Continuing Education for the Medical Device Industry

AAMI University
Course Catalog Spring 2015
There is no simple template for the diverse education needs of the medical technology profession. AAMI University is your resource for:

- Issue-specific webinars
- Seminars that engage the professional and regulatory community, and
- Courses and curriculum designed for professional development at all career stages

AAMI University is the go-to source for healthcare technology education.

AAMI University offers classes and curriculum developed in close consultation with industry leaders including the FDA and subject matter experts. Our on-demand courses are taught by the same instructors who teach our live training programs and speak at our conferences. Our technology allows discussion and interaction which optimizes your experience based on how you prefer to learn. Learning from experts and interacting with professional peers are part of every AAMI University program.

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Education for the Medical Device Industry

Biological Evaluation


ON-DEMAND WEBINAR This webinar addresses good clinical practice in clinical investigations of medical devices for human subjects using the 14155 standard as a guide.
Order Code CIMDWCD
$415 List / $315 AAMI member

Biological Evaluation of Medical Devices: Application of ANSI/AAMI/ISO 10993 Parts 1 and 17

ON-DEMAND WEBINAR This webinar addresses two parts of the international standard and its application for those involved in the development, testing, or approval of medical devices.
Order Code BEWCD
$415 List / $315 AAMI member

Electromedical Equipment

S3 Challenge 2015

AAMI | FDA Forum on Standards, Synthesis, Solutions

CONFERENCE The discussion will focus on IEC 60601, specifically on electrical and mechanical hazards and the importance of assessing and managing risk as a part of design, good manufacturing, and premarket and postmarket performance of medical devices.
Apr. 1-2, 2015, Herndon, VA [Registration Code ISC15]
$995 List / $795 AAMI member

The New 60601-1 Amendment: Risk Management and Essential Performance Requirements for Electronic Medical Devices

ON-DEMAND WEBINAR This webinar addresses Amendment 1 (2012) and includes perspectives from two of the committee members responsible for drafting it.
Order Code WDQS1302RM
$415 List / $315 AAMI member

How to Test to IEC 60601-1, 3rd Edition

ON-DEMAND WEBINAR This webinar provides up-to-date, detailed information about IEC 60601-1, 3rd edition and its requirements for manufacturers of medical electrical equipment.
Order Code HTIWCD
$415 List / $315 AAMI member
Human Factors

Human Factors for Medical Devices
TRAINING PROGRAM This three-day course provides an introduction to human factors, FDA regulatory requirements as they relate to human factors, and the role of human factors in design controls. This course also provides a basic foundation for application of human factors.
Mar. 11-13, 2015, Alexandria, VA [Registration Code HFM15]
Nov. 4-6, 2015, Arlington, VA [Registration Code HFN15]
$2,435 List / $2,135 AAMI member

Risk Management and Human Factors
TRAINING PROGRAM Properly identifying and mitigating use-related hazards is an important step in designing medical products. In this workshop, participants will learn how to incorporate risk management activities into their human factors planning.
$2,335 List / $2,035 AAMI member

Design Control: The Intersection of Human Factors, Industrial Design, and Risk Management
TRAINING PROGRAM This one-day program, held in conjunction with the 2015 International Symposium on Human Factors and Ergonomics in Health Care, will identify the role of risk management in the usability and human factors process. Special early-bird pricing for HFES Symposium registrants only.
Apr. 26, 2015, Baltimore, MD [Registration Code HFCDRMA15]
$765 List / $565 AAMI member (before March 26, 2015)
$965 List / $765 AAMI member (after March 26, 2015)

Advanced Topics in Human Factors
TRAINING PROGRAM This one-and-a-half-day program, held in conjunction with the 2015 International Symposium on Human Factors and Ergonomics in Health Care, will address advanced topics in postmarket human factors. Special early-bird pricing for HFES Symposium registrants only.
Apr. 29-30, 2015, Baltimore, MD [Registration Code HFADHFA15]
$965 List / $765 AAMI member (before March 26, 2015)
$1,215 List / $1,015 AAMI member (after March 26, 2015)

Good Design of Medical Device Instructions for Use and Training Materials
ON-DEMAND WEBINAR The primary purpose of this webinar is to lay out a process for the design of instruction and training materials that are well-integrated with other device design activities and successful when applied during the premarket process.
Order Code WAHF1408GD
$415 List / $315 AAMI member

