

**YOUR GUIDE TO
ADVANCING YOUR
REGULATORY
AFFAIRS CAREER**

Northeastern
University





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When you bite into

an apple from the grocery store or take a pill to fight a headache, you likely don't think of the long process those items underwent to reach you. Part of that process involves evaluation by regulatory professionals who ensure that every food item, medication, and medical device we use meets high standards of safety and efficacy.

Industry Outlook

Today, these regulatory professionals are in high demand. According to the [Centers for Disease Control](#), there are more than 31 known pathogens of food-borne illness, and medications can easily cause unanticipated and/or serious adverse effects if they are not properly formulated. Organizations need well-informed employees who understand how to develop products to combat those pathogens, and maintain compliance with safety regulations.

As new food production methods and medical technologies emerge, regulatory professionals who understand how to stay current without sacrificing quality will continue to find rewarding careers.

“Compliance cuts across so many diverse industries, and regulations are constantly evolving,” says Stephen Amato, PhD, teaching professor and lead faculty member for Northeastern’s **Master of Science in Regulatory Affairs**. “If you keep your skills current, you’ll very likely never be out of a job.”

In fact, available life sciences jobs—including those in regulatory affairs—are expected to reach 86,000 in Massachusetts alone by 2024, according to a 2019 MassBioEd report.

If you’re ready to advance your career in regulatory affairs, this guide will help you become a leader in the industry and reach your goals.





What is Regulatory Affairs?

Regulatory affairs professionals oversee the development, testing, manufacturing, marketing, and distribution of products in regulated industries, including pharmaceuticals, medical devices, biologics, and food. They have a deep understanding of how to apply domestic and international statutes that govern food and drug safety and work to ensure that all products meet established requirements.

The field is an interdisciplinary one that incorporates public policy, law, health, economics, data analytics, project management, and science. As a result, regulatory specialists work in a wide range of organizations, including pharmaceutical companies, medical device manufacturers, regulatory agencies, public advocacy groups, philanthropic organizations, and corporate offices.

When it comes to pharmaceuticals, medical devices, and biologics, regulatory experts are needed to contribute to every phase of the product life cycle. They participate in research and development, help to design and run clinical trials, submit regulatory documentation, and work cross-functionally throughout the manufacturing, marketing, and distribution processes as well. Once a product hits the market, regulatory affairs professionals also conduct post-market surveillance to help maintain compliance and react to any safety concerns identified.

In the food and food science industries, these professionals are responsible for monitoring facilities, manufacturing operations, and distribution processes. They also directly influence global health, food safety, agriculture, manufacturing, and marketing laws and regulations. Because many foods are distributed throughout the world, regulatory professionals in these industries must familiarize themselves with relevant state, federal, and global regulations.

Components of Regulatory Affairs





Regulatory Affairs Career Paths

Those interested in a regulatory affairs career will likely find many options available to them, particularly at senior levels. According to a [2019 MassBioEd report](#), the number of job postings across all education levels increased by 100 to 140 percent since 2010, outpacing the number of potential employees trained to fulfill those roles. Senior positions in particular are more difficult to fill because there are few opportunities for graduate-level regulatory affairs training.

“There just aren’t enough bodies to fill the seats for the regulatory positions out there,” Amato says. “It’s an opportune time for students to enter the field.”

[Learn More | Careers in Regulatory Affairs and Quality Assurance →](#)

The [Occupational Information Network](#) predicts 74,500 job openings in the 10 years to 2029, and salaries are increasing alongside job openings. The average regulatory affairs specialist salary is \$108,627, an increase of 5.6 percent from 2018 to 2019, according to a recent [RAPS report](#).

Here are some of the positions companies will be looking to fill in the coming years.

Regulatory Affairs Manager

Median Salary: \$103,859 ([Payscale.com](#))

Regulatory affairs managers prepare all documentation and materials needed to apply for product approval with global organizations. They may also help coordinate and document internal regulatory processes, including audits, inspections, license renewals, and registrations.

[Learn More | How to Become a Regulatory Affairs Manager →](#)

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teaching professor and
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Regulatory Project Manager

Median Salary: \$91,073 ([Salary.com](#))

Regulatory project managers create and manage timelines, coordinate submissions, manage budgets, organize resources, and facilitate process improvement initiatives. Their primary goal is to ensure that projects are completed on schedule so that materials can be submitted for approval in a timely manner.

