



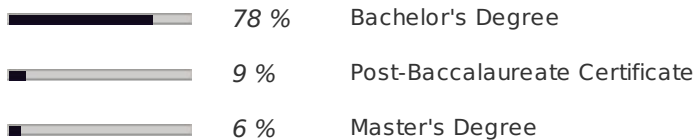
Regulatory Affairs Specialists

Description

Coordinate and document internal regulatory processes, such as internal audits, inspections, license renewals or registrations. May compile and prepare materials for submission to regulatory agencies.

Education

The following is a breakdown of the top three degrees that people in this job possess (each educational level is described in the legend at the end of this document):

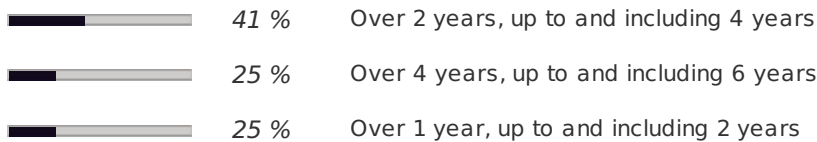


In order to pursue this career, you will need to be educated in one of the following areas:

- Auditing.ááá(NEW) (CIP = 52.0303)

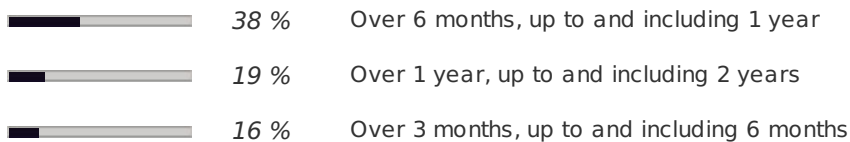
Experience

The following is a breakdown of the level of related work experience that people in this job possess:



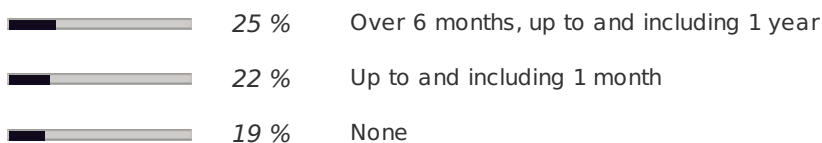
On-site Training

The following is a breakdown of the length of on-site training that people in this job typically receive:



On-the-job Training

The following is a breakdown of the level of on-the-job training that people in this job received:





Interests

The following is a list of the top three career interests (also known as Holland Codes) that people with this occupation possess, along with their level of importance to this career.

- Conventional (Very high)
- Enterprising (High)
- Investigative (Low)

Tasks

Here are the most common tasks and duties for which you would be responsible in this job:

- Coordinate, prepare, or review regulatory submissions for domestic or international projects.
- Provide technical review of data or reports that will be incorporated into regulatory submissions to assure scientific rigor, accuracy, and clarity of presentation.
- Review product promotional materials, labeling, batch records, specification sheets, or test methods for compliance with applicable regulations and policies.
- Maintain current knowledge base of existing and emerging regulations, standards, or guidance documents.
- Interpret regulatory rules or rule changes and ensure that they are communicated through corporate policies and procedures.
- Determine the types of regulatory submissions or internal documentation that are required in situations such as proposed device changes and labeling changes.
- Advise project teams on subjects such as premarket regulatory requirements, export and labeling requirements, and clinical study compliance issues.
- Prepare or maintain technical files as necessary to obtain and sustain product approval.
- Coordinate efforts associated with the preparation of regulatory documents or submissions.
- Prepare or direct the preparation of additional information or responses as requested by regulatory agencies.
- Analyze product complaints and make recommendations regarding their reportability.
- Coordinate recall or market withdrawal activities as necessary.
- Review adverse drug reactions and file all related reports in accordance with regulatory agency guidelines.
- Escort government inspectors during inspections and provide post-inspection follow-up information as requested.
- Communicate with regulatory agencies regarding pre-submission strategies, potential regulatory pathways, compliance test requirements, or clarification and follow-up of submissions under review.
- Identify relevant guidance documents, international standards, or consensus standards and provide interpretive assistance.
- Review clinical protocols to ensure collection of data needed for regulatory submissions.
- Compile and maintain regulatory documentation databases and systems.
- Recommend changes to company procedures in response to changes in regulations or standards.
- Obtain and distribute updated information regarding domestic or international laws, guidelines, or standards.

