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Biotechnology Job Catalog

Pharmaceutical Industry Association

2006 Edition

About This Material

This document is the biotechnology job catalog developed by a team comprised of PIA members that have biotechnology operations in Puerto Rico, PIA's Education Committee representatives and Hewitt Associates, an HR consulting and outsourcing firm. The catalog details the different jobs that have been identified by industry representatives as “core” and “hard to hire positions” for the biotechnology industry in Puerto Rico. The purpose of this catalog is to document the educational and technical requirements needed for core positions in the biotechnology industry and facilitate the dialogue among the industry, government and the academia.

The job catalog was developed using the following process:

- Hewitt Associates compiled a list of key biotechnology roles classified by job family. The list included typical tasks of the role, educational and experience requirements and technical skills.
- The list was discussed with representatives from Abbott, Amgen, J&J and Lilly del Caribe. Each job was reviewed to determine if it was “core” and/or “hard to hire.”
 - Core positions were defined as those "that manage active ingredients and product manufacturing components. The tasks of these positions cannot be outsourced and are essential to the manufacturing operations."
 - Hard to hire positions were defined as "positions that require a specialized set of technical skills for which there is a limited pool of candidates."
- A detailed catalog was developed for core and hard to hire positions. The organizational level, educational requirements and technical skills of these jobs were discussed with the team and further refined.

As you review this document, please note that the positions included in the final catalog are representative of the typical, core, positions for a Pharmaceutical Active Ingredient biotechnology operation. In addition, there may be more organizational levels for some positions, which are tied to career progression within the same role.

Job Catalog



Quality & Validation

Sr. Management

Head of QC/QA

Middle Management

Regulatory and Compliance Manager

QC/QA Manager

Validation Manager

Lower Manager/
Sr. Professional

QA Manufacturing

Quality Control Engineer

Senior Validation Specialist
/ Engineer

Bioestatician

Sr. Supervisor/
Professional

QA Specialist

QC/QA Section Supervisor

Validation Specialist /
Engineer

Supervisor/
Entry Professional

Technical Writer

General Staff

QC/QA Inspector

QC Technician

Documentation Specialist

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Biostatistician	Responsible for the statistical integrity, adequacy and accuracy of the clinical studies/databases. Provides guidance in statistical analysis methodology and performs statistical programming, design, and analyses for clinical trial projects. Plans, coordinates and provides statistical analyses, summaries and reports of studies in the support of product development including IND/ New Drug Applications (NDA) and Biological License Applications (BLA) submissions. Maintains and improves professional knowledge of technological advancements in data manipulation and statistical analyses.	Senior positions require a MS, a PhD is preferred and 4-8 plus years of experience in clinical trials, regression models, survival analysis and analysis of categorical data. Ability to manage several programs and protocols is required for senior positions. Intermediate positions require Bachelor, Master preferred, and 2-5 years of related experience.	Communication and interpersonal skills and a background in SAS and other programming skills. Application of these skills in a pharmaceutical environment is preferred. Knowledge of GMP regulations. Knowledge of SOP, investigation and computer programs. Bilingual; to speak, read and write in English and Spanish.
Documentation Specialist	Maintains records and documents such as validation master plan, SOP, technical transfer documents, or non compliance and any other documents related to the quality systems. Follow-up on the revision and approval of such documents. Responsible for the GMP library.	BS in Science with 0 to 5 years of related experience.	Knowledge of GMP regulations. Knowledge of SOP, investigation techniques and computer programs. Bilingual; to speak, read and write in English and Spanish.
Head of QC / QA	Responsible to maintain comprehensive, cost-effective, and progressive quality standards for the plant products. Activities include reviewing designs/plans of proposed new products; developing test instrumentation and procedures that economically maximize quality standards; establishing and directing laboratory facilities for quality testing of raw materials, finished goods, and goods in process.	Requires a Bachelor's degree in a specified scientific or engineering field. A minimum of 10 years of experience in the pharmaceutical and medical device industry	Knowledge of GMP regulations. Knowledge of SOP, investigation techniques and computer programs. Bilingual; to speak, read and write in English and Spanish.
QC / QA Inspector	Performs tasks that involve sampling,	Requires an Associate degree in	Knowledge of GMP regulations.