Simulating Invasive Medical Procedures During Usability Testing
ON-DEMAND WEBINAR Gain a heightened appreciation for the value of effective simulation of invasive medical procedures and the know-how to conduct an effective simulation.
Order Code WAHF1408SI
$415 List / $315 AAMI member

Creating Effective Quick Reference Guides
ON-DEMAND WEBINAR This webinar presents the ubiquitous quick reference guide as an unsung hero in the business of helping users to interact safely and effectively with medical devices.
Order Code WAHF1407RG
$415 List / $315 AAMI member

Writing an Effective Human Factors Engineering Procedure
ON-DEMAND WEBINAR This webinar discusses the need for medical device companies to create a human factors engineering (HFE) procedure that conforms to current HFE standards as well as the standards and expectations of the FDA and other regulators.
Order Code WAHF1406HF
$415 List / $315 AAMI member

Root Cause Analysis of Medical Device Use Error
ON-DEMAND WEBINAR This webinar explains the regulatory imperative to conduct thorough and accurate root cause analyses of use errors observed in validation usability tests of medical devices.
Order Code WDHF1405RC
$415 List / $315 AAMI member

Selling HF: The Business Case for Human Factors in Industry
ON-DEMAND WEBINAR Hear real-life experiences in “selling” Human Factors/Ergonomics (HF/E) to teams and to management that have not had HF/E experience in the past, or have an incorrect perception of what HF/E can offer.
Order Code WDQS1309HF
$415 List / $315 AAMI member

Applying Human Factors Engineering to Legacy Medical Devices
ON-DEMAND WEBINAR This webinar reviews the challenges associated with applying HFE retrospectively to legacy devices. It also reviews the content and status of a proposed annex to IEC 62366 (so-called Annex K) that offers a possible pathway toward meeting IEC 62366 without performing all of the HFE work the standard suggests is needed.
Order Code WDQS1303HF
$415 List / $315 AAMI member
Education for the Medical Device Industry

Writing a Human Factors Engineering Report
ON-DEMAND WEBINAR This webinar reviews the FDA’s guidance pertaining to HFE reports, recommends a good process for producing an HFE report, presents exemplars of well-conceived report sections, and describes potential pitfalls regarding the report’s content and level of detail.
Order Code WDQS1302HF
$415 List / $315 AAMI member

Microbiology for Medical Device Manufacturing and Sterilization
ON-DEMAND WEBINAR This webinar addresses concepts of microbiology as applied to sterilization and problem-solving microbial contamination issues for medical devices.
Order Code MMDWCD
$415 List / $315 AAMI member

Industrial Sterilization

Industrial Sterilization for Medical Devices
TRAINING PROGRAM This comprehensive four-day course covers essential information on sterilization technologies and methods, sterilization standards, FDA requirements, critical factors in product design and product release decisions, and much more.
May 4-7, 2015, Alexandria, VA [Registration Code IMMY15]
$2,735 List / $2,435 AAMI member

Industrial Ethylene Oxide Sterilization for Medical Devices Workshop
TRAINING PROGRAM This highly interactive, three-and-a-half-day advanced workshop is designed for those challenged with ensuring the continued effectiveness of an established ethylene oxide sterilization process.
Sept. 14-17, 2015, San Diego, CA [Registration Code EOS15]
$2,535 List / $2,235 AAMI member

Radiation Sterilization for Medical Devices
TRAINING PROGRAM This advanced three-and-a-half-day program covers principles, processes, industry best practices, and industry standards in radiation sterilization for medical devices.
$2,535 List / $2,235 AAMI member

Microbiology for Medical Device Manufacturing and Sterilization
ON-DEMAND WEBINAR This webinar addresses concepts of microbiology as applied to sterilization and problem-solving microbial contamination issues for medical devices.
Order Code MMDWCD
$415 List / $315 AAMI member

Management Skills

Communications for Quality System Managers
ON-DEMAND COURSE This course helps you explain the meaning and importance of communication for quality system managers, implement general tools and techniques you can use to achieve successful communication, determine how to communicate effectively with various audiences, and communicate with documentation.
Order Code WELP_COM
$250 List / $199 AAMI member

Training in a Regulated Environment
ON-DEMAND COURSE This course focuses on the value of training, not only from the employee perspective but also from the company perspective, and looks at training programs from a regulatory point of view. It also provides common tips on creating engaging training programs for various learners.
Order Code WELP_TRA
$250 List / $199 AAMI member

