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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



Hewitt

Engineering

Sr. Management

Head of Engineering

Middle Management

Maintenance Manager

Lower Manager/
Sr. Professional

Environmental Supervisor*

Health Safety Supervisor*

Sr. Supervisor/
Professional

Supervisor/
Entry Professional

General Staff

Maintenance Technician

Facilities Technician

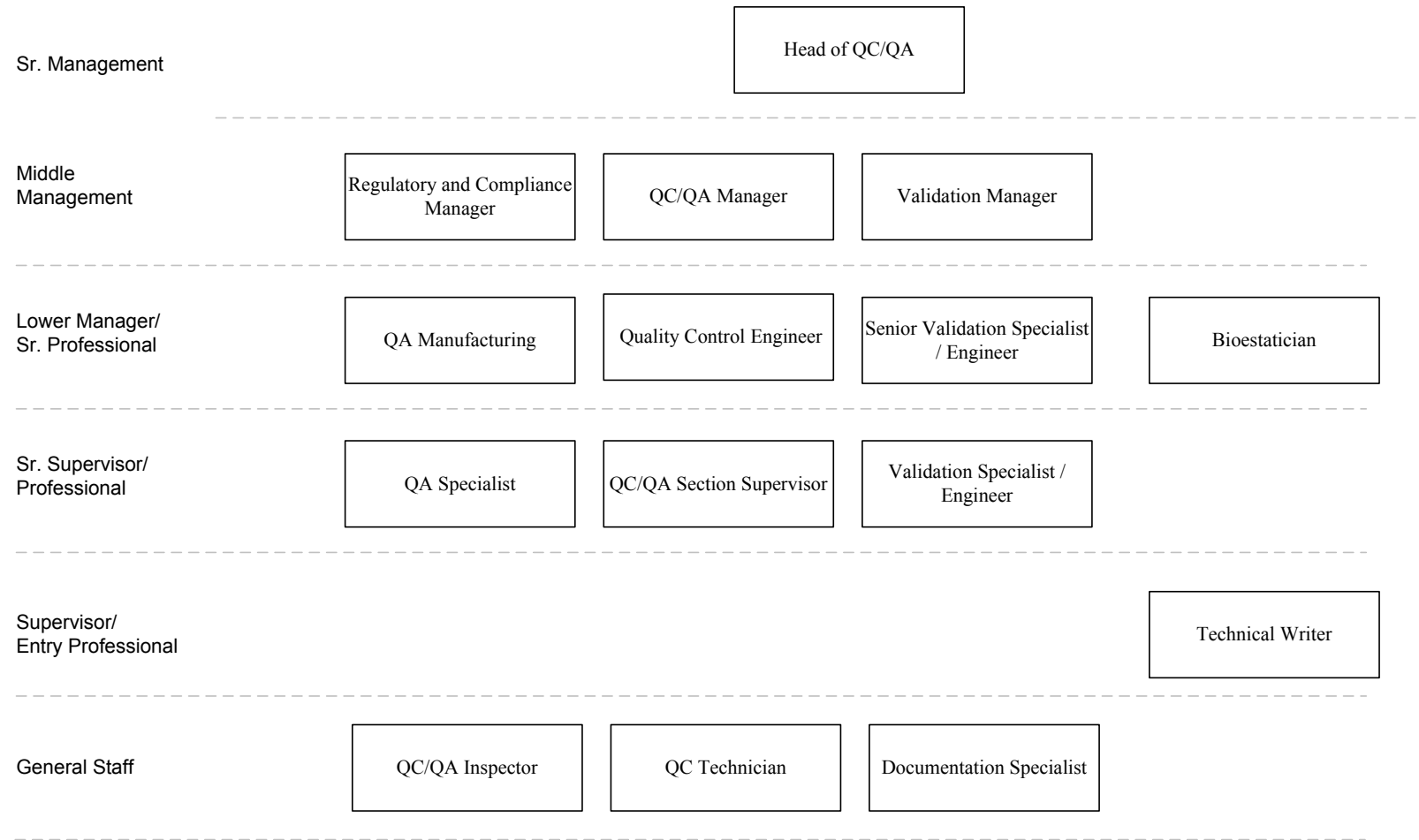
*For some companies, these positions report to different departments (e.g., HR)