Abilities

To pursue this career, you will need to display the following capacities:

- Written Comprehension
- Written Expression
- Oral Comprehension
- Oral Expression
- Problem Sensitivity
- Deductive Reasoning
- Information Ordering
- Near Vision
- Inductive Reasoning
- Speech Clarity
- Speech Recognition
- Category Flexibility
- Fluency of Ideas
- Flexibility of Closure
- Originality
- Perceptual Speed
- Selective Attention
- Speed of Closure
- Memorization
- Mathematical Reasoning



Knowledge

To pursue this career, it would be helpful to be well-versed in the following subject areas:

- English Language
- Law and Government
- Clerical
- Computers and Electronics
- Administration and Management
- Medicine and Dentistry
- Biology
- Mathematics
- Customer and Personal Service
- Production and Processing
- Chemistry
- Education and Training
- Communications and Media
- Engineering and Technology
- Design
- Sales and Marketing
- Public Safety and Security
- Personnel and Human Resources
- Telecommunications
- Psychology

Skills

The following skills are considered essential to this job:

- Reading Comprehension
- Critical Thinking
- Writing
- Speaking
- Judgment and Decision Making
- Systems Analysis
- Active Listening
- Complex Problem Solving
- Coordination
- Systems Evaluation
- Active Learning
- Time Management
- Social Perceptiveness
- Monitoring
- Persuasion
- Negotiation
- Instructing
- Service Orientation
- Management of Personnel Resource
- Learning Strategies



Activities

In this job, you will likely spend most of your time engaged in the following activities:

- Evaluating Information to Determine Compliance with Standards
- Getting Information
- Updating and Using Relevant Knowledge
- Interacting With Computers
- Communicating with Supervisors, Peers, or Subordinates
- Organizing, Planning, and Prioritizing Work
- Processing Information
- Establishing and Maintaining Interpersonal Relationships
- Interpreting the Meaning of Information for Others
- Making Decisions and Solving Problems
- Communicating with Persons Outside Organization
- Documenting/Recording Information
- Identifying Objects, Actions, and Events
- Analyzing Data or Information
- Performing Administrative Activities
- Developing Objectives and Strategies
- Provide Consultation and Advice to Others
- Coordinating the Work and Activities of Others
- Developing and Building Teams
- Scheduling Work and Activities

Job Zone

All occupations are categorized into job zones, based on the level of preparation (experience, education, and training) that is required. There are five job zone categories, with job zone one indicating that little to no preparation is required, to job zone five, where extensive preparation is needed.

This occupation is categorized as Job Zone Four: Considerable Preparation Needed

Occupations in this job zone tend to require the following:

Experience

A considerable amount of work-related skill, knowledge, or experience is needed for these occupations. For example, an accountant must complete four years of college and work for several years in accounting to be considered qualified.

Education

Most of these occupations require a four-year bachelor's degree, but some do not.

Training

Employees in these occupations usually need several years of work-related experience, on-the-job training, and/or vocational training.

Example

Many of these occupations involve coordinating, supervising, managing, or training others. Examples include accountants, sales managers, database administrators, teachers, chemists, environmental engineers, criminal investigators, and special agents.



Legend:

Educational Levels

1. **Less than High School:** No schooling or just grade school or some high school courses.
2. **High School Diploma:** Or GED or High School Equivalence Certificate.
3. **Post-Secondary Certificate:** Awarded for training completed after high school (for example, in Personnel Services, Engineering-related Technologies, Vocational Home Economics, Construction Trades, Mechanics and Repairers, Precision Production Trades).
4. **Some College Courses:** Can consist of college preparatory courses or regular courses taken while attending college, but credits attained are not sufficient to get a degree.
5. **Associate's Degree:** An undergraduate degree awarded by a junior, community technical or bachelor's degree-granting college/university. Requires a completion of a two-year course of study.
6. **Bachelor's Degree:** An academic degree awarded for an undergraduate major or course. Requires a completion of a four-year course of study.
7. **Post-Baccalaureate Certificate:** Awarded for completion of an organized program of study; designed for people who have completed a Baccalaureate degree, but do not meet the requirements of academic degrees carrying the title of Master.
8. **Master's Degree:** An academic degree awarded to people who, in addition to achieving a bachelor's, have taken additional courses or completed a research study in a specific field or subject area. Requires an additional one to three years of study.
9. **Post-Master's Certificate:** Awarded for completion of an organized program of study; designed for people who have completed a Master's degree, but do not meet the requirements of academic degrees at the doctoral level.
10. **First Professional Degree:** Awarded for completion of a program that: requires at least 2 years of college work before entrance into the program, includes a total of at least 6 academic years of work to complete, and provides all remaining academic requirements to begin practice in a profession.
11. **Doctoral Degree:** An academic or professional degree awarded for the completion of advanced graduate study beyond a Master's degree. Requires an additional two to four years of study.
12. **Postdoctoral Training:** Consists of advanced academic research completed after doctoral studies. Generally done within five years of the completion of a Doctoral Degree in order to deepen a person's knowledge of a particular subject, hone skills, and publish academic papers.