Pillars of Medical Device Quality System Leadership
ON-DEMAND COURSE No matter your level of accomplishment, this course will provide direction for you to develop your pillars, such as your knowledge base, experience, communication skills, staff selection, interdepartmental support, and teamwork.
Order Code WELP_LEA
$250 List / $199 AAMI member

Demystifying EO Calculations
ON-DEMAND COURSE This self-paced course demonstrates how to calculate appropriate humidity levels for static and dynamic conditioning, determine the correct pressure level in the sterilization cycle for a specified EO concentration, calculate the D-value to determine the appropriate exposure time for a sterilization cycle, and more.
Order Code WELP_EOC
$525 List / $395 AAMI member

EO Fundamentals
ON-DEMAND COURSE This self-paced course addresses ethylene oxide fundamentals such as sterilizing agent characterization, process and equipment characterization, product definition, process definition, and more.
Order Code WELP_EOF
$525 List / $395 AAMI member
# Quality Systems

**Quality Systems Requirements and Industry Practice**

**TRAINING PROGRAM** This comprehensive four-day course offers an optional online exam for experienced quality systems professionals. The content is based on the body of knowledge developed jointly by representatives of the medical device industry and the FDA.

- Feb. 9-12, 2015, Orlando, FL [Registration Code GMF15]
- Mar. 23-26, 2015, Boston, MA [Registration Code GMM15]
- Apr. 13-16, 2015, Sydney, Australia [Registration Code GMA15]
- June 15-18, 2015, Bethesda, MD [Registration Code GMN15]
- Aug. 31-Sept. 3, 2015, Munich, Germany [Registration Code GMS15]
- Sept. 21-24, 2015, Arlington, VA [Registration Code GMS15]
- Nov. 2-4, 2015, San Francisco, CA [Registration Code GMD15]
- Dec. 7-10, 2015, Arlington, VA [Registration Code GMD15]

$2,885 List / $2,585 AAMI member

**Design Control Requirements and Industry Practice**

**TRAINING PROGRAM** This two-and-a-half-day intensive course focuses on implementing a program that meets the FDA’s design control requirements while ensuring a fast and efficient flow of new products.

- Mar. 4-6, 2015, Arlington, VA [Registration Code DCM15]
- June 15-17, 2015, New Orleans, LA [Registration Code DCJN15]
- Dec. 2-4, 2015, San Francisco, CA [Registration Code DCD15]

$2,335 List / $2,035 AAMI member

**Integrating Risk Management into the Quality System**

**TRAINING PROGRAM** This two-and-a-half-day course presents risk management concepts used throughout the quality system, as well as the life cycle of the product from design to manufacturing through post-production.

- Mar. 23-25, 2015, Bethesda, MD [Registration Code RMM15]
- Sept. 16-18, 2015, Alexandria, VA [Registration Code RMS15]

$2,435 List / $2,135 AAMI member

**Process Validation Requirements and Industry Practice**

**TRAINING PROGRAM** This two-and-a-half-day, intensive workshop and optional online exam provide the knowledge and skills needed to comply with the FDA’s process validation requirements while offering information on how to implement an effective validation program.

- Apr. 15-17, 2015, Alexandria, VA [Registration Code PVA15]
- Oct. 7-9, 2015, Orlando, FL [Registration Code PVO15]

$2,335 List / $2,035 AAMI member

**Purchasing Controls and Supply Chain Management**

**TRAINING PROGRAM** This two-and-a-half-day course provides 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.

- Apr. 29-May 1, 2015, Arlington, VA [Registration Code PCA15]

$2,335 List / $2,035 AAMI member

**Corrective and Preventive Action Requirements and Industry Practice**

**TRAINING PROGRAM** This two-day course and optional online exam provide intensive coverage of the elements of a corrective and preventive action (CAPA) system.


$2,335 List / $2,035 AAMI member

**Safety Assurance Cases for Medical Devices**

**TRAINING PROGRAM** This two-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.


$2,435 List / $2,135 AAMI member

**Fundamental Statistical Tools and Methods for Quality Systems**

**TRAINING PROGRAM** This intensive three-day workshop provides product and process experts a solid understanding of how to use statistical tools and methods to support design control, process validation, and corrective and preventive action (CAPA).