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Environmental Supervisor	Responsible for the research, coordination, implementation and management of environmental issues including waste disposal, air/water quality, pollution, hazardous waste, and land management. Prepares permit applications and performs environmental regulatory reviews and participates in environmental audits. Develops and maintains appropriate documentation to assure compliance with governmental regulations.	Requires a BS in Environmental, Civil or Chemical Engineering, or related discipline, MS is preferred and a minimum of 3-5 years environmental engineering experience. Knowledge of engineering documentation including expertise in permitting, pollution prevention, environmental regulatory compliance, training and reporting is required.	Strong knowledge of SOP, Regulatory Agencies and OSHA regulations. Experience in GMP and other technical requirements. Skills in Refrigeration System (HVAC), Purified and Distilled Water System, Automation-computerized control system knowledge and PLC (Programmable Logistic Controllers). Investigation skills. Knowledge of computers programs. Bilingual; to speak, read and write in English and Spanish.
Facilities Technician	Performs daily monitoring, repair and preventive maintenance activities on critical systems and facility equipment. Also troubleshoots, install and repair new and existing systems, including refrigeration equipment, water systems, HVAC systems, and electrical systems. Documents, repairs, adjusts and replaces equipment and/or components per GMP standards. May also provide input and corrections to Standard Operating Procedures (SOP) and assist engineering in the evaluation of new equipment technology.	Requires AA/Asor Certificate of Completion at a 2-year technical school in mechanical/electrical field, or high school diploma with 1-2 years of experience in GMP maintenance. Experience in pharmaceutical or bio pharmaceutical environment is preferred.	Knowledge of GMP regulations. Knowledge of SOP, and major trades, such as electrical, plumbing and HVAC/refrigeration, including the ability to interpret blueprints, and specifications. Knowledge of investigation techniques and computer programs. Bilingual; to speak, read and write in English and Spanish.
Health and Safety Supervisor	Responsible for overseeing and ensuring compliance with governmental occupational and health regulations. Protects company assets by eliminating chance of personal injury or property damage from business activities. Oversees safety checks and inspections with appropriate safety representatives. Implements any necessary safety improvements, including corrective	Requires a BS in Environmental, Civil or Chemical Engineering, or related discipline, MS is preferred and a minimum of 3-5 years environmental engineering experience.	Strong knowledge of OSHA and Workers Compensation regulations. Experience in GMP and other technical requirements. Knowledge of investigations process and computer programs. Bilingual; to speak, read and write in English and Spanish.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
	actions, monitoring and reporting when required.		
Maintenance Manager	Provide maintenance and assure labor continuity, minimizing equipment failures. Maintain equipment and facilities in proper conditions. Responsible for the HVAC and preventive maintenance, replacement/installation of equipment, laboratory and building facilities. Supports the operation in a constantly changing mode and continuous growth.	BS in Mechanical, Electrical or Chemical Engineering	Knowledge of GMP regulations. Knowledge of SOP. Skills in Refrigeration System (HVAC), Purified and Distilled Water System, Automation-computerized control system knowledge and PLC (Programmable Logistic Controllers). Knowledge of investigations and computer programs. Bilingual, to speak read and write in English and Spanish.
Maintenance Technician	Responsible of reparation, installation, inspection, calibration, and preventive maintenance of manufacturing equipment, instrumentation, and utilities for biopharmaceutical products in accordance with applicable regulations (Company Standards, CGMP, OSHA, etc.).	Associate Degree in Industrial Electricity, Mechanics, Electrical Technology or related field.	Knowledge of GMP regulations. Knowledge of SOP, investigations and computer programs. Experience in calibration, utilities and/or instrumentation. Bilingual; to speak, read and write in English and Spanish.



Quality & Validation



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.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
	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.



