

# Regulatory Academic Programs: Deciding to Participate and Selecting a Quality Program

The mistake that others make, and that I trust you will never make, is to treat education as a chore instead of a joy; to treat graduation as an end of education rather than as a beginning.

—Arthur Burns

## Introduction

The variety of academic programs focused on educating those wishing to expand their understanding of the regulatory requirements for medical products, including drugs, biologics and medical devices, has increased dramatically in the past few years. Today, working professionals can choose from many educational forums—from attending topic-specific seminars, a single course, a course program that culminates in a professional certificate to enrolling in a full-fledged, two-year graduate programs offering advanced degrees from accredited universities. Each option offers benefits, but graduate programs in regulatory affairs provide a comprehensive curriculum not available from the other training opportunities. Upon researching the various regulatory programs now available, one notices these programs differ in some respects:

- courses offered online versus traditional lecture style;
- curriculums focused on a particular area of regulated industry (e.g., pharmaceuticals) versus those geared toward offering a breadth of knowledge about different types of regulated products; and
- programs providing the latitude of taking a single course versus those intended to culminate in a certificate or degree.

The authors participated in the program offered by the Center for Bio/Pharmaceutical and Bio/Device Development (CBBD), which is part of San Diego State University (SDSU). This article's purpose is two-fold. First, to describe what should be considered when deciding whether to participate in a regulatory academic program, as well as how committed you can be to such a program. Second, for those who have decided to participate in a more demanding program, that is, one intended to culminate in an advanced degree in regulatory affairs, this article will suggest particular features to look for in a quality curriculum.

## Should You Participate in a Regulatory Academic Program?

There are three key aspects to contemplate when considering whether to participate in an academic regulatory program:

- personal *objectives*;
- how the flexible *options* inherent in the structure of the program promote these objectives; and
- *opportunities* that may be realized as a result of participating in the courses.

## Objectives

Determining your ultimate objective for participating in an academic regulatory program is fundamentally important. These objectives will help decipher whether taking an individual course, a series of courses or a full graduate curriculum best suits your goals. Factors that may influence the decision include whether you are interested in:

- expanding knowledge of the type of regulated products with which you now work;
- making a career transition into working with medical product regulated by a different center of FDA; or
- learning more about other areas of regulatory affairs, possibly with the intent to move into another area of expertise.

Regardless, finding a broad-spectrum program is of paramount importance. Learning about products regulated by different centers at FDA can be a boon, not only for expanding one's overall understanding of regulations, but also for preparing for a professional accreditation such as Regulatory Affairs Certification (RAC).

### **Options**

Personal objectives will dictate which option might be selected regarding the extent of commitment to a regulatory program. Programs such as those offering an MS in RA will not only allow students to enroll in selected courses, but also may provide students with the option of obtaining a certificate upon successfully completing a predetermined set of introductory courses. For instance, the first three introductory courses offered at this institution not only provide an excellent springboard for launching into a more detailed comprehension of the regulations, but also grant the student a Professional Certificate upon completion.

Even veterans of the industry can benefit from refresher courses. Moreover, as legislative changes and innovations in technology arise, having a chance to learn the most current information is key to remaining contemporary in the field. Think of the courses as “intellectual Bondo.” These courses can help patch dents in your knowledge.

### **Opportunities**

Joining a formal regulatory education program can open doors for those already working in regulatory, as well as those wishing to enter the field. For those considering regulatory affairs as a career, participating in introductory courses may make the student a more attractive candidate for entry-level positions.

For those already in the regulatory arena, academic programs can help both personally and professionally. Hopefully, the program selected provides students with information germane to daily responsibilities. Similarly, programs can help diversify expertise, thereby leading toward promotion or a shift in responsibilities.

### **What to Look for in an Academic Regulatory Affairs Program**

As if deciding to participate in continuing education or even enrolling in a graduate program were not challenging enough, the next decision is equally demanding—How does one choose which program to join? As graduates of one such program, we suggest the “Top 10” key attributes to seek in a regulatory program.

### *1. Diverse Curriculum*

Ideally, the program will discuss the breadth of the types of products FDA regulates including drugs, biologics, devices, veterinary products, foods and cosmetics. Additionally, a graduate program should be comprehensive enough to allow the student to have a clear comprehension of how different government entities, such as the Federal Trade Commission (FTC), Consumer Product Safety Commission (CPSC) and other entities work together to regulate medical products.

A broadstroke understanding of the laws with which one must comply invites the student to draw parallels between and elucidate differences in the requirements for various types of medical products. For instance, a student with a strong comprehension of the Good Manufacturing Practices (GMPs) for drug and biological products should have a general gut-feeling for how to implement the Quality System Regulations (QSR) requirements for medical devices. Similarly, given that FDA investigators are trained to conduct inspectional audits of companies manufacturing a wide range of products, comprehending underlying compliance issues will aid the regulatory professional.