*Available as a private course.*

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**PRIVATE COURSES**

AAMI offers all of its quality system training programs on an in-house basis. If your organization has 20-50 employees to train, it can save valuable hours of travel time and costs while providing a training program with focused discussions on specific products and processes. Between training discounts and smaller travel costs, you can save your organization 20%-70%.

For more information, please contact Jeanine Beisel at +1-703-253-8277 or jbeisel@aami.org.
### Quality System Management for Medical Devices Certificate Program

<table>
<thead>
<tr>
<th>Required Course</th>
<th>Format</th>
<th>Program Hours</th>
<th>Assessment</th>
</tr>
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<tbody>
<tr>
<td>Quality System Requirements and Industry Practice</td>
<td>Training Program</td>
<td>32 hours</td>
<td>Online Exam</td>
</tr>
<tr>
<td>Integrating Risk Management Into the Quality System</td>
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<td>Corrective and Preventive Action Requirements and Industry Practice</td>
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<td>Documents and Records Management for Medical Devices</td>
<td>On-Demand Course</td>
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<td>Module Quizzes</td>
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<td>Pillars of Medical Device Quality System Leadership</td>
<td>On-Demand Course</td>
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<td>Plan of Action</td>
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<td>Training in a Regulated Environment</td>
<td>On-Demand Course</td>
<td>2 hours</td>
<td>Online Post-Test</td>
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<tr>
<td>Quality Audits for Medical Devices</td>
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<td>4 hours</td>
<td>Module Quizzes</td>
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<tr>
<td>Contrasting ISO 13485 with the FDA’s Quality System Regulation</td>
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<tr>
<td>Crisis Management</td>
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<td>Archived Webinar</td>
<td>1 hour</td>
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<tr>
<td>Statistical Methods and Tools for a Quality System: An Overview</td>
<td>Archived Webinar</td>
<td>2 hours</td>
<td>Online Post-Test</td>
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</table>

This certificate is awarded at the end of a cohesive program targeted to quality management system professionals in supervisory roles. The program includes live course work with exams; webinars; and on-demand, web-based courses totaling 94 hours, plus assessments.

### Documents and Records Management for Medical Devices

**ON-DEMAND COURSE** Document controls and records management affect all aspects of a manufacturer’s operation and activities. This course covers process architecture, management responsibility, the process of change control, and quality records.

Order Code WELP_DOC  
$625 List / $495 AAMI member

### U.S. FDA Medical Device Premarket Submissions

**ON-DEMAND COURSE** The six modules in this course address the requirements, best practices, and relevant regulations and guidance documents when preparing a premarket submission.

Order Code WELP_SUB  
$625 List / $495 AAMI member

### FMEA Without Tears

**ON-DEMAND WEBINAR** The goal of this webinar is to facilitate the successful application of FMEA as a valuable risk analysis and risk management tool.

Order Code WAQS1410FM  
$415 List / $315 AAMI member

### Medical Device Risk Management and Safety Assurance Cases

**ON-DEMAND WEBINAR** This webinar provides an overview of limitations with existing risk management practices and gives examples about how these limitations can be addressed through integrating with assurance cases.

Order Code WAQS1408AC  
$415 List / $315 AAMI member

### Current Issues in Medical Device Risk Management: FDA and EU Issues

**ON-DEMAND WEBINAR** Learn about the FDA risk management expectations for product submissions, review the FDA indicators of risk management shortcomings, and compare the FDA risk requirements to Europe’s expectations in the medical product directives.

Order Code WAQS1407CI  
$415 List / $315 AAMI member
Quality Systems (continued from page 5)

Sampling Plans Part 1: Making Statistically Valid, Risk-Based Decisions
ON-DEMAND WEBINAR This webinar focuses on sampling plans that are vital to approving a new production process. It then introduces fundamental concepts for acceptance sampling plans.
Order Code WAQS1405SA
$415 List / $315 AAMI member

Sampling Plans Part 2: Acceptance Sampling Plans for Inspection by Variables
ON-DEMAND WEBINAR This webinar focuses on acceptance sampling plans using inspections that result in variable measurements.
Order Code WAQS1406SA
$415 List / $315 AAMI member

Sampling Plans Part 3: Attribute Acceptance Sampling Plans
ON-DEMAND WEBINAR This webinar focuses on acceptance sampling plans depending on attribute inspections.
Order Code WAQS1407SA
$415 List / $315 AAMI member