Tech Ops /Services

Sr. Management

Middle
Management

Technical Operations
Manager

Sr. Scientist

Lower Manager/
Sr. Professional

Cell Culture Scientist

QA Analyst/Scientist

Scientist

Sr. Supervisor/
Professional

Purification/Formulation
Supervisor

Supervisor/
Entry Professional

Research Scientist

General Staff

Technician

Biologic Operator

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Biologic Operator	Operates equipment like washers, bioreactors, filtration systems, chromatography equipment. Weighs and verifies raw materials and tools. Performs specific tests, conductivity, and filter integrity. Assembles equipments and execute cleaning and sterilization procedures.	Associate Degree in Natural Sciences, preferably in Chemistry, Biology, Microbiology or related areas.	Knowledge of SOP and GMP regulations. Knowledge of investigation and computer programs. Bilingual, to speak, read and write in English and Spanish.
Cell Culture Scientist	Provides supervision to cell culture associates (exempt and non-exempt). Accountable for ensuring adherence to manufacturing schedule and maintaining detailed production records. Ensures that cleaning, inspection, maintenance and calibration of equipment take place on schedule and assures use of calibrated lab equipment. Develops and revises Standard Operating Procedures (SOP) and other related documentation.	BS in a related scientific discipline (such as Chemistry, Biochemistry, Biology, Microbiology or Engineering). Six years of experience in a pharmaceutical, medical device, or biotechnology environment including 3 years of experience in a supervisory role.	Knowledge of industry and company SOP, Regulatory Agencies and OSHA regulations. Technical experience working with GMP and ISO. Knowledge of investigation and computer programs. Bilingual to speak, read and write in English and Spanish.
Mgr. Mfg./ Tech Services	Directs activities of the technical services group to support manufacturing. Leads an organization to ensure quality support. Coordinates and implements manufacturing technical service activities, which include new product introductions. Manages the process of equipment characterization, trouble shooting, validation, and monitoring and data management. Interfaces with plant managers, production managers, senior process development staff to assess needs and update progress. Develops goals and objectives for the group. Provides technical guidance. Makes budget recommendation and oversees expenditures. Supervises staff, providing performance appraisals, hiring, and handling staff relation issues.	BS in biochemical or chemical engineering or related field. Master Degree or Ph.D. preferred. Nine years or more of experience in process development or manufacturing and/or technical management experience or equivalent. Five years or more of supervisory experience.	Experience managing a technical group. Ability to listen to needs, formulate into action and prioritize. Solid written and verbal communication, skills in English and Spanish.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Purification/Formulation Supervisor	Provides supervision to the Purification associates (exempt and non-exempt). Accountable for ensuring adherence to manufacturing schedule and maintaining detailed production records. Ensures that cleaning, inspection, maintenance and calibration of equipment take place on schedule and assures use of calibrated lab equipment. Develops and revises Standard Operating Procedures (SOP) and other related documentation.	BS in a related scientific discipline (such as Chemistry, Biochemistry, Biology, Microbiology or Engineering). Six years of experience in a pharmaceutical, medical device, or biotechnology environment including 3 years of experience in a supervisory role.	Knowledge of industry and company SOP, Regulatory Agencies and OSHA regulations. Technical experience working with GMP and ISO. Knowledge of investigation and computer programs. Bilingual to speak, read and write in English and Spanish.
QA Analyst / Scientist	Responsible for the analysis of the company's biochemical products. Develops, implements and maintains biochemical quality control systems. Evaluates procedures and processes to ensure products meet design specifications and established quality control requirements according to SOP and GMP.	BS in Biology, Biotechnology, Microbiology or Chemistry. Requires 4-5 years of experience.	Knowledge of 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.
