

2012 Quality System Training Programs



Helping you to make
medical devices safer
and more effective.

2012 Offerings:

- Quality System **Updated!**
- Design Control
- Risk Management
- Process Validation
- Software Validation—Requirements
- Software Validation—Tools and Techniques
- Corrective and Preventive Action (CAPA)
- Human Factors
- Documents and Records
- Purchasing Controls
- Fundamental Statistical Tools and Methods
- Safety Assurance Cases
- Industrial Sterilization
- Radiation Sterilization
- Industrial Ethylene Oxide Sterilization

2012 Quality System Training Programs

Designed to facilitate and enhance the dialog among medical device professionals from both the manufacturing and regulatory environments, AAMI's comprehensive and interactive 2 to 4 day training programs provide a unique learning experience for quality assurance/regulatory affairs professionals; design, human factors, process, and software engineers; risk management managers; process owners of CAPA or supplier/purchasing activities; document control specialists; compliance officers; and standards application managers.

Participate, share, and learn with industry and regulatory representatives from around the globe.

Program Formats:

A combination of situation analyses; case study exercises; industry examples, tools, and best practices; examination of sample recall and warning letters; and both formal and informal discussions are used throughout the programs to provide maximum opportunity to apply classroom learning to real-life situations.

Faculty:

Faculty for AAMI's training programs are drawn from an experienced group of professionals from the medical device industry, academia, and FDA, ensuring a balanced presentation of requirements and paths to quality system compliance, as well as an improved understanding of industry practices and standards application.

Distance Learning

AAMI offers distance learning on quality systems, sterilization, and standards-related topics. To see a list of upcoming programs, visit www.aami.org/meetings/events/.

In-House Programs

Call +1-703-253-8283 about bringing our training programs in-house. Website: www.aami.org/meetings/courses/inhouse.html.

>>Program Descriptions, Dates, and Locations at a Glance:

Quality System Requirements and Industry Practice **UPDATED!**

4 day comprehensive course, with optional ½ day exam, providing the basic knowledge and skills needed to develop a quality system program that conforms with FDA's Quality System regulation. Content is based on the body of knowledge developed jointly by representatives of the medical device industry and FDA.

February 20–23
February 24 (Exam).....Washington, DC
April 23–26
April 27 (Exam).....San Francisco, CA
June 11–14
June 15 (Exam).....Orlando, FL
September 17–20
September 21 (Exam).....Alexandria, VA
October 8–11
October 12 (Exam).....Dublin, Ireland
December 3–6
December 7 (Exam).....Alexandria, VA

Design Control Requirements and Industry Practice

2½ day intensive course focusing on the how-to's of implementing a program that meets FDA's design control requirements while ensuring a fast and efficient flow of new products. Upon completion, participants will be able to evaluate the degree of compliance of a design control system, including identification of noncompliance issues, and be prepared to implement improvements to meet regulatory and business strategies.

March 26–28.....Alexandria, VA
October 29–31.....Arlington, VA
December 3–5.....Arlington, VA

Integrating Risk Management into the Quality System

2½ day course presenting risk management concepts and practices used throughout the quality system as well as the lifecycle of the product, from design, to manufacturing, through post-production. Those looking for guidance on regulatory requirements and ways that standards are related to risk management will also benefit from this program.

April 30–May 2.....Silver Spring, MD
September 10–12.....Alexandria, VA

Process Validation Requirements and Industry Practice

2½ day intensive course providing the knowledge and skills needed to comply with FDA's process validation requirements while offering information on how to implement an effective validation program. Upon completion of the course, participants will be able to apply the principles of process validation to their operations.

April 16–18.....Arlington, VA
October 1–3.....Alexandria, VA
Optional Post-Test.....Online

Software Validation Requirements

3 day intensive course supplying information needed to comply with FDA's software validation requirements while providing tips on how to implement an effective validation program. Participants will also come away from the program with an awareness of relevant standards, FDA guidance documents, and other resources that will assist in defining acceptable compliance practices.

April 2–4.....Silver Spring, MD

>>Program Descriptions, Dates, and Locations at a Glance:

Software Validation Workshop: Practical Tools and Techniques

3 day workshop providing practical tools and techniques for software validation for embedded device software, off-the-shelf software, and quality system (non-device) software. The program includes real-life software validation examples utilizing engineering and software quality "best practices". Specific topics include writing useful and testable requirements, techniques for testing, and streamlining quality processes for development and validation efforts.

