

Quality Assurance Management for Medical Devices Certificate Program Guide 2021-2022

Career Highlights

Medical devices is a growing industry sector that is regulated by strict and evolving FDA standards that require trained employees to understand and enforce quality control measures. Quality Assurance and Control Specialists develop procedures to ensure compliance with regulatory requirements, review and evaluate testing protocols, conduct quality systems audits, and implement timely follow-up and corrective actions.

For more information regarding this career visit: [Career Coach](#).

Program Information

The Quality Assurance Management for Medical Devices Certificate Program prepares students for entry-level positions as Quality Control Inspectors, Quality Associate, Data Entry Associate, and Manufacturing Assembler/Operator within the medical device industry. The program provides in-depth instruction on the standards and regulations that govern the development of medical devices.

Eligibility Requirements

To be eligible for the program candidates must:

- 18 years or older.
- [Apply online](#) or in-person at any NOCE Center.
- Complete an online General Orientation at least 24 hours prior to registering for Quality Assurance Certificate Program courses.

Program Location and Contact Information

NOCE Anaheim Campus
1830 W. Romneya Drive
Anaheim, CA 92801

Career Technical Education (CTE)
Office, Room 513
714-808-4915
careers@noce.edu

Contact for general program
information

Counseling and Student Services
Department, Room 215
714-808-4682
counseling@noce.edu

Contact for course advisement,
career counseling, and college
planning

Program of Study Leading to a Certificate

This information is for advisement purposes only and subject to change

Required Core Courses for Quality Assurance Certificate				
Core courses are listed in the order of the program's recommended sequence				
Course #	Course Title	Hours	Prerequisite(s)	Completion Status
QAMD 400	Medical Device Quality Assurance Specialist, Introduction	36	-	
QAMD 410	Document and Database Management for Medical Devices	36	-	
QAMD 425	Quality Auditing for Medical Devices	36	-	
QAMD 405	Regulatory Affairs for Medical Devices	36	-	
QAMD 415	Quality Assurance for Medical Devices	36	-	
QAMD 420	Technical Writing for Bio-Medical Industries	36	-	

Completion Timeline

All required courses for the Quality Assurance Certificate must be completed and students must maintain Catalog Rights. NO EXTENSIONS and/or EXCEPTIONS WILL BE GIVEN. Students not meeting the requirements and/or not maintaining catalog rights will be required to repeat any classes and/or complete any additional program requirements.

It is recommended that students see a NOCE Counselor to complete a student educational plan. Counselor appointments can be made in person at the Anaheim campus in room 215 or by phone at 714-808-4682.

Additional Program Information

Catalog Rights and Completion Deadline

The course requirements for a specific certificate program may change from one catalog to the next and, therefore, may change during the period of time that a student attends NOCE. Catalog rights established when a student first takes classes at NOCE protect the student from being held for additional program requirements that may be added to a later catalog.

Students maintain catalog rights by maintaining continuous enrollment in one of the following courses at NOCE: Basic Skills, Career Technical Education, Disability Support Services, and English as a Second Language. Continuous enrollment is enrollment in any two of the previous consecutive terms, including Summer, resulting in an academic record of A, B, C, D, F, P (Pass), NP (No Pass), SP (Satisfactory Progress), or W

(Withdrawal). Missing more than two consecutive terms will result in loss of catalog rights due to a break in continuous enrollment.

If continuous enrollment is broken the student must adhere to the catalog requirements in effect at the time continuous enrollment is re-established and maintained. The lab enrollment in CCTR 100, keyboarding exams, and required certifications (e.g. CPR card) cannot be used to maintain catalog rights. Course substitution and course challenges do not maintain catalog rights.

This policy supersedes all previous catalog rights provisions and applies only to the programs at NOCE.

Course Substitutions:

This program does not allow any course substitutions.

Challenge Exams

This program does not offer any challenge exams.