Research Scientist	Focus is on designing, implementing, and directing specific scientific experiments which significantly contribute to attaining goals established by the Research Staff. Designs, implements and directs specific scientific research projects. Plans detailed procedures for defined projects, including timelines, milestones, approaches, expected results and necessary resources.	Ph.D. or equivalent in Life Sciences, Physical Sciences, or a related field. Four to six years of postdoctoral research experience.	Problem solving skills requiring the application of scientific theory; scientific analysis & troubleshooting skills; creative skills in the development of new hypotheses for scientific experiments & detailed interpretation of results; knowledge of IND's and NDA's.
Scientist	Independently evaluates, selects, and applies standard scientific techniques, procedures, and criteria using judgment in adapting standard methods and techniques. Assignments have clear and specified objectives requiring the investigation of a limited number of variables. Receives instructions on specific assignment objectives, complex features, and possible solutions. Assistance is given on unusual problems and is normally reviewed for	Performs work requiring application of knowledge of a specialized field of science acquired through a Bachelor's degree in Sciences (Biotechnology or related field) or equivalent experience plus 2-4 years of experience.	Knowledge of GMP regulations. Knowledge of SOP, investigation techniques and computer programs. May require knowledge in purification, separation, cell culture and chromatography. Protein expression and purification skills, particle analysis. Design of chromatography skids. Bilingual; to speak, read and write in English and Spanish.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
	application of sound professional judgment. May supervise or coordinate the work of the Technicians and is assisted by lower level scientists.		
Sr. Scientist	Independently evaluates, selects, and applies standard scientific techniques, procedures, and criteria using judgment in adapting standard methods and techniques. Assignments have clear and specified objectives requiring the investigation of a limited number of variables. Receives instructions on specific assignment objectives, complex features, and possible solutions. Assistance is given on unusual problems and is normally reviewed for application of sound professional judgment. May supervise a group of Scientists and/or coordinate the work of the Technicians.	Performs work requiring application of knowledge of a specialized field of science acquired through a PhD in Sciences or equivalent experience plus a minimum of 0-2 years experience or MS in Science with 8-10 years of experience.	Knowledge of GMP regulations. Knowledge of cell culture, molecular and cellular biology. Knowledge of SOP, investigation techniques and computer programs. Bilingual; to speak, read and write in English and Spanish.
Technical Operations Manager	Manufacturing batch record reviewing, maintenance coordination, documentation, production planning, training, etc. Is responsible for the organization, administration, and general supervision of the group. In addition, the incumbent is responsible for assuring that: products are manufactured within the specifications and quality claims. Provide support to assurance of timely maintenance to equipments when required, batch records review, request of Non-BOM materials and commodities, proper planning of manufacturing activities and projects, proper training of all manufacturing personnel, updates to documents such as SOP related to manufacturing activities, and garments supplies for all environmental controlled areas.	BS in Natural Sciences/Chemistry, Pharmacy or Engineering. PhD Good technical background and current knowledge of Quality Engineering principles are necessary for decision making and troubleshooting of quality incidents for corrective action development to avoid non-conformance recurrence.	Knowledge of SOP, and GMP regulations. 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
Technician	Under close supervision receives specific and detailed instructions as to required tasks and results expected. Performs a variety of routine scientific tasks, which provide experience and familiarization with the scientific staff, methods, practices, and programs. Usually assumes no responsibility for direction of others except for possible assistance in collection of data.	BS (Biotechnology, Chemistry, Biochemistry, Chemical Engineering). 0-2 years of experience.	Knowledge of SOP, and GMP regulations. Knowledge of investigation and computer programs. Bilingual; to speak, read and write in English and Spanish.



