



AdvaMed Regulatory & Compliance Certificate Program

Exclusively for Medical Technology Professionals



Today's Medical Technology organizations demand mastery of specific regulatory compliance and quality issues, and a commitment to continuous improvement to remain competitive.

That's why AdvaMed and UL EduNeering have teamed up to develop the online AdvaMed Regulatory & Compliance Certificate Program. This Certificate Program offers three separate program options (tracks) for Medical Technology professionals. The program leverages UL's extensive online libraries, including both FDA and AdvaMed-approved content.

Each track includes 3-4 required courses and 6-7 electives which have been specifically tailored to roles within the Medical Technology industry, including:

- **Corporate Compliance** – for compliance, legal and/or sales management professionals.
- **Medical Technology Overview** – for Medical Device industry generalists.
- **RA/QA** – for Medical Device Regulatory Affairs and Quality professionals.



Each track includes core and advanced topics such as Global Regulatory Planning and Strategy for Medical Devices, Regulatory Filings, Medical Device Regulation (MDR), Quality System Regulation (QSR), Clinical and Basics of the AdvaMed Code.

The courses are mastery-based, self-paced, interactive and take 30-45 minutes each to complete. An AdvaMed certificate is awarded at the completion of each track.

Whether you are new to the industry or a seasoned professional, these programs are a valuable resource to help you hone your expertise and enhance your professional development. What's more, you can be assured the courses cover the latest information on relevant Medical Device issues, FDA regulations and practical skills that you can use immediately.

**CORPORATE COMPLIANCE**

The **Corporate Compliance Certificate** is ideal for compliance, legal and/or sales management professionals.

This track covers four core topics, including:

- Basics of the AdvaMed Code
- Introduction to Medical Device Compliance and HIPAA
- Privacy Guidelines for Medical Device Sales Representatives
- Your choice from these options:
 - Doing the Right Thing: Anti-Bribery (FCPA)
 - Global Anti-Bribery

This track also offers the choice of six electives from an extensive list of courses, which include:

- Introduction to Quality System Regulation
- Risk Management: Key Concepts and Definitions
- Compliance Improves Business Performance

**MEDICAL TECHNOLOGY**

The **Medical Technology Overview Certificate** is ideal for industry generalists who may be new to the Medical Device industry or whose job role requires broad knowledge of several key areas.

This track offers three core topics, including:

- Basics of the AdvaMed Code
- Global Regulatory Strategy and Planning Process
- Introduction to Quality System Regulation (QSR)

This track also offers the choice of seven electives from an extensive list of courses, which include:

- FDA Inspections
- Complaint Management
- Introduction to Medical Device Compliance

**RA / QA**

The **RA/QA Certificate** is ideal for Regulatory Affairs and Quality professionals.

This track offers four core topics, including:

- Global Regulatory Strategy and Planning Process
- Medical Device Filings: 510(k), PMA and IDE
- Introduction to Quality System Regulation (QSR)
- ISO 14155: Obligations of Sponsors & Monitors for Medical Device Trials

This track also offers the choice of six electives from an extensive list of courses, which include:

- Failure Investigations for Medical Device Manufacturers
- Handling a Product Recall
- QS Regulation: Overview and General Provisions



AdvaMed
Advanced Medical Technology Association

\$1,695**AdvaMed Members****\$2,095****Non-Members**

For complete details and to enroll, go to advamedcertificate.org