

# Regulatory Affairs for Medical Devices

*Specialized Certificate*

## The Field of Medical Device Development

Medical device development is a dynamic area for professionals considering a career in regulatory affairs and can be as simple as a Band-Aid or as highly complex as lifesaving robotic equipment. Medical devices are increasing in complexity and becoming ubiquitous in the medical field. More recently, the convergence of medical devices with other industries has propelled growth and required more professionals to learn regulations. New products built from a combination of information technology and software enabled medical devices have expanded the need for those involved to learn regulatory requirements, including engineers and other technical associates. Additionally, a convergence of medical devices and drugs brings new treatment opportunities to healthcare, including drug coated stents used for cardiovascular procedures. The advent of such combination products make it necessary for therapeutics professionals involved in regulatory affairs to also become knowledgeable of regulations that apply to such devices.

## Program Overview

The Regulatory Affairs for Medical Devices certificate provides professionals with the essential knowledge to work in this highly regulated environment and the process needed to develop medical devices from concept to commercialization.

## Program Benefits

- Understand the overall product development life cycle
- Understand how to work proactively with the FDA
- Understand how a quality management system works within a medical device company
- Understand the overall design control process and risk analysis
- How to prepare a 501(k) submission to the FDA
- How to perform post market surveillance to insure safety

## Program Details

### Prerequisites

There are no prerequisite required to enroll in the certificate program.

### Length

You technically have up to 5 years to complete your certificate once you apply, however, we do not recommend you take that long as this field could change significantly in that time span. On average, most students finish the certificate in 1 year.

## Cost

UCSD Extension courses fees are different for each course. In general, it will cost the student roughly \$3,450 to finish the program.

## Requirements

There are five required courses in the Regulatory Affairs for Medical Device certificate. It is strongly encouraged that students take the Overview of Regulatory Affairs for Medical Devices course first.

Course Title	Course No.	Units	Course Offered			
			Fall	Winter	Spring	Summer
<b>Required Courses</b>						
<a href="#">Overview of Regulatory Affairs for Medical Devices</a>	BIOL-40322	3.00	Online			
<a href="#">Quality Management Systems for Medical Devices</a>	BIOL-40323	3.00				Online
<a href="#">Design Control for Medical Devices</a>	BIOL-40324	3.00	Online			
<a href="#">Regulatory Submissions for Medical Devices</a>	BIOL-40325	3.00	Online		Online	
<a href="#">Post Market Topics for Medical Devices</a>	BIOL-40326	3.00		Online		Online

## Electives

There are no electives for this certificate.

## Frequently Asked Questions

### About the Certificate

#### How do I apply to the certificate program?

**STEP 1:** If you have a My Extension student account, skip to Step 2. If you do not have a My Extension account, go to [myextension.ucsd.edu](http://myextension.ucsd.edu), click “Create an account” on the right side of the page, and follow the instructions to create an account. Once you have a My Extension account, continue to Step 2.

**STEP 2:** Click on the “Apply Now” button on the certificate page. Complete the required fields on the application. Then click the “Save” button. Once you have saved the application, the “Submit” button will appear. Click the “Submit” button to submit your application for review and consideration. Once submitted, your application cannot be changed. You can track the progress of your application at [My Extension](#).

#### Is there an application fee for the certificate program?

Current application or certificate enrollment fees, if any, are listed under the “Apply Now” button on [the certificate page](#) on our website.

## Can I register for the certificate program at any time?

Yes, you may enroll in the program at any time. However, it is recommended that you enroll as soon as possible. The program curriculum may be updated at any time; if certificate requirements change, you must adhere to the curriculum *at the time of your enrollment into the certificate*. Enrolling in the certificate also gives you access to quarterly, personalized enrollment reminders from the program manager.

## Can this certificate program be completed entirely online?

Yes! This program is designed for you to take it online in the convenience of your own home or office. Some courses may also have in-class options, but all program requirements can be completed online. For online courses, all assignments, tests, and quizzes can be completed online and submitted through [Blackboard](#), our online learning platform.

## How long do I have to complete the certificate?

You officially have five years from when you begin taking courses in the program to complete all requirements for the certificate.