Process Development & Automation

Sr. Management		Process Development Director		
Middle Management	Process Control Automation Manager	Process Development Associate Director	Principal Engineer	
Lower Manager/ Sr. Professional	Process Control Engineer	Process Development Engineer	Senior Engineer	Engineer I
Sr. Supervisor/ Professional	Biostatistician I		Manufacturing Engineer	Engineer II
Supervisor/ Entry Professional	Biostatistician II			Engineer III
General Staff				

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Biostatistician I	Understanding and application of various statistical and programming principles, theories, and techniques to a wide range of problems that may be vaguely specified. Reviews and interprets data. Writes reports of clinical studies, including statistical sections of the BLA, IND, etc.; writes reports describing sources of data, results of statistical analyses, interpretation of data, and limitations of the data. Conducts programming for data extraction, construction of data analysis files, and statistical analyses. Collaborates with investigators and internal departments (Clinical Research, Regulatory Affairs, Clinical Data Management, etc.).	MS and/or Ph.D. degrees should be in Biostatistics, Applied Statistics, or related field. PhD preferred. Three to 4 years or more of experience (w/Master). Two years or more of experience (w/PhD). Usual years of relevant pharmaceutical experience 2 to 3 years (relevant pharmaceutical experience includes experience working at a pharmaceutical, biotechnology, or medical company, the FDA or other regulatory agency, a CRO, or an academic position with a concentration of activities related to the design, implementation, analysis, interpretation, and reporting of clinical trials.)	Good presentation skills, project management, time management standard or average statistical. Bilingual; to speak, read and write in English and Spanish.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Biostatistician II	<p>Understanding and application of various statistical and programming principles, theories, and techniques to a wide range of complex problems and has working knowledge of other related disciplines. Conducts programming for data extraction, construction of data analysis files, and statistical analyses. Makes presentations to management groups, investigator meetings, and regulatory agencies in the areas of technical information, summaries of data, and results of studies. Provides assistance and review in the preparation of abstracts, manuscripts, and material to be used for presentations. Interactions are both internal and external. May represent the Biostatistics department in providing solutions to technical issues. May interact with, oversee, or review work done by external individuals or organizations. May supervise day to day activities of department staff working on same team or project.</p>	<p>MS and/or Ph.D. degrees should be in Biostatistics, Applied Statistics, or related field. PhD preferred. Management of external technical resources 1+ year (management of external technical resources includes data management, programming, and data analysis done by consultants, and other vendors.).</p>	<p>Must have proficient communication and presentations skills. Project management skills. Statistical knowledge, study methods (data flow, design analysis, interpretation). Bilingual; to speak, read and write in English and Spanish.</p>
Engineer I	<p>Responsible to provide and/or direct the characterization of process optimization strategies and/or troubleshooting of operational issues in the operations, manufacturing, pilot plant or capital project environment. Develops, organizes, analyzes and presents interpretation of results for operational issues of engineering projects of significant scope and complexity. Completes complex or novel assignments requiring new and/or improved engineering techniques and procedures. Develops engineering policies and procedures that affect multiple organizational units. Supervises, coordinates and reviews work of a small staff of engineers, associates and/or technicians on a</p>	<p>BS in Engineering, Science or related technological field or equivalent combination of education and experience. Eight years or more of relevant work with 7 years or more in manufacturing environment. Direct experience with regulated environments (GMP, OSHA, EPA) required.</p>	<p>Ability to interpret and apply GLP and GMP. Demonstrated skills in the following areas: problem solving and applied engineering, basic technical report writing, verbal communication and comprehensive understanding of validation protocol execution requirements. Bilingual (English/Spanish).</p>

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
	<p>regular basis as well as on a project basis. Serves as a peer-recognized engineering technology specialist in at least one area, with overall responsibility for determining methodologies in that area. Application of mature engineering knowledge in planning and conducting projects.</p>		
Engineer II	<p>Responsible to provide characterization of process optimization strategies and/or troubleshooting of operational issues in operations, manufacturing, pilot plant or capital project environment. Applies advanced engineering principles to the design and implementation of system modifications, experiments and/or capital projects. Develops, organizes, analyzes and presents interpretation of results for operational issues or engineering projects of moderate scope and complexity. Independently evaluates, selects and/or modifies standard engineering techniques, procedures and criteria. Performs assignments that have loosely defined objectives that require investigation of a large number of variables. Interprets and executes policies and procedures. Recommends modifications to operating policies. Leads small group of engineers and/or technicians on an ongoing or project basis.</p>	<p>BS in Engineering, Science or related technological field or equivalent combination of education and experience. Six years or more of relevant work experience with 5 years experience in operations/manufacturing environment. Direct experience with regulated environments (GMP, OSHA, EPA) required.</p>	<p>Ability to operate specialized laboratory equipment and computers as appropriate.</p> <p>Ability to interpret and apply GLP and GMP.</p> <p>Demonstrated skills in the following areas: problem solving and applied engineering, basic technical report writing, verbal communication and comprehensive understanding of validation protocol execution requirements. Bilingual (English/Spanish).</p>

