AAMI Training

Serving the health technology industry for more than 50 years.

www.aami.org/training
Navigate the fast-paced regulatory world with confidence.
AAMI leads global collaboration in the development, management, and use of safe and effective health technology. We are a world leader in medical device standards, a growing community of engaged thought leaders, and a provider of high-quality training in health technology.

Our training, developed in collaboration with industry subject matter experts, aligns cutting-edge industry experience with course design that supports peer-to-peer interaction and hands-on learning.

Let our experienced instructors help you stay up-to-date in the fast-moving regulatory world. Learn directly from and interact with FDA staff who participate in most AAMI training programs and gain the insight and skills you need to succeed in your role.

AAMI training is delivered as 2, 3, or 4.5-day sessions in the following areas:

- Quality Systems
- Human Factors
- Sterilization
- Software/Cyber

AAMI training is offered at the AAMI Center for Excellence in Arlington, VA. The Center boasts nearly 4,400 square feet of conference room space for up to 300 participants, and leverages the latest audio, visual, and teleconferencing technology. AAMI courses can also be delivered on-site at your location, and content can be tailored to your specific needs.

For more information, visit www.aami.org/training
Quality Systems
Learn how to develop and maintain a quality system program that conforms with the FDA’s Quality System Regulation (21 CFR 820) and ANSI/AAMI/ISO 13485:2016. Course content is the culmination of years of consensus development on the part of a respected group of quality system experts from leading device manufacturers, the FDA, industry consultants and members of ISO standards development teams.

Design Control Requirements—Integrating the Quality System Regulation and ANSI/AAMI/ISO 13485
Benefit from an intensive focus on design control requirements for the FDA’s Quality System Regulation, ANSI/AAMI/ISO 13485:2016, and the Medical Device Single Audit Program (MDSAP). With the participation of FDA representatives during the entire course, attendees have the unique opportunity to participate in a shared learning experience.

Document Control and Records Management for Medical Devices—

Available as private training only
Learn to use documentation as a tool to facilitate compliance with the Quality System Regulation and the ANSI/AAMI/ISO 13485:2016 Standard. Implement your quality management system using classic systems architecture to establish appropriate links between core processes. Make better informed decisions and use documentation and objective evidence for implementing change.

Corrective and Preventive Action Requirements and Industry Practice
Experience intensive coverage of the elements of a corrective and preventive action (CAPA) system. Learn the purpose of a CAPA system; its integration throughout a quality management system; appropriate data sources and how to coordinate, analyze and manage them; methods for verifying and/or validating actions; writing good CAPA plans; the use of risk management in conjunction with the CAPA system; and 21 CFR and ISO 13485 requirements.

Process Validation Requirements and Industry Practice
Obtain practical tools and techniques for process validation requirements for the FDA’s Quality System Regulation and recognized process validation guidance from the Global Harmonization Task Force.

Purchasing Controls and Supply Chain Management
Industry experts will help you understand effective implementation of supplier selection and controls. Training covers the key aspects of supplier controls, from planning for supplier assessment/selection, to defining acceptance activities, to monitoring supplier performance. Each topic is presented from a practical perspective, with links to the requirements of the Quality System regulation, the ISO 13485 standard, risk management considerations, and pertinent Global Harmonization Task Force guidance.

Statistical Tools & Methods for a Quality System—
Available as private training only
Stressing application over theory, this training provides product and process experts an understanding of how to use statistical tools and methods to support Design Control, Process Validation, Corrective and Preventive Action (CAPA), and Complaint Monitoring. The content is based on the requirements of the FDA’s Quality System Regulation and the recommendations of the process validation guidance document developed by the Global Harmonization Task Force.

Integrating Risk Management into the Product Life Cycle
Understand risk management concepts used throughout the quality system to successfully meet FDA, ANSI/AAMI/ISO 14971, and ANSI/AAMI/ISO 13485:2016 requirements. Learn how to use risk management to make risk-based decisions for product realization, from cradle to grave. Present throughout the course, FDA representatives outline expectations for submissions and compliance, as well as how to apply risk management principles to various aspects of a quality system.
Human Factors
Human Factors for Medical Devices

Medical device manufacturers with robust human factors processes are leading the market, proving to have better clinical outcomes and better quality. Take this course to understand critical human factors processes to consider when designing a medical device, how they affect its safety, and which steps to take to mitigate risks. FDA representatives from CDRH and CDER will speak to expectations for device usability.

Applying Human Factors to Improve Instructional Materials as Part of the User Interface—Available as private training only

Developed for those involved in the design, development, and human factors testing of instructional materials for medical device users, this training outlines processes that are consistent with industry standards and guidelines, including FDA regulations and AAMI TIR 49, Design of training and instructional materials for medical devices used in non-clinical environments. Faculty with a combined 58 years of experience lead participants through case studies and interactive exercises to create a dynamic and high-immersion environment.