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	measuring, auditing and other quality tests as required to determine if a product and/or procedure meet established specifications. Responsible for line clearance inspections. Stores samples of raw materials that have been tested and files the results of these tests for determination of product's stability. Stores samples of final products with its appropriate identification. Obtains samples of in-line products and raw materials on scheduled dates and submits them to the laboratory for respective analysis. Compares test and audits results and informs the supervisor accordingly. Standardizes equipment and performs clerical duties.	Science and good mathematical skills plus 0-1 year of work-related experience.	Knowledge of SOP, investigation techniques and computer programs. Bilingual; to speak, read and write in English and Spanish.
QC / QA Manager	Responsible for in-process testing, quality engineering and technical services. Manages a group of supervisors and/or technicians. Provides technical leadership, cross functionally and to subordinate managers.	Requires a Bachelor's degree in a scientific field or Engineering. Typically requires a minimum of 8 years of experience in work-related activities.	Knowledge of LIMS, and GMP regulations. Knowledge of SOP, investigation techniques and computer programs. Bilingual; to speak, read and write in English and Spanish.
QC / QA Section Supervisor	Responsible for the supervision of the quality control/assurance function within the plant. Take the necessary decisions for material and finished goods disposition, components and products received, processed and distributed, and for document control and specification changes. Reviews process and/or final batch records.	Requires a Bachelor's degree in a scientific discipline plus 2-4 years previous experience in the pharmaceutical industry or related field.	Knowledge of LIMS, and GMP regulations. Knowledge of SOP, investigation techniques and computers programs. Bilingual; to speak, read and write in English and Spanish.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
QC / QA Specialist	Performs moderately complex tasks requiring planning, scheduling, and testing of the company's biological and chemical products. Responsible for developing, implementing and maintaining test plans and procedures to ensure that products meet design specifications and are within total quality management limits and standards. Follows SOP (Standard Operating Procedures) and GMP (Good Manufacturing Practices). Communicates with product developers and supports specialists on product issues. May maintain the ISO certification. Operates under general supervision.	Typically requires 4-5 years of experience in development, research, or product testing. BS in Science (Biotechnology, Microbiology, Chemistry, Biochemistry, Medical Technology, Biology).	Knowledge of industry and company SOP, technical experience working with GMP and ISO. Have techniques in electrophoresis, immunoassays, and molecular biology techniques. Techniques in HPLC (High Performance Liquid Chromatography), GC (Gas Chromatography), and TFF (Tangential Flow Filtration). Decision making skills. Advance investigation skills. Knowledge of investigation and computer programs. Bilingual; to speak, read and write in English and Spanish.
Quality Control Engineer	Responsible for developing, implementing and maintaining quality standards for the company's biological and biotech products. In some organizations, will be responsible for computer systems validation. Designs and applies procedures and processes to ensure that products meet design specifications and established quality control requirements. Develops and oversees implementation of corrective measures. Trains analysts on quality control procedures and processes.	BS degree in Electricity, Mechanics, or related discipline. Usually requires four to five years of quality control engineering experience in a biotech environment.	Knowledge of industry SOP, GMP and Six Sigma. Skills in Refrigeration Systems (HVAC), Purified and Distilled Water System, Automation-computerized control system knowledge and PLC (Programmable Logic Controllers). Knowledge of investigations and computers programs. Bilingual; to speak, read and write in English and Spanish.
Quality Control Technician	Performs a wide variety of inspections, checks, tests and sampling procedures of the manufacturing process according to Standard Operating Procedures (SOP). Performs in-process inspection and documents results. Monitors critical equipment and instrumentation. Writes and updates inspection procedures and checklists, as necessary.	Requires a BS (Biotechnology, Microbiology, Chemistry, Biochemistry, Medical Technology, and Biology) or equivalent experience with a scientific background and a minimum of 0-3 years in quality control systems with knowledge of good manufacturing practices (GMP).	Knowledge of LIMS, industry and company SOP, technical experience working with GMP. Knowledge of investigation and computer programs. Bilingual, to speak, read and write in English and Spanish.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Regulatory Compliance Manager	Responsible to develop strategies and implement programs to assure regulatory compliance of quality standards. Provide leadership in responding to Regulatory Agencies and GMP requirements. Manage GMP compliance audit programs. Executes control over all or some of the following programs/systems: change control system, documentation control, product complaint investigation and analysis, and stability program.	Requires a Bachelor's degree in a specified scientific or engineering field. Typically requires a minimum of 8 years of experience in GMP and regulatory compliance activities.	Strong knowledge of Regulatory Agencies and GMP. Knowledge of GMP regulations. Knowledge of SOP, investigation techniques and computer programs. Bilingual; to speak, read and write in English and Spanish.
Senior Validation Specialist / Engineer	Researches and solves moderately complex problems involving the production or use of biochemical equipment and systems. Plans and tests methods of manufacturing products and treating byproducts. Works under general supervision. Assists in process validation. Uses validation plans, protocols, and testing specifications to validate equipment, instruments and systems. Works under minimal supervision with wide-latitude for independent judgment.	BS degree in Science or Engineering. Usually has 4-5 years of biochemical validation experience.	Knowledge of GMP regulations. Knowledge SOP. Skills in Refrigeration System (HVAC), Purified and Distilled Water System, Automation-computerized control system knowledge and PLC (Programmable Logistic Controllers). Knowledge of investigation and computer programs. Bilingual, to speak, read and write in English and Spanish.
Technical Writer	Responsible for writing and editing standard operating procedures, clinical study protocols, laboratory procedure manuals, and other related documents. He or she edits and/or rewrites various sources of information into a uniform style and language for regulatory compliance, and assists in developing documentation for instructional, descriptive, reference, and/or informational purposes. Ensures accuracy and completeness of technical documentation.	Requires a Bachelor's degree in science or equivalent and a minimum of 3 years of experience in writing technical documentation. Or an equivalent combination of relevant education and experience.	Requires excellent oral and written communication skills in English and Spanish. Knowledge of scientific investigation techniques and terminology.
Validation Manager	Responsible for managing, developing and implementing validation protocols and test procedures to ensure products meet	Requires a BS/MS or equivalent in a scientific discipline with 8-10 years of experience.	Knowledge of GMP regulations. Knowledge of SOP, investigation techniques and computer programs.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
	appropriate regulatory agency validation requirements, SOP and industry current practices. Oversees and reviews validation process and procedures. Recommends changes and improvements. Supervises the coordination of the activities of a department with responsibility for the results in terms of costs, methods and employees.		Bilingual; to speak, read and write in English and Spanish.
Validation Specialist / Engineer	Responsible for developing and recommending validation strategies and design studies for the purpose of providing documented evidence that a system, equipment, method, or process has been validated. Conducts qualification programs, writes detailed protocols and reports to document the validation of systems/ equipment and provides support for facility/utility expansion, compliance upgrades, etc.	Requires BS in a scientific, engineering or other related technical field with a minimum of 3 years experience in a regulated industry. Knowledge of current industry practices and GMP requirements related to validation tasks.	Knowledge of GMP regulations. Knowledge of SOP, investigation techniques and computer programs. Bilingual; to speak, read and write in English and Spanish.