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Engineer III	Responsible to provide characterization of process optimization strategies and/or troubleshooting of operational issues in the operations, manufacturing, pilot plant or capital project environment. Applies basic Engineering principles to the design and implementation of system modifications, experiments and/or capital projects. Organizes, analyzes and presents interpretations of results for operational issues or engineering projects. Provides solutions to a variety of technical problems of moderate scope and complexity. Under general supervision, will evaluate, select and apply standard engineering techniques and procedures. Performs assignments that have clear and specific objectives and require investigation of limited number of variables. Initiate and complete routine technical tasks.	BS in Engineering, Science or related technological field or equivalent combination of education and experience. Three years or more of relevant work experience with 1 year experience in operations/manufacturing environment. Direct experience with regulated environments (GMP, OSHA, EPA) preferred.	Ability to operate specialized laboratory equipment and computers, as appropriate. Ability to interpret and apply GLP and GMP Demonstrated skills in the following areas: problem solving and applied engineering, basic technical report writing, verbal communication and comprehensive understanding of validation protocol execution requirements. Bilingual (English/Spanish).
Manufacturing Engineer	Responsible for engineering, design, specification, construction, procurement, and validation activities for biochemical manufacturing systems and equipment. 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.	BS in Engineering (Electrical, Mechanical, Industrial, Chemical). Usually has 4-5 years of biochemical engineering experience.	Knowledge of SOP and GMP regulations. Skills in Refrigeration System (HVAC), Purified and Distilled Water System, Automation-computerized control system's knowledge and PLC (Programmable Logistic Controllers). 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
Process Control / Automation Manager	Manages, directs, maintains and supports all process control computer systems equipment, improves the efficiency of the operations, solves complex systems problems, designs and implements new systems. Provides internal customers technical support and advice as needed. Develops, maintains, and updates operational procedures for systems implemented.	BS in Computer Engineering/ Electrical Engineering, or Computer Science.	Knowledge of Regulatory Agencies, OSHA, SOP and GMP regulations. Skills in Refrigeration System (HVAC), Purified and Distilled Water System, Automation-computerized control system knowledge and PLC (Programmable Logic Controllers). Knowledge of investigation and computer programs. Bilingual; to speak, read and write in English and Spanish.
Process Control Engineer	Manage, direct, maintain and support all process control computer systems equipment, layered applications, operating systems and control's network management systems including the distributed control systems, LIMS equipment, and other PLC. Provide the technical expertise and leadership to the process control systems section staff to improve the efficiency of the Operations, solve complex systems problems, design and implement new systems, manage projects and manage effectively existing network resources. Provide internal customers technical support and advice as needed. Drive and produce results following the applicable FDA, GMP, Safety, OSHA and other government regulations and laws and company policies and procedures as well. Development of a short, long range plan, including the corresponding cost estimates to support the plant operations. Incumbent will participate in the establishment of a divisional	BS in Engineering, Electrical Engineering and Computer Science.	Knowledge in FDA, GMP, Safety, OSHA and other government regulations. Technical expertise in Distributed Control Systems, PLC, Laboratory PLC, PC and peripherals infrastructure, and servers.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
	business system and a corporate network systems strategy plan. Manufacturing sites to assure the successful implementation of the systems strategy, following corporate and divisional guidelines and standards.		
Process Development Associate Director	Responsible for evaluating, improving and scaling-up manufacturing processes order to improve product yield and reduce overall costs of production. Execute small-to-medium scale production work, which may involve cell culture, fermentation, purification and/or chromatography. May research and implement new technologies to enhance operations and may assist in validation of product processes. Establishes operating policies and procedures that affect department/sites. Interprets, executes, and recommends modifications to departmental policies. Responsible for all projects assigned to their functional organization. Acts as an advisor to subordinate supervisors or staff members to meet schedules or resolve technical or operational problems. Participates in establishing and administering many centralized departmental projects. Introduces new technologies and concepts to functional area. Serves as a scientific, functional area mentor, questions assumption of project teams and participates in site projects review.	Requires a BS/MS degree in a scientific discipline or equivalent. A minimum of 5 years experience in the development and optimization of manufacturing processes is required. Ten years of experience in process development, technical services and testing pharmaceuticals and/or biological products. Experience in downstream processing (Formulation, Fill, Lyophilization Inspection and Packaging). Five years of management experience.	Works under consultative direction toward predetermined long-range goals and objectives. Acknowledged internally and externally as an emerging leader within one's field of specialization. Applies and/or advanced technical principles, theories, and concepts and contributes to the development of new principles and concepts within functional area. Serves as a scientific/functional area mentor. Knowledge of SOP and GMP regulations. Bilingual,; to speak, read and write in English and Spanish.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Process Development Director	<p>Supervises one or more of the functional areas (such as fermentation or purification) within process development with responsibility for designing and scaling-up production process from laboratory scale through pilot plant scale, and transferring production processes to the manufacturing department. Plans and implements the development of new process formulas, establishing instrument and operating equipment specifications and improving manufacturing techniques to maximize product yield and reduce manufacturing costs.</p> <p>Responsible for site projects and technical leadership for two or more functional areas or sub-groups.</p> <p>Manages one functional unit with corporate responsibilities. Establishes operating policies and procedures that affect multiple departments or sites. Interprets, executes, and recommends modifications to company-wide policies.</p> <p>Accomplishes results through mid management levels or senior scientist and engineers. Held accountable to evaluate and reject or accept recommended options as part of risk management involving projects of major significance to the pipeline.</p>	<p>Requires BS/MS in Sciences, Engineering or equivalent with 10-12 years of relevant experience. Experience with process development/scale-up and methods/process validation is required. Eight years of supervisory or managerial experience.</p>	<p>Knowledge of SOP and GMP regulations. Knowledge of investigation and computer programs. Bilingual; to speak, read and write in English and Spanish.</p>

