

# Regulatory Affairs

## PhD Career Insights

Regulatory Affairs professionals work at the interface of industry and government to help ensure that biomedical technologies are safe, effective, high quality, and correctly labeled and marketed. You will help protect the public by evaluating the safety and efficacy of healthcare products before and after commercial release.

Regulatory affairs specialists in medical device, diagnostic, biotech and pharma companies Biotech and Pharma work in teams composed of scientists, market professionals, clinicians, manufacturing teams, payment experts, and corporate leadership designing clinical trial programs that support marketing claims. They also advise the company on legal requirements and product development strategy.

Regulatory Health Authority reviewers evaluate data submitted by product developers as part of investigational new drug applications, new or generic drug applications, and biologics license applications. They determine the scientific validity of the preclinical data, clinical trial data, manufacturing process, product quality, drug safety, and efficacy claims.

### What would I do?

- Assist with regulatory application preparation and submission process
- Prepare or review labeling and promotional materials to ensure compliance with FDA and international requirements
- Review and approve applications, and consult with companies to improve their applications
- Handle FDA customs import/export requests, customer service needs, and other requests from internal customers
- Develop, document and implement a regulatory strategy plan to support product development and company goals
- Initiate and update technical files and registrations
- Review proposed product changes for impact on regulatory status of the product
- Develop new governmental safety regulations
- Ensure that the regulatory file complies with applicable laws and regulations
- Identify potential issues that might impact product quality, safety, or efficacy
- Make scientifically sound risk-based assessments, and recommend regulatory actions
- Provide feedback and guidance to the sponsor as it relates to their drug development program and the review of their application

Johns Hopkins Medical Institute Professional Development and Career Office

<http://pdco.med.jhmi.edu/>

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## Where could I work?

- US Food and Drug Administration
- Biotechnology Companies
- Pharmaceutical Companies
- Academic Clinical Centers
- Cosmetic Companies
- Nutritional Products Industry
- Medical Device Companies
- National Institutes of Health
- Federal agencies engaged in clinical research (CDC, DOD, etc.)

## What skills should I have?

- Writing skills that meet regulatory requirements and standards for documentation, including the ability to effectively describe complex situations.
- Comfort with multiple projects and multiple deadlines
- Ability to evaluate and interpret reports and other documents to be used in regulatory submissions
- Knowledge of 21 CFR, FDA Guidance Documents and FDA guidelines (though this may be learned on-the-job)
- Demonstrated ability to coordinate and work effectively with cross-functional teams
- Understanding of the drug development and drug approval process
- Ability to communicate effectively and maintain excellent relationships despite often dealing with demanding or complex issues
- Strong organizational skills and attention to detail

## What is the salary range?

- Entry Level: \$80 to \$90K
- The FDA will hire a new reviewer at GS12 (\$60-80K) or GS13 (\$73-95K)
- Five years' experience: \$100K+

## Where can I find out more about Regulatory Affairs careers?

- [Tooling Up: The Regulatory Affairs Career Track, Science Careers](#)
- [Feature: Scientists in Regulatory Affairs, Science Careers](#)
- [All in the Details: Careers in Regulatory Science Careers](#),
- [Finding Job Satisfaction in Regulatory Affairs](#)
- [Regulatory Affairs Career Panel](#) (video)
- Learn about the work done at the FDA through the [FDAVoice](#) blog post.

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## How can I gain skills and experience for a Regulatory Affairs career?

- The Regulatory Affairs Certification (RAC) is the only certification specifically for regulatory professionals in the healthcare product sector, which is obtained by passing a rigorous exam. Learn the regulations that apply to drugs, biologics or medical devices.
- Join regulatory organizations, both local and national. ([Regulatory Affairs Professionals Society](#), [Drug Information Association](#) and [Association of Clinical Research Professionals](#))
- [Sign up](#) for FDA updates on regulation changes
- [Complete on line tutorials, classes or internships at FDA](#)
- [WEBLINKS to FDA Educational and Development Opportunities](#)
- [FDA and the Regulation of Healthcare Interventions – A Spotlight Session](#)
- Work for a contract research organization or a contract manufacturing organization
- [FDANews](#) provides [webinars](#) and [newsletters](#) to keep up with the latest developments in the field
- Familiarize yourself with [regulatory guidelines](#)

## Where can I find Regulatory Affairs internships or fellowships?

[ORISE Research Participation Postdoctoral Fellowships](#), Oak Ridge Institute for Science and Education

[FDA Commissioner's Fellowship Program](#) (Application period opens in March/April)

[FDA – National Cancer Institute Inter-Agency Oncology Task Force Joint Fellowship Program](#)

[Pathways Program for Recent PhD Graduates](#)

[Service Fellowship Plan for FDA](#)

[Medical Device Fellowship Program](#)

[List of FDA Fellowships for Post-Graduates](#)

[Tobacco Regulatory Science Fellowship](#)

[Foreign National Training Program \(NCTR\)](#)

[Cato Research Fellows](#)

[TRIUMPH Postdoctoral Fellowship – MD Anderson Cancer Center](#)

## **What professional organizations can I join?**

[Regulatory Affairs Professional Society \(RAPS\)](#)

[The Organization for Professionals in Regulatory Affairs \(TOPRA\) – European Regulatory Affairs](#)

[Association of Clinical Research Professionals](#)

[CASSS](#): a non-profit scientific society facilitating the interaction among industry, academic and regulatory professionals.

[Parenteral Drug Association](#)

### **LinkedIn Groups**

[Regulatory Affairs Professionals](#)

[Drug Regulatory Affairs](#)

[Regulatory Affairs, Drug Safety, Quality](#)