Measurement System Analysis (or Whatever You Call It): Attribute Measurements
ON-DEMAND WEBINAR Learn how to organize an attribute MSA, collect data, analyze the results, and improve the measurement system.
Order Code WDQS1403MS
$415 List / $315 AAMI member

Measurement System Analysis (or Whatever You Call It): Variable Measurements
ON-DEMAND WEBINAR This webinar provides a working knowledge of measurement system analysis (MSA), also known as gage R&R (GR&R) and test method validation (TMV), for variable measurements.
Order Code WDQS1311MS
$415 List / $315 AAMI member

EN ISO 14971:2012 and Its Impact on You
ON-DEMAND WEBINAR This webinar addresses the impact of the new harmonized standard, EN ISO 14971:2012, Medical devices - Application of risk management to medical devices.
Order Code WDQS1310RM
$415 List / $315 AAMI member

FDA Compliance Overview: What Else Is There (Besides 21 CFR 820)?
ON-DEMAND WEBINAR This webinar provides a summary of some of the main FDA regulatory compliance topics other than the Quality System Regulation (21 CFR 820).
Order Code WDQS1309CO
$415 List / $315 AAMI member

Statistical Methods and Tools for a Quality System: An Overview
ON-DEMAND WEBINAR This webinar is targeted to professionals concerned with the application of valid statistical methods and tools to satisfy the requirements of the FDA’s Quality System Regulation.
Order Code WDQS1309ST
$415 List / $315 AAMI member

Combination Products: Understand and Implement the Requirements
ON-DEMAND WEBINAR This webinar aims to identify gaps in the existing quality system to meet 21 CFR 4 requirements and demonstrates how to bridge the gap between requirements coming from 21 CFR 210 and 211 versus 21 CFR 820.
Order Code WDQS1306CP
$415 List / $315 AAMI member

House of Quality/Quality Function Deployment: A Key Toolset for Design Control
ON-DEMAND WEBINAR This program introduces the key concepts of quality function deployment, illustrates how the first “House of Quality” is constructed and the value of the result, illustrates how a sequence of houses fosters cross-functional integration for a new product, and more.
Order Code WDQS1306DC
$415 List / $315 AAMI member

Standard Operating Procedures for Quality Systems: Are You Meeting Regulatory Requirements?
ON-DEMAND WEBINAR This program addresses why procedures are needed, issues that occur when procedures are not well prepared, main sections in a normal SOP, preparing forms, document control, and training.
Order Code WDQS1312OSO
$415 List / $315 AAMI member
Quality System Engineering for Medical Devices Certificate Program

This certificate is awarded at the end of a cohesive program targeted to quality management system professionals with hands-on responsibilities for implementing quality objectives (QS/QA engineers, associates, administrators) in the medical device industry. The program includes live course work with exams; webinars; and on-demand, web-based courses totaling 102-112 hours, plus assessment.

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<td>Human Factors for Medical Devices</td>
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<td>Select any (1-2 hour) webinar on implementation of a consensus standard such as IEC 60601, IEC 62304, ISO 10993, etc.</td>
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Introduction to Design of Experiments for Design Control
ON-DEMAND WEBINAR The goal of this webinar is to demonstrate the value of design of experiments as a valid statistical tool to support design control efforts.
Order Code WDQS1210DC  
$415 List / $315 AAMI member

Introduction to Valid Statistical Techniques for Design Control
ON-DEMAND WEBINAR The goal of this webinar is to demonstrate the value of valid statistical tools and methods to design control efforts.
Order Code IVSDCWCD  
$415 List / $315 AAMI member

Introduction to Valid Statistical Techniques for Process Validation
ON-DEMAND WEBINAR The goal of this webinar is to demonstrate how valid statistical techniques contribute to process validation efforts.
Order Code IVSPWVCD  
$415 List / $315 AAMI member

Labeling and Labeling Controls
ON-DEMAND WEBINAR Program content is focused on applying the principles described in the FDA regulations related to labeling guidance.
Order Code LLCWCD  
$415 List / $315 AAMI member
Quality Systems (continued from page 7)

Statistical Tools for CAPA and Complaint Monitoring
ON-DEMAND WEBINAR The goal of this webinar is to promote the application of valid statistical tools in an area that frequently generates warning letters from the FDA.
Order Code STCWCD
$415 List / $315 AAMI member