Compliance Manager

Median Salary: \$79,004 ([Payscale.com](#))

Compliance managers examine, evaluate, and investigate compliance with industry-specific regulations. They work across teams and departments to plan and coordinate projects that help maintain compliance, updating them accordingly when new laws or regulations come into effect.

Learn More | [Compliance Specialists: Who They Are and What They Earn](#) →

Clinical Study Manager

Median Salary: \$123,370 ([Salary.com](#))

Clinical study managers plan, design, and oversee clinical trials and related research projects to improve efficacy and ensure compliance with government regulations. This includes developing and writing study protocols and analyzing clinical data to produce related documents. They are also responsible for managing teams of clinical research associates.

Regulatory Writer

Median Salary: \$83,079 ([Salary.com](#))

Regulatory writers specialize in preparing a wide range of clinical study and regulatory submission documents for national and international agencies. They must interpret and summarize large quantities of data for investigator brochures, clinical trial protocols, study reports, and other materials.

Quality Assurance Manager

Median Salary: \$80,718 ([Payscale.com](#))

Quality assurance managers, or QA managers, ensure that a product remains in compliance with applicable regulatory measures throughout the development and design process. They work closely with cross-functional teams to improve processes and maintain established ones as well. QA managers also partner with regulatory agencies on submissions, audits, and approvals and advise internal stakeholders on the best way to bring a product to market.

Director of Quality Assurance

Median Salary: \$116,189 ([Payscale.com](#))

A director of quality assurance oversees the entirety of an organization's quality processes. They implement and audit procedures for efficiency and compliance and also help develop and approve standard operating procedures, change control orders, and other regulatory documentation.

74,500 +

**regulatory job openings
in the 10 years to 2029.**

(U.S. Bureau of Labor Statistics)

Director of Food Safety

Median Salary: \$90,547 ([Salary.com](#))

An organization's director of food safety manages, implements, and oversees all company safety and quality policies. They conduct audits on systems, raw materials, and suppliers; schedule and coordinate regulatory agency visits and third-party audits; and oversee all recall procedures, reporting, and action plans if necessary.

Learn More | [Food Safety Specialists: Who They Are and What They Earn](#) →

With a degree in regulatory affairs, students have the opportunity to work at leading food and pharmaceutical brands, including:





Trends in Regulatory Affairs

Constantly evolving laws and regulations are hallmarks of the global regulatory affairs industry. While continued learning is important in any field, it's indispensable for regulatory affairs professionals. Here are the **top trends** industry leaders should know about.

Medical Device Regulation

Many biomedical products, such as pacemakers and insulin delivery devices, can now be controlled through Bluetooth and cloud-based technologies, necessitating new standards for cybersecurity in addition to medical safety and efficacy. Regulatory agencies worldwide, including the FDA and the European Union, continue to develop medical device cybersecurity regulations to account for these concerns. These regulations often impact specifically how device manufacturers can develop, market, and receive approval for their products, making them an important development for regulatory affairs professionals.

[Learn More | Understanding Medical Device Regulations →](#)

Biopharma Approval Processes

In some cases, physicians will prescribe medications to treat conditions other than those the drug was approved to treat. For example, a doctor may choose to treat a cancer patient with a type of chemotherapy that was intended to be used for a different type of cancer. This practice, known as [off-label use](#), is common in medicine today. In December 2016, Congress approved new legislation to allow the FDA to consider real-world evidence from off-label use in regulatory approvals.

“This is a mechanism for the FDA to approve new drug products sooner,” Amato says. “As part of that approval, they’re asking manufacturers to continue to collect data by observing how the drug is being used in clinical practice, which enables a more rigorous safety profile.”

Learn More | [What You Need to Know for a Career in Biopharma Regulatory Affairs](#) →

Clinical Trials

Typically, regulatory agencies rely on lab tests, such as blood panels, to determine a drug’s safety and efficacy. Legislation to include patient-reported outcomes in the approval process is underway, adding a new element to agency decision making.

“If you look at insomnia medications, for example, what really matters to the patient is whether they fall asleep at night,” Amato says.

Taking a patient’s feelings of a drug’s effectiveness into consideration can result in more effective medications, and regulatory affairs professionals must understand how including this evidence in approval requests can affect their outcome.

Learn More | [Working in Clinical Trial Design](#) →

Blockchain Management

In the food industry, professionals use blockchain technology to improve transparency, efficiency, and safety within food supply chains. Regulatory professionals may find themselves working with these new technologies or providing their creators with guidance on how to best support regulatory needs.