Program Attendance and Grading Requirement

In-Person Classes	Online Classes
<p><u>First Day Of Class</u> ATTENDANCE ON FIRST DAY OF CLASS IS MANDATORY to secure your place in class. If you are not in class ONE HOUR after the scheduled start time, your spot could be assigned to a student on the waitlist.</p> <p>No student will be allowed to enroll in a class after the established deadline.</p>	<p><u>First Week of Attendance</u> FIRST WEEK OF ATTENDANCE IS MANDATORY to secure your place in class. If you do not sign in to your Canvas course and/or contact your instructor by 11:59 p.m. on the third day from the start of the course, your spot could be reassigned to a student on the waitlist and you will be dropped from the course.</p> <p>If you are enrolled in a hybrid class and the first class meeting is scheduled to be in-person, see the First Day of Class policy for in-person classes.</p> <p>No student will be allowed to enroll in a class after the established deadline.</p>
<p><u>Ongoing Attendance</u> Regular attendance is expected of every student.</p>	<p><u>Ongoing Active Participation</u> Ongoing active participation is expected of every student. Active participation requires more than just logging into Canvas. Students who do not actively participate on a weekly basis will be dropped from the class up until the second census date.</p>

In-Person Classes	Online Classes
<p><u>Waitlisted Students</u> Students on the waitlist should attend the first day of class.</p> <p>Through the first week of classes, students on the waitlist will be notified via e-mail as soon as seat is available. Once you receive the e-mail, you will have up to 24 hours to accept the seat. If you do not accept, by the deadline given in your e-mail notification, the seat will be offered to the next student on the waitlist.</p> <p>The waitlist process is only valid through the end of the first week of the class. During the 2nd week of classes students still interested in adding a closed class must contact StarHelp at 714.808.4679 or e-mail starhelp@noce.edu. Students on the waitlist will be notified as soon as possible when seats open up in classes. If you do not accept, by the deadline given in your e-mail notification the seat will be offered to the next student on the waitlist.</p>	<p><u>Waitlisted Students</u> Through the first week of classes, students on the waitlist will be notified via e-mail as soon as seat is available. Once you receive the e-mail, you will have up to 24 hours to accept the seat. If you do not accept, by the deadline given in your e-mail notification, the seat will be offered to the next student on the waitlist.</p> <p>The waitlist process is only valid through the end of the first week of the class. During the 2nd week of classes students still interested in adding a closed class must contact StarHelp at 714.808.4679 or e-mail starhelp@noce.edu. Students on the waitlist will be notified as soon as possible when seats open up in classes. If you do not accept, by the deadline given in your e-mail notification the seat will be offered to the next student on the waitlist.</p>
<p><u>Grading Policy</u> All courses in this program are graded (Pass or No Pass).</p> <p>In order to be eligible to receive a passing grade, students in this program must meet both the minimum attendance requirements and the 80% or higher grading requirement.</p>	<p><u>Grading Policy</u> All courses in this program are graded (Pass or No Pass).</p> <p>In order to be eligible to receive a passing grade, students in this program must meet both the minimum attendance requirements through ongoing active participation and the 80% or higher grading requirement.</p>

Graduation Check for Program Certificate and Commencement

To receive the certificate and participate in the Commencement Ceremony, students must schedule and attend a Graduation Check/Exit Interview appointment with a NOCE Counselor at the end of your final term to complete the application for program certificate. If you do not plan on participating in the commencement ceremony, you still must schedule a Graduation Check/Exit Interview appointment with a NOCE counselor.

Once the Records Office receives your application and verifies that all the requirements have been met, the program certificate will be mailed to you.



Accredited by the Accrediting Commission for Schools,
Western Association of Schools and Colleges
533 Airport Blvd., Suite 200 Burlingame, CA 94010
Website: www.acswasc.org

The North Orange County Community College District's (NOCCCD) North Orange Continuing Education (NOCE) Administrative Offices are located at 1830 W. Romneya Drive in Anaheim, California 92801. For more information, call 714.808.4645 or visit www.noce.edu. It is the policy of NOCCCD to provide an educational, employment, and business environment in which no person shall be unlawfully subjected to discrimination or sexual harassment, nor unlawfully denied full and equal access to the benefits of District programs or activities on the basis of ethnic group identification, national origin, religion, age, gender, race, color, ancestry, sexual orientation, marital status or physical or mental disability as defined and prohibited by state and federal statutes. The District is also committed to maintaining campuses that are free of harassment, drugs and alcohol. To read the entire NOCCCD nondiscrimination statement, see the policy in the General Information section in the back of the NOCE class schedule.