

Certificate in Product Safety Management: Spring 2011 Program

Offered by the Center for Supply Chain Management Studies of Saint Louis University in cooperation with ADK Information Services, LLC.

Starting date: January 24, 2011

Course Overview:

The Certificate in Product Safety Management is offered to enhance the skills and knowledge of product safety managers. The program uses a combination of classroom instruction, distance learning modules with instructor teleconferences, case study presentations, and communications techniques for dealing with product safety programs and issues in a company setting. Instructors are all experienced product safety professionals. Students can expect to develop understanding and technique use in the following areas:

Compliance and regulatory environment at the national and international level

Risk management at the company and product level

Product safety program design and hazard analysis

Understanding of the standards, testing, and certification requirements under current regulations

Managing the supply chain for product safety

Data base management in the product safety system and during product recalls

Product recall management and product retrieval from the marketplace and managed disposal

The subjects will be introduced and discussed as critical elements in a product safety process during the opening two-day workshop at the John Cook School of Business on January 24, 2011. Following this workshop, a four month period of 8 distance learning modules and instructor-led teleconferences will walk student participants through the practical elements in managing the product safety process in a company. Each distance learning module consists of an hour spent reviewing on-line instruction and material, plus an hour teleconference with classmates in an instructor-led discussion around the specific topic. The program will conclude in a two-day workshop on June 20 – 21, 2011 at the Cook School of Business during which students will make presentations on case studies in product safety that have been previously assigned. There will be a communications workshop on how to present and communicate product safety issues and

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programs within a company. There will be a final examination which will complete the certificate program.

The program recognizes the importance of confidentiality in a product safety system. Students are discouraged from sharing company confidential information. Instructors are asked to present instruction that does not violate confidences or confidential information. Individual student information is treated confidentially. Students receive 'complete' or 'incomplete' grades following the final examination. Students with incomplete grades will have the opportunity to obtain complete grades.

COURSE CONTENT

January 24 & 25 On campus instruction at Saint Louis University

1. Product safety in a legal and regulatory system

Explores product safety at the national and international level and focuses on the current state of compliance, regulation, and legislative issues. Instruction will touch on some of the issues relating to specific industries as reflected in the make-up of the class. The instruction will include requirements for meeting voluntary and mandatory standards, testing, certification, labels and warnings, and issues around harmonization between countries.

2. Risk Assessment and product safety system design:

The specific steps that a company can design for its risk management process are explained. Risk assessment brought down to the specific product level is explained. All students will receive their own copy of the *Product Safety Manager's Risk Assessment Manual*©, with over 160-pages of 'how-to' information that includes step-by-step procedures in validating the steps necessary to building a verifiable product safety system.

Instruction covers the design of a product safety system and an understanding of how all of the elements of production interconnect, including product design, engineering, production, supply chain management, distribution, and customer feedback. Instruction will include a focus on how to develop a hazard analysis process to identify and respond to products that are in the design process, prior to manufacturing and distribution, when hazard identification can be much more costly to a company.

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Standards, Testing, Certification are introduced as concepts of compliance and quality control through a set of conformance protocols. Current domestic and international regulations and compliance obligations include the necessity to understand the standards applicable to individual products. Companies are finding that standards may vary from country to country, requiring a more disciplined approach to research and information gathering to assure compliance. The testing requirements that exist in order to be in compliance must be properly managed and documented. Instruction will include examination of methods of certification that have changed in recent years to reflect the globalization of product manufacturing and importing/exporting.

3. Managing data and the supply chain for product safety

It is now common knowledge that companies anywhere in the supply chain are part of the product safety system. Companies that make component parts need to be managed as closely as the manufacturing process within the OEM's own factories. Supplier compliance to design or material standards are recognized as critical to a successful product safety process. Distribution and shipping issues can affect final product quality. Suppliers are often integral to product recalls and remedy programs that are agreed to by recalling companies and government agencies with oversight.

Database management for product safety and product recalls is a discipline that is now mandated by government regulation. Product safety systems must account for data that includes design, testing, and production information at a microscopic level. In addition, a new focus on traceability requires that companies develop data strategies to be in compliance with recently-enacted regulations. Data schematics now include three primary elements: design and production; inventory and distribution; and end-user data. When companies need to recall products, the more thorough their data base strategy is, the greater the likelihood that their recall procedures will be recognized for thoroughness and attention to product safety. This will help companies in their risk management area.

4. Product Recalls and Retrieval

A comprehensive product safety system must incorporate planning for the need to conduct a product recall. A company that has a well-documented plan will reduce risk, and increase the effectiveness of their efforts in the event of a recall. Company lawyers should be involved in the design and management of all product recall related activities. Instruction will include how to manage legal requirements with respect to notification of the distribution chain and consumers. Corrective action plans, including appropriate

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remedies, must be approved by federal agencies with oversight. Management of remedies including returns, refunds, or retrofits all require specific documentation for each consumer reporting a hazardous product under recall. Documentation of every phase of a product recall event, including product disposal, can help a company reduce risks and enhance its position in the event of litigation.