[Learn More | Blockchain and Food Safety →](#)

Social Media Marketing

Social media platforms offer new marketing methods for companies in regulated industries. These companies will need to develop guidelines that regulate communication via social media and keep their ads consistent with product and labeling information. As a result, regulatory professionals who understand the effective and proper use of social media marketing channels will be in high demand.

Keeping up with new trends in regulatory affairs can be challenging, but it's a necessary task for professionals at any stage of their careers. Understanding the latest developments ensures that professionals can provide their employers with up-to-date information to improve a product's chances of approval, helping it get to the market safely and quickly.

[Learn More | Emerging Trends in Regulatory Affairs in 2021 →](#)



Essential Regulatory Affairs Skills

Leaders in the regulatory affairs industry have strong technical and soft skills that help them succeed in this multidisciplinary field.

Technical Skills

A strong foundation in the following technical skills is essential for regulatory professionals in any industry:

- > Basic science, including molecular biology, biochemistry, statistics, and pharmacology
- > Regulatory compliance and practice
- > Lab maintenance and safety
- > Manufacturing processes
- > Ethics
- > Regulatory strategy for product development
- > Methodological issues in human experimentation
- > International law and regulation
- > Regulatory submissions processes

Soft Skills

Soft skills, like clear and effective communication and collaboration strategies, are also important.

Here are several more soft skills regulatory affairs professionals need:

- > A global perspective, which helps professionals work across cultures and worldviews
- > Critical thinking
- > The ability to negotiate
- > Project management and organization
- > A commitment to lifelong learning

[Learn More | Skills You Need to Robot-Proof Your Career in Quality Assurance](#) →

Lifelong Learning

Lifelong learning is particularly crucial in regulatory affairs. Regulations and legislation change constantly, and staying informed can be the difference between a smooth approval and a costly mistake. Networking, reading daily news sources, taking classes, and attending lectures and trainings can all help. Northeastern University recommends the following organizations and resources to its students:

- > [Regulatory Affairs Professional Agency](#)
- > [The Organisation for Professionals in Regulatory Affairs](#)
- > [The U.S. Food & Drug Administration](#)
- > [Federal Register](#)
- > [Drug Information Association](#)
- > [Food Safety Magazine](#)
- > [Medical Device Manufacturers Association](#)



The Benefits of an Advanced Degree



Many regulatory professionals have a degree in a scientific or technical field, and a specific educational background is not required for roles in this industry. In fact, most regulatory professionals start out in a different field, with about half of their career work experience in regulatory affairs, according to a [2020 RAPS report](#).

A dedicated regulatory affairs degree, however, can give students a competitive advantage by teaching them foundational regulatory affairs skills and giving them the opportunity to undertake industry-specific internships and research.

[Learn More](#) | [4 Ways to Stay Competitive in Regulatory Affairs](#) →

“A graduate degree helps students gain the expertise companies are looking for through intensive curricula, specialized concentration coursework, and experiential learning opportunities,” Amato says.

Here are four advantages to earning an advanced degree in regulatory affairs:

1 | **Develop New Skills**

Earning a graduate degree provides students with in-depth knowledge about regulatory trends, compliance, practices, and global regulations. It also offers them the opportunity to address complex, real-world issues facing regulated industries, often before graduation. This real-world experience gives graduate students a competitive advantage when applying to jobs.

2 | **Stay Competitive**

More than two-thirds of regulatory affairs professionals have pursued postgraduate studies, and a growing number of employers specifically seek advanced degree holders for new roles. Investing in a master’s degree can help stand out when applying to jobs.

66% +

of regulatory affairs professionals have pursued postgraduate studies.

(2020 RAPS Report)

3 | **Grow Your Network**

Attending graduate school helps you connect with a new network of fellow students, professors, and industry professionals. These connections may give you new insight into current regulatory issues and can connect you with a variety of resources and job opportunities to help you grow your career.

4 | **Earn More**

According to a 2019 study by the National Association of Colleges and Employers, professionals with a master's degree typically earn **significantly higher** salaries than those with bachelor's degrees alone by as much as \$27,000 per year.

Investing in your education now can pave the way for higher-paying roles in the future, giving you greater career flexibility. Regulatory affairs specialists earn an average of \$10,000 more than counterparts with a bachelor's degree alone, according to the 2020 RAPS compensation report, and more than two-thirds of regulatory affairs directors surveyed in the same study have at least a master's degree.

