ABOUT CfPIE

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In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

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INTEGRATION OF RISK MANAGEMENT PRINCIPLES AND ACTIVITIES INTO THE QUALITY SYSTEM

May 6 & 7, 2019 - Malvern, PA
November 4 & 5, 2019 - Los Angeles, CA

WHO SHOULD ATTEND

This two-day course is designed for quality/production managers, engineers, auditors, regulatory/quality professionals, clinical/product specialists, R&D engineers, laboratory professionals, product-development professionals, and management. Those responsible for Quality System compliance and certification to ISO 13485 are urged to attend. Attendees will learn the value of risk-management principles, integration with QMS, and how to better utilize resources.

This program provides a broad introduction to risk management for both new and experienced personnel, including management. It establishes awareness and understanding of the advantages of integrating QMS and Risk Management. Attendees will learn how to enhance the sustainability of product and business by improving patient safety, clinical outcomes, and business predictability. In workshop exercises applying those principals, participants will broaden and update their knowledge of both U.S. and international risk-management requirements.

CFPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.
Jonathan Lee has more than 25 years of broad-based medical device experience with extensive Quality System experience encompassing ISO, MDD & GMP standards and regulations, through consulting and senior management positions in QA/RA, R&D, Project Management, Product Management, and Product Introduction disciplines, in both the United States and Australia. A multiple patent holder, Mr. Lee’s prior roles include VP R&D at Cardiac Control Systems, Vice President Quality, Regulatory & Clinical affairs at Medtronic. In addition, his consulting roles supporting implantable bio stimulation telemetry systems, implantable heart sub-system, catheter defibrillation system, surgical tool, vertebral stiffness measuring system, respiratory interfaces, cardiac catheter development, medical device process V&V, quality system development & implementation, and product approvals, have provided for an extensive accumulated experience.

Today, as Principal Consultant and Managing Member of “MedDev Consulting Solutions International” he provides strategic direction and tactical solutions for unique medical device challenges. Including areas such as integration of quality systems with compliance, product performance and elevated stakeholder expectations.

Mr. Lee holds an Electrical Engineering (Biomedical) BE degree from the University of NSW in Australia with post graduate work in Computer Studies at the same University. He has participated in compliance symposia at Harvard University and served as an instructor on quality systems at University of Southern California School of Pharmacy Master’s Degree Program.

**HOTEL INFORMATION**

- The Hilton LAX, Los Angeles, CA (CfPIE room rate of $167/night if booked 3 weeks in advance of the course date)
- The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of $141/night if booked 3 weeks in advance)
- Club Quarters Hotels, Boston, MA (CfPIE room rate of $255/night if booked 4 weeks in advance)
- DoubleTree by Hilton London - Victoria (CfPIE room rate of £199.00/night if booked 4 weeks in advance)

**INSTRUCTOR CREDENTIALS**

**FIRST DAY**

**Introduction to Terms and Definitions**
- What is Risk?
- What is Risk Management?
- What are Quality Management Systems?

**Regulatory Perspectives and Requirements**
- Understanding the difference between: laws, regulations, standards, guidances, and methods
- Major standards and guidances for Pharma, Medical Device and IVD
- Reviewing the contribution of ICH for Pharma and GHTF/IMDRF for Medical Devices and IVDs
- Quality System and Risk Management requirements for Pharma, Medical Devices, and IVDs
- Requirement comparisons between the E.U., U.S., and other countries
- Comparisons of FDA/GMP/Q10, ISO 13485/Q10, ISO 14971/Q9
- Review of ISO, MedDev and EURDALEX

**Key Factors of Risk Management**
- Understanding the terms and their relationships: Risk Assessment, Mitigation, Residual Risk, Risk Management
- Real world examples and exercises reviewing: Harm, Likelihood, Severity
- Considerations for determining Acceptable Risk

**The Risk Management Process**
- Understanding Risk Management and the Product Life Cycle
- The Pharma approach
- The Medical Device/IVD approach
- The common elements and the differences
- What about "Detectability"?
- Hazards leading to Harm
- Introduction to key tools
- Lessons Learned from the real world
- Top level integration with the QMS
- The importance of the Risk/Benefit analysis

**SECOND DAY**

**Focus on tools and their application**
- Key IEC standards
- Importance of Usability and Operability
- Risk tables and FMEA: analysis of examples

**Workshop Session I**

Participants are divided into two groups and are presented with a combo-product description. An Initial Risk Assessment (IRA) is performed by each group: one assesses the pharma component; the other assesses the device component. Each group presents their results then the combined assessment is discussed.

**Deeper Dive into Product Life Cycle and Risk Management**
- Product Life Cycle stages
- Comparison between Pharma and Devices and identification of difference
- Product Life Cycle and Risk Management
- Comparing Risk Assessment with clinical experience: The importance of trending

**Real World Risk Management Integration into the QMS**
- Medical Device and the Significance of EN ISO 13485:2016 (released March 2016)
- Pharma and 210/211, Q8, Q9, Q10
- Review of the QMS elements and examples of integration
- The importance of risk control effort being proportional to the significance of risk
- Preconception, misinterpretation: Their potential impact on Calculating Risk

**Implementing Risk Management Integration**
- Identifying and overcoming the obstacles and pitfalls
- How to start

**Workshop Session II**

**Part 1**: Participants will select a QMS element and complete an initial Risk Assessment. Results will be shared and discussed by the group.

**Introduction to a Wider Application of Risk Management Principals**
- Types of “Risk”
- Other Management System standards
- ISO 31000 and the impact of redefining ‘Risk’

**Part 2**: Using a selected QMS element participants identify an associated Business Objective and complete an initial Risk Assessment using ISO 31000 concepts. Results are shared and discussed by the group.

**Conclusion**
- Day 1 Summary
- Day 2 Summary
- Final Q&A
- Meeting Objectives: Assessment of the Course
- Close