May 15-17.....Orlando, FL
October 8-10.....San Francisco, CA

Corrective and Preventive Action Requirements and Industry Practice

2 day course providing intensive coverage of the elements of a corrective and preventive action (CAPA) system. After completing the course, participants will understand the essentials of an effective CAPA system and understand what is required for compliance with FDA's Quality System regulation.

May 10-11.....Silver Spring, MD
Optional Post-Test.....Online

Human Factors for Medical Devices

3 day course presenting an introduction to human factors, regulatory requirements of FDA as they relate to human factors, and the role of human factors in design controls. Provides a basic foundation for application of human factors, with discussions on user models and task analysis; anatomy of use errors; and task analysis as a basis for planning human factors efforts.

May 7-9.....Alexandria, VA
November 7-9.....Alexandria, VA

Document Control and Records Management for Medical Devices

2½ day program focusing on how documents and records are controlled, the objective evidence required for compliance, and the linkages between documents and records to the various processes and activities within a QMS. Upon completion of this course, participants will be able to use documentation as a tool to facilitate quality improvement as well as compliance with the Quality System regulation and the ANSI/AAMI/ISO 13485:2003 standard.

October 8-10.....Phoenix, AZ

Purchasing Controls and Supply Chain Management

2½ day course imparting extensive information on effective implementation of supplier selection and controls. The course also covers life-cycle management approaches for a medical device manufacturing organization's supply chain. Also covered are the key aspects of supplier controls, from planning for supplier assessment/selection, to defining acceptance activities, to monitoring supplier performance.

June 4-6.....Alexandria, VA
November 12-14.....Alexandria, VA

Fundamental Statistical Tools and Methods for Quality Systems

3 day workshop presenting product and process experts a solid understanding of how to use statistical tools and methods to support design control, process validation, and CAPA activities. Hands-on computer-based training will stress practical application over theory.

October 15-17.....Las Vegas, NV

Safety Assurance Cases for Medical Devices

3 day course provides attendees with an understanding of safety assurance cases and how they can be used to demonstrate the validity of safety claims made for medical devices.

May 14-16.....Arlington, VA
October 22-24.....Alexandria, VA

Industrial Sterilization for Medical Devices

4 day course covering sterilization processing in a medical device manufacturing environment. Topics addressed include sterilization technologies and methods, sterilization standards, FDA requirements, and critical factors in product design and product release decisions. Recommended for those who are relatively new to the sterilization process environment and need information to help them better understand the principles and science of industrial sterilization.

May 8-11.....Minneapolis, MN

Radiation Sterilization for Medical Devices

3½ day course providing intensive coverage of principles, processes, best practices, and industry standards in radiation sterilization for medical devices. Topics covered include the scientific theory and principles of radiation sterilization; FDA expectations regarding successful submissions and inspections, recalls, problem solving, and risk avoidance; and review of the 11137 series radiation sterilization standards.

October 2-5.....Denver, CO

Industrial Ethylene Oxide Sterilization for Medical Devices

3 day workshop presenting intensive coverage of principles, processes, best practices, and industry standards in ethylene oxide sterilization for medical devices. Topics touched upon include validation and requalification; validation reports, protocols, and documentation; product adoption; troubleshooting; process changes and process equivalency; product release methods; and optimization of sterilization process. The workshop is for individuals who are experienced in working with an established ethylene oxide sterilization process, but are now challenged with ensuring the continued effectiveness and assessing change for the product or process.

September 17-19.....Las Vegas, NV

For more detailed
information on program
outlines, content, target
audiences, and locations,
please visit:

[www.aami.org/
meetings/courses/](http://www.aami.org/meetings/courses/)



>> Fees and Registration:

Quality System course:

Fee includes the textbook, *The Quality System Compendium*; PowerPoint presentations and case studies; pertinent FDA documents and additional references; welcome reception; and continental breakfast, lunch, and refreshments for four days.

AAMI corporate and institutional members	\$2185
AAMI individual members	\$2485
Nonmembers	\$2785
Government employees	\$785

Quality System exam (includes continental breakfast):

AAMI members	\$250
Nonmembers	\$350
Government employees	\$150

Fundamental Statistical Tools and Methods for Quality Systems

Fee includes pertinent FDA documents, additional references, and PowerPoint presentations; software and a data disk; and continental breakfast, lunch, and refreshments.