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– Stephen Amato, PhD, teaching professor and lead faculty member for Northeastern's Master of Science in Regulatory Affairs

Advancing Your Career



Graduates of Northeastern’s **master’s in regulatory affairs program** have a deep understanding of compliance requirements for the development, marketing, and approval processes of drugs, medical devices, and foods.

The program’s comprehensive curriculum is aligned with today’s market demands and encompasses every step of product commercialization, with more than 40 classes available. Faculty members use their extensive industry experience to create new courses in response to market demands, assign classwork based on current events, and advise students throughout their education.

This multidisciplinary degree program is designated as a STEM program, allowing students to qualify for unique scholarships to fund their education.

[Learn More | What to Expect from Regulatory Affairs Courses →](#)

You can choose to deepen your studies by undertaking one of the following concentrations:

- Biopharmaceutical Regulatory Affairs
- Clinical Research Regulatory Affairs
- Medical Device Regulatory Affairs
- Nonclinical Biomedical Product Regulation
- Quality Assurance and Compliance

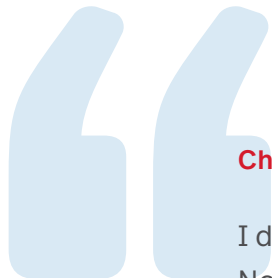
Northeastern students can also take advantage of experience-based learning opportunities, including [co-ops](#) and [Experiential Network](#) projects that allow them to solve real-world problems for businesses. An optional capstone course uses case-based individual and group assignments to help students further apply their studies to their careers.

To encourage lifelong learning for both students and alumni, regulatory affairs faculty members developed the Advancing Lifelong Excellence in Regulatory Trades (ALERT) program in 2017.

Since its founding, the program has featured lectures from speakers in industry, government, and academia on a range of topics, including clinical trial startup, digital health initiatives, and gene therapy.

ALERT also offers career development services for professionals at all stages of their careers, including cover letter and resumé reviews, interview prep, and one-on-one consultations to help answer specific questions. There are more than 750 ALERT members, about half of whom are alumni working in some of the biggest pharmaceutical, biological, nutraceutical, and cosmeceutical companies in the world.

An Insider's Perspective



Christopher Fulmer, CPS, Master of Science in Regulatory Affairs, '21

I decided to transition from a legal career into regulatory affairs, and Northeastern's program has provided me with the knowledge I was lacking, as well as practical field experience through XN projects and a capstone class. During my time in the program, two of my term papers have been published in peer-reviewed journals, which has helped further my career.

I'd say there are six main benefits of being a graduate student in Northeastern's Master of Science in Regulatory Affairs program.

1

Students can get involved in numerous XN projects before enrolling in a capstone class to obtain practical experience in a variety of areas involving regulatory affairs. A highlight of my educational experience is the XN project I participated in with Sen-Jam Pharmaceutical. Our team analyzed the increasing importance of the 505b(2) pathway and crowdfunding in the repurposing of small molecules to develop innovative drugs.

2

The courses are taught by instructors who have very diverse backgrounds, expertise, and perspectives regarding regulatory affair matters, adding an additional layer of education to the courses outside the class reading materials.

3

The ability to grow your network in the field cannot be overlooked. As a graduate student, I was able to network with instructors currently practicing in the field, network with other graduate students working in related industries, and network with corporate leaders at pharmaceutical, biotechnology, and medical device companies.

4

The university has an excellent reputation in STEM fields among employers, both in Boston and beyond.

5

The program curriculum keeps evolving with the industry, maximizing both the educational and practical application value to graduate students in the program.

6

Students can attend additional free lectures on current topics.

Regulatory Affairs at Northeastern: Fast Facts

Master's Program

Locations

- Boston
- Toronto
- Online

Available Concentrations:

- > Biopharmaceutical Regulatory Affairs
- > Clinical Research Regulatory Affairs
- > Medical Device Regulatory Affairs
- > Nonclinical Biomedical Product Regulation
- > Quality Assurance and Compliance

Commitment

- > Full Time
- > Part Time

Duration

- > 1 - 1.5 Years



LEARN MORE →

Are you ready to take the next step in your regulatory affairs career?

Northeastern can help you get ahead.
Visit northeastern.edu/graduate to learn how.

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