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