## If I already have the skills taught in one of the courses, can I skip that course?

If you have taken a course from an accredited university covering the learning objectives of a program course, you may be able to transfer your previous coursework to Extension. If you have not taken a course elsewhere, but already have the skills covered in a course, you may be able to substitute an alternate Extension course in its place. Please contact the program representative at [unexbio3@ucsd.edu](mailto:unexbio3@ucsd.edu) or 858-534-9353 for more information.

## Is this certificate program open to non-California residents?

Yes, the program is open to non-California residents, including non-US residents. The tuition is the same for all students. If you have questions about how enrolling in courses may or may not affect your visa status, please contact our International Department at [ipinfo@ucsd.edu](mailto:ipinfo@ucsd.edu) or (858) 534-6784.

## If I work full-time, will I still be able to complete this program?

Yes. Our programs are designed to be working-student friendly and most of our students are working professionals. The courses vary between two and three units, which amount to approximately 18-20 hours of class time for a two unit course and 27-30 hours of class time for a three unit course.

## Is the program accredited?

UC San Diego is accredited by the Western Association of Schools and Colleges (WASC). UC San Diego Extension — like all other UC San Diego schools, colleges, and departments — is accredited by WASC through the University. All courses and certificate programs offered by UC San Diego Extension have been developed and are administered in accordance with Extension policy and the regulations of the Academic Senate of the University of California.

## Will this program prepare me for a certification exam?

This program is not aligned with any one certification exam. Our programs are designed to provide students with knowledge that will make them valuable in the workforce.

## How do I get my certificate once I have completed the requirements?

When you have paid your certificate fee and successfully completed all program requirements, you will need to request an audit by Student Services. To request an audit:

- In your [My Extension](#) account, click on “My Courses.”
- On the right side of the page under “My Certificates,” click on the name of the certificate.
- On the right side of the page under “Tools,” click on “Request Certificate Audit.”
- Complete and submit the form that appears.

Once you have formally submitted your audit request, your certificate will be mailed to the address we have on file for you within ten business days.

## Do you provide job or internship placement?

No, we do not currently offer job placement assistance, internships, or career services assistance.

## Is financial aid available?

- UCSD Extension offers continuing education loans through UC Approved Lenders. Each institution offers low competitive interest rates and flexible payment options. You are also encouraged to contact your personal financial institution about possible lending solutions. Direct links to UC Approved Lenders can be found on our website's [Financial Resources](#) page.
- The Employment Development Department (EDD) provides a comprehensive range of employment and training services in partnership with state and local agencies/organizations. More information is available on their website at [edd.ca.gov](http://edd.ca.gov).
- Career Centers Located throughout San Diego County offer their communities comprehensive employment and training services benefiting both business and job seekers. More information is available on their website at [workforce.org](http://workforce.org).
- [Please click here for information about Veteran's Benefits.](#)
- Free Application for Federal Student Aid (FAFSA) funds are limited to degree programs only, and cannot be used for courses or certificate fees at UCSD Extension.

## About the Courses

### When does course enrollment open for each quarter?

Our classes post to our website and become open for enrollment approximately two months prior to the new quarter starting. If you'd like to get an email reminder you can sign up for our newsletter(s) in [My Extension](#), under the "Preferences" tab.

### When should I enroll in a course?

We recommend enrolling as soon as possible, as occasionally classes will reach capacity.

### Once I have enrolled in a course, when will I get online access to it?

If you have enrolled at least three days before the course begins, you will have access starting on the first day of class. You should receive an email from Student Services with instructions for how to login to the course. If you have enrolled on or after the start date of the course, you will have access to the course within one business day.

### When does enrollment for a course close?

Enrollment in a course may be closed for one or more of the following reasons:

- The course is at capacity. If the course is at capacity you will only be able to join the waitlist. If space becomes available in the course, students on the waitlist are contacted in the order they joined the waitlist.
- The course has progressed to a point where students will no longer be able to make-up missed work and be successful in the course.
- The course is cancelled due to low enrollments.

For all three of these reasons we recommend students enroll early in the courses they are interested in.

### When is the refund deadline for courses?

The refund deadline for courses in this program is typically one week after the start of the course. This allows you to enroll in a course and participate in the course for approximately one week to determine if the course is a good fit. Then,

if needed, either you may either transfer your enrollment to a different course or submit a drop request. The exact refund deadline for each section is listed in the section notes on the course page in our website, and you can also find it in [My Extension](#) by clicking on “My Courses” and then the name of the course.