AAMI corporate and institutional members	\$1935
AAMI individual members	\$2035
Nonmembers	\$2435
Government employees	\$635

Risk Management, Software Validation Requirements, Safety Assurance Cases, and Human Factors courses and Software Validation Tools workshop:

Fee includes PowerPoint presentations and case studies; relevant standards and/or technical information reports; pertinent FDA documents and additional references; and continental breakfast, lunch, and refreshments.

AAMI corporate and institutional members	\$1835
AAMI individual members	\$1935
Nonmembers	\$2235
Government employees	\$635

Industrial Sterilization course:

Fee includes PowerPoint presentations and case studies; relevant standards and technical information reports; pertinent FDA documents and additional references; and continental breakfast, lunch, and refreshments.

AAMI corporate and institutional members	\$2135
AAMI individual members	\$2235
Nonmembers	\$2635
Government employees	\$835

Radiation Sterilization course and Industrial Ethylene Oxide Sterilization workshop:

Fee includes PowerPoint presentations and case studies; relevant standards and technical information reports; pertinent FDA documents and additional references; and continental breakfast, lunch, and refreshments.

AAMI corporate and institutional members	\$1935
AAMI individual members	\$2035
Nonmembers	\$2435
Government employees	\$635

Design Control, Process Validation, CAPA, Documents and Records, and Purchasing Controls courses:

Fee includes PowerPoint presentations and case studies; relevant standards and technical information reports; pertinent FDA documents and additional references; and continental breakfast, lunch, and refreshments.

AAMI corporate and institutional members	\$1735
AAMI individual members	\$1835
Nonmembers	\$2135
Government employees	\$635

NEW CAPA and Process Validation Optional Online Post-Test:

AAMI members & Government employees	\$50
Nonmembers	\$75

>> Registration Information

In the event you are unable to attend this course, you may transfer your registration to a qualified colleague or apply your registration fee to a subsequent program, on a space-available basis. AAMI's policies on refunds, transfers, and substitutions are:

- **Send a colleague to attend in your place**—Substitutions can be made at any time prior to a program without penalty. No substitutions will be honored once a program begins.
- **Transfer to a subsequent program**—AAMI allows a one time transfer to a subsequent program as an alternative to cancellation. Transfer requests must be received by AAMI in writing (via e-mail or fax) no later than one week prior to the start of the originally registered program. (Please note: for those requests received within one week of the program, AAMI will assess a \$400 transfer penalty in addition to the registration fee). Transfer requests must state alternate name and date of the program choice. Since programs are not all priced identically, the registrant is responsible for any increases in registration fees resulting from the transfer. No refunds for the difference between program prices will be made should the price of the program choice be less than the price of the originally registered program. Any request for a transfer beyond this one-time allowance will be treated as a cancellation (See Cancellation below).
- **Cancellation**—If AAMI receives a cancellation request at least one week prior to the program date, the registration fee minus a \$400 cancellation fee will be refunded. No refunds will be granted for cancellations received by AAMI less than one week before the program.

No Shows—Failure to attend a program for which you are registered will result in forfeiture of registration fees.

Multiple Registrations—Please photocopy the registration form for additional registrants.

Group Discounts—Rates for group discounts are available upon request. For more information, please call +1-800-332-2264, ext. 1411.

Confirmation—Confirmation notices will be distributed one week after your registration has been processed.

Are You a Member of AAMI? - Are you entitled to the member discount? Please call +1-800-332-2264, ext. 1214, before you register and find out.

To register, visit www.aami.org/meetings/courses/registration.html or call +1-800-373-3174.

When registering, refer to source code: **GPBM**

2012 Training Program Registration Form

Follow the four easy steps to register.