### *2. Focus on Practical Regulatory Issues*

Because the practice of regulatory affairs is much more complicated than merely “knowing” the regulatory laws with which one must comply, finding a program that provides guidance on the “implementation” and enforcement of the regulations is of paramount importance. The most useful of programs will discuss topics including Good Laboratory Practices, Good Clinical Practices, GMPs, Quality Assurance/ Quality Control, product development, project management, validation and international issues.

### *3. Caliber of Educational Staff*

Programs taught by professionals with current and extensive industry experience in specific regulatory specialties are necessary for a quality education. Knowledgeable instructors gladly share “regulatory folklore” and their personal experiences and will entertain students’ questions with joy.

### *4. Multi-Dimensional Instructional Platforms*

Remembering that many who participate in such regulatory programs also work full-time, selecting a program that strives to keep the instructional setting fresh and interesting is important. Granted, this may be difficult to screen for when selecting a program. Nevertheless, students appreciate learning via a diverse set of tools and media, such as in-class lectures, video tours, case studies, on-site mock audits of local companies, team projects, as well as discussion boards offered online. Such variety not only adds flavor to a program, but also appeals to preferred learning styles students may have.

### *5. Access to Networking Opportunities*

It may surprise some to hear that we learned a great deal not only from the formal instructors, but from fellow students as well. And these networking opportunities may well continue long after final assignments are submitted at the end of the course.

### *6. Convenience*

In an effort to make programs more accessible to prospective students, many regulatory programs are transitioning to an online format. Although the face-to-face interaction between students, instructors and peers is diminished, the upside is greater convenience in self-managing your study schedule.

### *7. Flexibility*

Students commit to a program with every intention of completing the coursework in the time stipulated in instructional guides. Yet, for the working professional, “life” may well get in the way. Busy travel schedules, time-crunches in the workplace and personal commitments may interfere. Don’t think such inconveniences could only happen to someone else. Check with the program administrators and determine up front what latitude is extended to accommodate students and to promote their successful completion of the coursework.

### *8. Helpful and Supportive Administrative Staff*

In any program, practical administrative issues such as enrolling in courses, paying tuition, receiving CDs and reference materials shipped for online courses, issuing final grades, submitting theses and turning in the correct paperwork to ensure graduation must be managed. Having a staff composed of people who will happily and helpfully resolve concerns is a lifesaver.

### *9. Affordability*

Let’s talk dollars and “sense.” When weighing options, considering personal financial resources is necessary. Some employers may offer tuition reimbursement for at least part of the expenses, and certain programs may qualify for government financial aid.

### *10. Respectability of Institution*

As mentioned earlier, career advancement is a primary reason for participating in such a program. Therefore, selecting a program that has earned and maintained respect from the regulatory community must be key in program selection.

## **Conclusion**

Never stop learning.  
—Jerry Waak

The MS in RA program, in which the authors of this article participated, offered a firm foundation for understanding the basics of regulatory requirements, as well as how FDA interprets and enforces the laws. Although we completed the program only one year apart, due to the dramatic shift in the focus of the program from an in-class lecture style setting to a largely online format, our experiences differed. If the challenge to participate in an academic regulatory

program at any level is accepted, consider personal needs and how likely it is that those needs will be met.

The importance of continuing education is recognized by professional societies, such as the Regulatory Affairs Professional Society (RAPS) and the American Society for Quality (ASQ). As such, coursework will help individuals who have to renew their RAC certification or the various certifications available through ASQ to earn credit toward recertification. Most important, however, you will be doing something positive and stimulating for your career path.

And these programs are not just for those who are already working for companies that make medical products. The three core courses are excellent for manufacturing, marketing and even executive personnel. How much easier would explaining regulatory concepts and decisions to upper management be if those in authority understood the background behind those decisions? Those of us who have worked for Total Quality Management-focused or ISO-certified companies have been indoctrinated to understand the importance of continuous improvement. Regulatory courses are a wonderful way of striving not only for personal growth, but for the betterment of your company as well.

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*Laura Guy, MS, RAC, was a member of the first graduating class of San Diego State University's MS in RA program. She is the manager of regulatory operations for Santarus Inc. and can be reached at [lguy@santarus.com](mailto:lguy@santarus.com). Kristin Godfredsen, MS, RAC, was a member of the second graduating class of SDSU's MS in RA program. She is a manager for the quality and regulatory team at Scantibodies Laboratory Inc. and can be reached at [kristin.godfredsen@scantibodies.com](mailto:kristin.godfredsen@scantibodies.com).*