### What are the grading options for courses?

You may take a course for one of three options: Letter Grade, Pass/No Pass, or Not for Credit. If you are taking a course towards a certificate you *must* complete your courses for credit (i.e. Pass/No Pass or Letter Grade) and receive a C-/Pass or higher grade. Grades below a C-, No Pass, and Not for Credit will *not* count towards certificate requirements.

### What kind of credit do I earn?

The courses in this program are post-baccalaureate, professional-level, credit bearing courses. Credit earned in these courses may lead to the award of a formal certificate by UC San Diego Extension or may be applied toward an academic degree or professional credential, *subject to the approval of the receiving institution*.

If you wish to transfer credit, it is your responsibility to confer with the receiving institution before enrolling, as each individual academic institution decides whether or not to accept Extension’s credits.

### Are courses transferrable?

UC San Diego Extension is not a degree granting institution, however many UC San Diego Extension courses can be transferred to other colleges or universities. The transferability of credit is determined solely by the *receiving* institution. You should discuss how your individual courses will transfer with the Office of the Registrar at the receiving institution *prior to enrolling*.

### Can I take a course without registering for the certificate?

Yes, you may take any course in this program without registering for the certificate, provided you have fulfilled any and all prerequisites for the course.

### How long is each course?

Two unit courses run for approximately 6-7 weeks; three unit courses run for approximately 9-10 weeks. For exact course dates of upcoming sections, visit the webpage of the course you are interested in taking on our website.

### When is each course offered?

Please visit the course page on our website to see when courses are typically offered. You can also see a full program schedule by clicking on the “View Schedule” button under the “Courses” section on [the certificate page](#) or under [the Program Requirements section of this document](#).

### How many hours can I expect to spend studying outside of class time?

Each student has their own learning style so this can vary greatly. As a rule of thumb, expect to spend an average of two hours studying for every hour you spend in-class. For online courses, students should plan to spend approximately 8-10 hours per week viewing lectures and completing coursework.

### How are online classes formatted?

The online courses are asynchronous: they have a start and end date but all the lessons are uploaded on [Blackboard](#), our online learning management system, so you can learn at your own pace. However, please be aware that you may have weekly assignments, quizzes, or tests that are due on specific dates. Please [click here](#) to view a sample course tour to see if this format suits your learning style.

## What are the instructors' credentials?

The program courses are taught by seasoned professionals and overseen by an advisory board of leaders in the field. You can view the advisor list under the "Advisors" section on [the certificate page](#). You can find information about a course instructor, including a biography and credentials, on the course page.

## How do I communicate with a course instructor if I have a question during the course?

Each instructor has his/her own preferred method of communication and response policy, which will be detailed on the course syllabus. However, most instructors utilize email or the discussion board and will respond within 24-48 hours.

## Will I get any hands-on experience in the program?

Most courses combine theory with hands-on exercises. For more information about practical experience in any course, visit the course page on our website.

## What are the required textbooks for a course?

Instructors will post the current text requirements and recommendations on the course page on our website. Please note the textbooks requirements are subject to change every quarter and different instructors may require different books, even if they are teaching the same course in the same quarter, so be sure to check the textbook requirements *for the section in which you are enrolling*.

## Will I be able to order the required textbooks before the class begins?

Yes, you can order the book(s) any time after enrolling in the course. You may order books through the campus bookstore or online retailers, such as Amazon.com.

## After I enroll in a course, how can I retrieve a receipt or enrollment verification for my records?

Login to your [My Extension](#) account and select "Documents" as the top of the page.

## How will I receive my final course grade?

Once the course is completed, the instructor has 10 business days to submit your grades. Once grades have been posted, you can view and print them from your [My Extension](#) account.

## What if I am having trouble with Blackboard or My Extension?

Please contact Student Services at (858) 534-3400 or [unex-reg@ucsd.edu](mailto:unex-reg@ucsd.edu) if you experience any issues logging in to any of our systems.

## For More Information

For program specific questions, please visit [the certificate page](#) on our website or contact a program representative at [unexbio3@ucsd.edu](mailto:unexbio3@ucsd.edu) or 858-534-9353. For administrative questions, please contact our Student Services Department at [unex-reg@ucsd.edu](mailto:unex-reg@ucsd.edu) or (858) 543-3400.