Risk Management and Human Factors—Available as private training only

Training focuses on managing risk across the product life cycle, identifying use-related hazards and failure modes and crucial tasks for testing, evaluating failures, and addressing use-risk design changes and postmarket complaint investigations. Obtain an understanding of the expectations of the FDA as well as best practices for human factors risk management. Participants will learn how to incorporate risk management activities into their human factors planning.

Human Factors Methodologies—Available as private training only

AAMI’s industry expert faculty will help you identify the role of human factors in developing and testing instructions for use/training tools and the role postmarket surveillance (dealing with complaints and adverse events) plays in medical device design. Learn to develop methods and strategies to advance product design, using formative human factors studies such as contextual inquiry, review of predecessor products, concept evaluation, and task analysis.
Industrial Sterilization for Medical Devices
Learn about sterilization technologies and methods, sterilization standards, FDA requirements, critical factors in product design, and product release decisions.

Learn how to apply the principles of sterilization and address requirements during product design. Participants will also learn how to select and implement an appropriate sterilization process and how to identify the elements of a successful sterilization validation. Walk through the design of process validation for moist heat, ethylene oxide (EO), and radiation sterilization processes, and compare and contrast sterilization cycle developments based on product bioburden and those based on combined bioburden/overkill method.

Ethylene Oxide Sterilization for Medical Devices
Training focuses on participants 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. The combination of a classroom lecture with real-life scenarios helps to illustrate concepts and situational analyses. Faculty will address validation and requalification; validation reports, protocols, and documentation; product adoption; troubleshooting; process changes and process equivalency; product release methods; and optimization of sterilization process.

Radiation Sterilization for Medical Devices
Develop an understanding of FDA expectations regarding successful submissions and inspections, recalls, problem solving, and risk avoidance; scientific theory and principles of radiation sterilization; and the 11137 series of radiation sterilization standards. Faculty will address principles, processes, industry best practices, and industry standards in radiation sterilization for medical devices.
Software/Cyber
Regulatory Requirements for Software Validation in the Medical Device Industry

Training focuses on the application of the principles of software validation to medical device products, production processes, and quality systems. FDA representatives will explain the expectations for meeting compliance requirements.

Developing and Validating Software for the Medical Device Industry

Learn how to design software validation plans that build confidence in the software and comply with regulatory requirements for device, commercial off-the-shelf, and quality system software; use risk management to focus validation activities to minimize risk; streamline elements of the quality system for cost-efficient validation; select appropriate life-cycle models; synchronize validation activities for all types of software; and integrate best development engineering practices to support validation efforts.

Effective Application of Agile Practices in the Development of Medical Device Software

Learn how to evaluate the challenges with the use of Agile practices and adapt these practices to ensure the development of compliant, safe, and effective products. This course builds on the concepts in AAMI TIR45: Guidance on the use of AGILE practices in the development of medical device software.

Application of Agile to the Development of Medical Device Systems

For many years, software development teams have been using Agile software development methods, but Agile is not just for software. Agile’s lean product development principles also apply to the development of hardware-based products and systems. Go beyond small-team and software-only applications and discover how Agile practices can be used in the development of medical device systems.

For more information, visit www.aami.org/training
Our Mission is Your Success

Want to bring AAMI training in-house? Let us bring our expert faculty to your location and deliver a training experience based on your business goals and objectives. All AAMI classes can be deployed to the location of your choice. Based on your organization’s specific needs, AAMI’s experienced faculty can also tailor training to fit your organization’s needs that will:

- Establish a common language and understanding of regulatory requirements across your organization.
- Provide a training program with focused discussions on your organization’s specific products and processes.
- Use customized case studies and problem-solving exercises.

Have a need that is not met by our current offerings? We can leverage our global network of experts to develop a custom training solution that meets your needs.

For more information, contact the AAMI Education team at 703.525.4890, option 3 or at education@aami.org.

At AAMI, our mission is your success. We look forward to meeting your training needs and to helping you succeed in the exciting, challenging, and always changing medical device industry.

Robert Burroughs
SVP of Education
AAMI
Experience
Quality
and Success
”The quality of the course, the materials, the presenters and the facility were all top notch. I’ve already recommended other AAMI courses to my colleagues.”

— TRISH BOLECHOWSKY
SENIOR PROJECT MANAGER, R & D EPOCAL INC.
A SIEMENS HEALTHINEERS COMPANY

”If not the best of the best, then AAMI trainings, in my opinion, are among the best. AAMI’s materials and instructors are top notch.”

— KEVIN RANDALL, ASQ CQA, RAC (U.S., CANADA, EUROPE)
PRINCIPAL CONSULTANT
COMPLIANCEACUITY, INC.

”This course helped me understand the risk management big picture and key concepts from industry and FDA POV. Lively discussion and expert instruction of the history, current state, and future state of the various laws, regulations, standards, and guidance that govern risk management. Thank you for condensing so much information in just three days.”

— SCOTT BARTON
REGENERON PHARMACEUTICALS, INC.

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