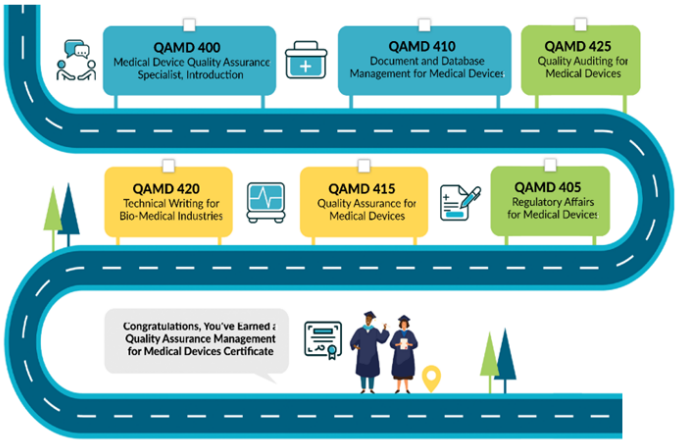
QUALITY ASSURANCE MANAGEMENT FOR MEDICAL DEVICES



Certificate of Completion

Program #3P24128

The Quality Assurance Management for Medical Device certificate prepares students for prospective careers in quality assurance within the medical device industry. Topics covered include regulatory agencies and laws pertaining to the medical device industry; introduction to the medical device industry and trends in the field; document control and database management; quality assurance concepts for medical device manufacturing; technical writing; the quality audit process; and employability skills. Upon successful program completion, students will be prepared for entry level positions in areas such as quality assurance specialist, quality compliance specialist and quality systems auditor depending on work experience and academic skill sets. This certificate will also benefit incumbent workers seeking promotional opportunities within the industry.

To earn a certificate, students complete the required and elective courses as listed with a grade of P (pass). The exception is for WFPR 100 Career Skills and Resource Lab and/or WFPR 101 Virtual Career Skills and Resource Lab courses. If those courses are required or listed as an elective, students will not receive a grade and instead must complete at least 36 hours in either WFPR 100 Career Skills and Resource Lab or WFPR 101 Virtual Career Skills and Resource Lab. For programs/courses that allow credit for prior learning, at least 75% of all course work must be completed at North Orange Continuing Education.

Code	Title	Hours
Core Courses		
QAMD 400	Medical Device Quality Assurance Specialist, Introduction	36
QAMD 405	Regulatory Affairs for Medical Devices	36
QAMD 410	Document and Database Management for Medical Devices	36
QAMD 415	Quality Assurance for Medical Devices	36
QAMD 420	Technical Writing for Bio-Medical Industries	36
QAMD 425	Quality Auditing for Medical Devices	36
Total Hours		**216**

Plan of Study

First Year

First Semester	Hours	Second Semester	Hours
QAMD 400		36 QAMD 415	36
QAMD 405		36 QAMD 420	36
QAMD 410		36 QAMD 425	36
		108	**108**

Total Hours 216

List of Courses

QAMD 400 **36 Hours**

Medical Device Quality Assurance Specialist, Introduction

(Formerly BMGR 645 Introduction to Medical Device Quality Assurance)

This course introduces students to the medical device industry in preparation for an entry-level position as a quality assurance specialist. Learn the role and responsibilities of a quality assurance specialist within the medical device industry. Learn about the industry's size and scope, current trends, and products used in healthcare settings. *(Apportionment)*

QAMD 405 **36 Hours**

Regulatory Affairs for Medical Devices

(Formerly BMGR 648 Regulatory Affairs for Medical Devices)

Course will provide students with an in-depth understanding of the regulations and regulatory agencies that are specific to the medical devices industry. The course will cover U.S. and European Union (EU) regulations and related agencies. Includes laws governing the development, manufacturing and approval of medical devices. *(Apportionment)*

QAMD 410 **36 Hours**

Document and Database Management for Medical Devices

(Formerly BMGR 651 Document and Database Management for Medical Devices)

An overview of regulatory requirements for document control and database management for the medical device field. Covers the fundamentals of writing documents that meet regulatory compliance. Equips students for handling document management systems efficiently. *(Apportionment)*

QAMD 415 **36 Hours**

Quality Assurance for Medical Devices

(Formerly BMGR 654 Quality Assurance for Medical Devices)

This course provides students with an in-depth overview of quality assurance and its role within the medical device industry. The course covers the role of assurance during the manufacturing and production stages. Topics will include the step-by-step process of ensuring quality requirements are met for a product or service. *(Apportionment)*

QAMD 420 **36 Hours**

Technical Writing for Bio-Medical Industries

(Formerly BMGR 657 Technical Writing for Bio-Medical Industries

This course will provide students with an overview and understanding of technical writing for the bio medical industry. The course will cover principle writing methodologies for quality assurance, engineering, manufacturing, and production of a medical device product. Topics will address documentation as related to FDA mandated requirements, ISO standards and for writing GMP procedures. *(Apportionment)*

QAMD 425 **36 Hours**

Quality Auditing for Medical Devices

(Formerly BMGR 660 Quality Auditing for Medical Devices)

This course presents the principles and techniques for assessing the adequacy of a quality system for a medical device manufacturer. Topics include evaluating the quality system as it conforms to FDA regulatory requirements, standards, review of standard audit terms and other audit concepts. *(Apportionment)*