4. **Case study**

Each student will be assigned a case study that focuses on a fictitious product safety event within a company. Students must use elements of the Product Safety Risk Assessment Manual to prepare a response to the event. They will be required to present their response in the form of a presentation at the final workshop of the course in June.

Distance Learning Phase

1. Feb. 10: Distance learning module 1: Compliance and Regulations

Update on regulatory environment. Elements in setting up a tracking system for legislation, regulations, and compliance matters. Approaches to tracking standards through associations, standards bodies, and governmental authorities.

Feb. 15: Follow-up instructor teleconference

2. Feb. 24: Distance learning module 2: Risk Assessment

How to set up a product safety risk assessment process within your company. Focus is on a checklist of steps in developing a product safety system, including product safety design, hazard analysis, standards, testing, certification, supply chain, product recalls and product retrieval.

March 1: Follow-up instructor teleconference

3. March 10: Distance learning module 3: Product safety system design

Organizing a process for managing a product safety program system, supported by a hazard analysis process for individual products. Industry standards will include discussion of Design Failure Modes Effect Analysis (DFMEA), probability of

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occurrence, design and manufacturing defects, safety manual development, and test protocol development.

March 15: Follow-up instructor teleconference

4. March 24: Distance learning module 4: Product hazard analysis

An in depth look at how to set up a hazard analysis system that begins at the design phase and incorporates best practices through research, testing, supply chain selection and compliance, and after market consumer feedback system. An explanation of how human factors affects individual hazard analysis functioning is explained. This will include how to set up a 'foreseeable use' process to examine how consumers could interact with a company's products.

March 29: Follow-up instructor teleconference

5. April 21: Distance learning module 5: Standards, testing, and certification

Setting up a system to test conformity to standards and product design is essential in a product safety system. This module will discuss the role of standards in a product safety system, and how standards are developed. With standards as one critical component a product's design and manufacturer, a system for testing conformity must be established. Finally, government regulations place an increased reliance on certification that a product is in compliance with applicable government requirements. Certification systems and options will be explained.

April 26: Follow-up instructor teleconference

6. May 5: Distance learning module 6: Warnings and instructions

This session focuses on the need to warn about potential hazards in the use of a product, and the importance of clear instructions for safe and proper use of products. There are accepted standards for the design, use, and placement of products, as well as signal words. The use of focus groups to gather data on effectiveness of warnings and instructions is discussed.

May 10: Follow-up instructor teleconference

7. May 19: Distance learning module 7: Data Management

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Managing data is an increasingly critical element in a product safety system. The documentation of product design, engineering, production, distribution, and consumer ownership of products are all part of a data management system. Managing data during a product recall is essential for a thorough plan, and for reporting purposes. The design of a data management system and the technology architecture to develop that system requires resources and careful supervision.

May 24: Follow-up instructor teleconference

8. June 2: Distance learning module 8: Product recall and retrieval

Product recalls are visible, highly regulated events that publicize the hazard that a product can create. A company's reputation and marketing are affected. A company's ability to do a product recall event effectively can be a positive reflection, and an element of defense in litigation. Recalls require plans, a notification strategy, a remedy satisfactory to government, and the ability to manage customer service and registration in a challenging environment. The retrieval, disposal, and accounting for recalled products require a well designed data management strategy.

June 7: Follow-up instructor teleconference

9. June 14: Webinar: Distance learning module 9

A summary session will include a discussion on product safety systems, and any recent developments that affect companies with compliance responsibilities. Students will be able to ask questions of participating instructors. Case study presentations and final examination will be discussed.

June 20 & 21: On campus instruction at Saint Louis University

The final workshop of the Certificate in Product Safety Management will include 5 sessions:

1. Case study presentations by each student. Students will have the opportunity to share their PowerPoint presentations with the class. The purpose of the presentations is to demonstrate knowledge of the product safety system, and to use their communications skills in sharing that knowledge.
2. A communications workshop on techniques and technology for communicating product safety information, plans, and situations within a company. One of the traits of a

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successful product safety manager is the ability to communicate effectively with senior management, department heads, suppliers, and co-workers on behalf of the company's risk management program.

3. Final Examination
4. Class feedback and survey to provide feedback to course planners
5. Graduation ceremony with guest speaker

The number of topics and the subtopics may vary from class-to-class, with a goal of providing students with both theoretical and practical insights into product safety management. This will be supported with case studies and use of the Product Safety Risk Assessment Manual. Together, they will create a foundation upon which participants can support their company's product safety goals with specific plans and structure. The Certificate in Product Safety Management will attest to the student's accomplishments in completing in class and distance learning objectives, as well as the company's commitment to a strong product safety program.