Documentation Specialists

What They Do

Documentation Specialists handle the regulatory affairs, compliance, and electronic submission aspects of a biotechnology company. In smaller firms there may be one Specialist handling all related tasks, while larger biotechnology firms may hire several professionals to divide the responsibilities. These workers are sometimes known as regulatory affairs specialists, electronic submission specialists, or compliance specialists.

Documentation Specialists coordinate and prepare document packages for submission to regulatory agencies. They compile all materials required for regulatory submissions, license renewal, and registrations. They must stay current with regulatory procedures and changes. They monitor and improve tracking and control systems and recommend strategies for earliest possible approvals of clinical trial applications.

Some Documentation Specialists focus on electronic submission of documentation. They train others on e-submission procedures and software and coordinate submission issues between departments. They authorize applications, notices, and electronic submission forms required by government agencies such as the Food and Drug Administration and Information Security Office.

Documentation Specialists who concentrate on compliance coordinate, prepare, and perform internal and external audits, ensuring compliance with regulatory standards. They collaborate with clients to develop positive and productive approaches to regulatory compliance. They participate in Good Laboratory Practices (GLP) training of functional areas and assist in development of training sessions. They coordinate activities for regulatory agency inspections.

*Documentation Specialists in the biotech industry share characteristics of Management Analysts. Detailed descriptions of this occupation may be found in the Occupational Information Network (O*NET) at online.onetcenter.org.*

Important skills, knowledge, and abilities include:

- Administration and Management – Knowledge of business and management principles involved in strategic planning, resource allocation, human resources modeling, leadership technique, production methods, and coordination of people and resources.
- Writing – Communicating effectively in writing as appropriate for the needs of the audience.
- Reading Comprehension – Understanding written sentences and paragraphs in work related documents.
- Speaking – Talking to others to convey information effectively.
- Systems Evaluation – Identifying measures or indicators of system performance and the actions needed to improve or correct performance, relative to the goals of the system.
- Active Listening – Giving full attention to what other people are saying, taking time to understand the points being made, asking questions as appropriate, and not interrupting at inappropriate times.
- Critical Thinking – Using logic and reasoning to identify the strengths and weaknesses of alternative solutions, conclusions or approaches to problems.

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Documentation Specialists

Training/Requirements

- Bachelor's degree in a scientific field.
- Three to five years experience in documentation, quality control, or quality assurance.

What's the California Job Outlook?

While the Bureau of Labor Statistics does not collect data on Documentation Specialists, the occupation listed below is found in the biotechnology industry and has similar duties. The California outlook and wage figures are drawn from all industries and represent an occupation comparable to Documentation Specialist.

Standard Occupational Classification	Estimated Number of Workers 2004	Estimated Number of Workers 2014	Average Annual Openings	2007 Wage Range (per hour)
Management Analysts 13-1111	71,000	86,200	2,490	$27.02 to $47.35

These figures do not include self-employment.
Average annual openings *include new jobs plus openings due to separations.*
Source: www.labormarketinfo.edd.ca.gov , Employment Projections by Occupation and OES Employment & Wages by Occupation, Labor Market Information Division, Employment Development Department.

Additional Source of Information

American Management Association International
(800) 262-9699
www.amanet.org

Occupational Information Network (O*NET)
http://online.onetcenter.org

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