STEP 1

Please select program date and location:

• Quality System courses:

- February 20–23, Washington, DC
- February 24 (Exam), Washington, DC
- April 23–26, San Francisco, CA
- April 27 (Exam), San Francisco, CA
- June 11–14, Orlando, FL
- June 15 (Exam), Orlando, FL
- September 17–20, Alexandria, VA
- September 21 (Exam), Alexandria, VA
- October 8–11, Dublin, Ireland
- October 12 (Exam), Dublin, Ireland
- December 3–6, Alexandria, VA
- December 7 (Exam), Alexandria, VA

• Design Control courses:

- March 26–28, Alexandria, VA
- October 29–31, Arlington, VA
- December 3–5, Arlington, VA

• Integrating Risk Management courses:

- April 30–May 2, Silver Spring, MD
- September 10–12, Alexandria, VA

• Process Validation Requirements courses:

- April 16–18, Arlington, VA
- October 1–3, Alexandria, VA

• Software Validation Requirements course:

- April 2–4, Silver Spring, MD

• Software Validation: Practical Tools and Techniques workshops:

- May 15–17, Orlando, FL
- October 8–10, San Francisco, CA

• Corrective and Preventive Action course:

- May 10–11, Silver Spring, MD

• Human Factors courses:

- May 7–9, Alexandria, VA
- November 7–9, Alexandria, VA

• Document Control and Records course:

- October 8–10, Phoenix, AZ

• Purchasing Controls courses:

- June 4–6, Alexandria, VA
- November 12–14, Alexandria, VA

• Fundamental Statistical Tools and Methods for Quality Systems workshop:

- October 15–17, Las Vegas, NV

• Safety Assurance Cases courses:

- May 14–16, Arlington, VA
- October 22–24, Alexandria, VA

• Industrial Sterilization course:

- May 8–11, Minneapolis, MN

• Radiation Sterilization course:

- October 2–5, Denver, CO

• Industrial Ethylene Oxide Sterilization workshop:

- September 17–19, Las Vegas, NV

STEP 2

Please select the applicable registration fee:

Quality System course:

- AAMI corporate and institutional members \$2185
- AAMI individual members \$2485
- Nonmembers \$2785
- Government employees \$785

Quality System exam:

- AAMI members \$250
- Nonmembers \$350
- Government employees \$150

Fundamental Statistical Tools and Methods for Quality Systems:

- AAMI corporate and institutional members \$1935
- AAMI individual members \$2035
- Nonmembers \$2435
- Government employees \$635

Risk Management, Software Validation Requirements, Safety Assurance Cases, and Human Factors courses and Software Validation Tools workshop:

- AAMI corporate and institutional members \$1835
- AAMI individual members \$1935
- Nonmembers \$2235
- Government employees \$635

Industrial Sterilization course:

- AAMI corporate and institutional members \$2135
- AAMI individual members \$2235
- Nonmembers \$2635
- Government employees \$835

Radiation Sterilization course and Industrial Ethylene Oxide Sterilization workshop:

- AAMI corporate and institutional members \$1935
- AAMI individual members \$2035
- Nonmembers \$2435
- Government employees \$635

Design Control, Process Validation, CAPA, Documents and Records, and Purchasing Controls courses:

- AAMI corporate and institutional members \$1735
- AAMI individual members \$1835
- Nonmembers \$2135
- Government employees \$635

CAPA and Process Validation Optional Online Post-Test:

- AAMI members and Government employees \$50
- Nonmembers \$75

STEP 3

Please provide the following information:

FULL NAME _____

NAME ON BADGE _____

TITLE _____

COMPANY _____

ADDRESS _____

PHONE _____

FAX _____

EMAIL _____

SPECIAL NEEDS (accessibility, dietary restrictions, etc.) _____

- Your contact information will be provided on an attendee roster that will be distributed to program attendees and faculty. If you do not want your telephone number, fax number, and e-mail address provided to course attendees and faculty, please check here. (This does not apply to AAMI's on-line membership directory.)

STEP 4

Please provide your payment information:

Payment method

All registrations must be prepaid prior to start date by credit card or check.

- Payment enclosed (US dollars payable to AAMI)
- Please charge my:
 - MasterCard VISA AmEx

Card Number _____

Exp. Date _____

Cardholder Name _____

Authorized Signature _____

Join AAMI and Save!

- Individual members \$220
- International individual members \$280
- New Professional \$60
- Student \$30

TOTAL PAID: \$ _____

NOTE: Please confirm program availability prior to submitting payment and making travel reservations. AAMI is not responsible for any airline or hotel cancellation fees if program availability is not confirmed prior to making travel reservations.

To register, visit www.aami.org/meetings/courses/registration.html or call +1-800-373-3174 or fax to +1-240-396-5781.