Leading Practices on Compliance Series
ON-DEMAND WEBINAR This series of leading practices provide practical guidance to medical device manufacturers on historically problematic areas of compliance with the FDA’s Quality System Regulation.
Complaint Files [Order Code LPCFWCD]
Designing the ‘Right’ Device [Order Code WDQS1210DI]
Design History File (DHF): Tips for Creating a Successful DHF [Order Code WDQS1210DH]
Corrective and Preventive Action (CAPA) [Order Code WDQS1211CP]
Controlling Nonconforming Products [Order Code WDQS1212NC]
Verifying and Validating CAPAs [Order Code LPVWCD]
Management Responsibility [Order Code LPMWCD]
Quality Audits [Order Code LPQAWCD]
$99 List / $79 AAMI member

Software Validation

Regulatory Requirements for Software Validation in the Medical Device Industry
TRAINING PROGRAM (Regulatory Focus) This three-day course focuses on the requirements contained in the Quality System Regulation specific to software validation. This program also explores the latitude and flexibility of the FDA’s expectations and provides conceptual ways to meet compliance requirements.
Apr. 22-24, 2015, Baltimore, MD [Registration Code SVA15]
$2,435 List / $2,135 AAMI member

Developing and Validating Software for the Medical Device Industry
TRAINING PROGRAM (Practical Application Focus) This three-day workshop provides attendees with guidance on designing software validation plans that build confidence in the software and comply with regulatory requirements. The workshop is exercise-driven and includes case studies.
$2,435 List / $2,135 AAMI member

Effective Application of Agile Practices in the Development of Medical Device Software
TRAINING PROGRAM Learn to evaluate the challenges with the use of Agile practices and be prepared to adapt these practices as needed to ensure the development of compliant, safe, and effective products.
Oct. 6-7, 2015, Arlington, VA [Registration Code APO15]
$2,335 List / $2,035 AAMI member

Cyber Risk Management for Embedded Medical Devices
ON-DEMAND WEBINAR This webinar offers a practical perspective and approach rooted in two decades of field-tested cyber risk management and embedded medical device development.
Order Code WAQS1412CR
$415 List / $315 AAMI member
Cybersecurity for Medical Devices

ON-DEMAND WEBINAR The co-chairs of AAMI’s Medical Device Security Working Group address the nature of the security problem and provide information on how organizations can prepare to meet what the FDA has recently issued in its draft guidance on cybersecurity. Order Code WDSQ1312CY
$415 List / $315 AAMI member

Mobile Apps in Healthcare, 2-Part Series

ON-DEMAND WEBINAR Part I addresses possible formats; getting approval from Apple, Windows, and Android; costs; and other factors. Part II covers the specific FDA requirements, impact on the process and documentation, timing, and other considerations. Order Code WDSQ1304SW
$775 List / $595 AAMI member

AAMI TIR45:2012, Guidance on the use of AGILE practices in the development of medical device software

ON-DEMAND WEBINAR This webinar provides detailed information on AAMI TIR45:2012 and its recommendations for complying with international standards and FDA guidance documents. Order Code WDSQ1310AG
$415 List / $315 AAMI member

Enemy at the Gates: Security for Medical Devices

ON-DEMAND WEBINAR This webinar provides a brief survey of recent cybersecurity incidents, looks at attack pathways for medical devices, and advocates a more structured consideration of security as a design-driver for medical devices with an explicit documentation of trade-offs. Order Code EGSWCD
$415 List / $315 AAMI member

Our Way of Saying “Thanks”

As a small thank you for your participation, we are pleased to offer you or a colleague 10% savings on an additional AAMI open-enrollment course. Within the next month, simply enter TRRF10 in the coupon code when registering online or call +1-800-373-3174.

BENCHMARKING SOLUTIONS—QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

Designed for medical device companies, this web-based tool features more than 100 measurements covering risk management and corrective and preventive action (CAPA):

RISK MANAGEMENT:
• Adherence to industry standards
• Policy development
• Staff training
• Documentation and record keeping
• Hazards and hazardous situations

CORRECTIVE AND PREVENTIVE ACTION (CAPA):
• Process performance
• Issue escalation
• Proposal, approval, and implementation of actions
• CAPA management and prioritization
• Preventive action statistics

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