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Process Development Engineer	Responsible for engineering, design, specification, construction, procurement, and validation activities for biochemical manufacturing systems and equipment. 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.	BS/MS in Chemical, Biochemical or Mechanical Engineering. Usually has 4-5 years of biochemical engineering experience.	Knowledge of SOP and GMP regulations. Skills in Refrigeration System (HVAC), Purified and Distilled Water System, Automation-computerized control system's knowledge and PLC (Programmable Logistic Controllers). Knowledge of investigation and computer programs. Bilingual; to speak, read and write in English and Spanish.
Principal Engineer	Manages and/or applies extensive technical expertise in the coordination of multiple, complex, non-routine projects involving the planning, design, reconfiguration, construction, maintenance and alteration of systems, facilities or processes. Applies industry-wide technical knowledge in development of novel approaches to facility, system or process engineering and design. Serves as an authority in an engineering field of major importance to the organization. Demonstrates a consistent and highly advanced level of process knowledge in more than one area of engineering. Participates with senior management in developing and establishing division, group, company, or corporate-wide policies as they pertain to engineering solutions. Orchestrates multiple projects or significant portions of projects with complex scope, schedule, quality and management objectives. Develops engineering practices that extend corporate knowledge in a business critical field. Information may form	BS in Engineering, Science or related technological field or equivalent combination of education and experience. MS degree or other graduate education is preferred. Sixteen or more years of relevant work experience with 12 or more years of experience in operations /manufacturing environment. Ten or more years of experience with regulated environments (i.e., GMP, OSHA, EPA) preferred.	Working knowledge of pharmaceutical/biotech processes. Familiarity with validation processes and documentation in a highly regulated environment. Ability to operate specialized laboratory equipment and computers as appropriate. Ability to interpret and apply GLP and GMP. Able to develop solutions to routine technical problems of limited scope. Interacts effectively with variety of communication and working styles. Ability to handle multiple projects at one time. Demonstrated skills in the schedule development, facilitation, collaboration, basic project management and completion and follow-up. Established expertise in at least 3 separate areas of engineering technology. Ability to independently determine when additional external resources are required to solve problems.

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	<p>the basis of newly developed concepts, theories and products.</p> <p>Determines program objectives and requirements.</p> <p>Organizes programs and projects. Develops standards and guidelines for diverse engineering activities. Plans, organizes and coordinates work of a large staff of Scientists, Research Associates, Engineers and Technicians. Explores and resolves unique or controversial complexities that have impact on major company programs. Participates in determining basic process development/engineering policies and devising economical ways of reaching objectives.</p> <p>Makes significant contribution to Process Development technology and/or the development of a system, facility or product.</p> <p>Reviews and evaluates technical work.</p>		
<p>Senior Engineer</p>	<p>Manages and/or applies extensive technical expertise in the coordination of multiple, complex, non-routine projects involving the planning, design reconfiguration, construction, maintenance and alteration of system facilities of processes. Responsible for establishing engineering policies for a major segment of the company. Interprets, executes, and recommends modifications to company-wide policies. Develops organizational budgets or project budgets encompassing all disciplines for large or complex projects. Applies advanced technical principles, theories, and concepts in the development of new principles and concepts. Performs work that involves in-</p>	<p>BS in Engineering, Science or related technological field or equivalent. Twelve or more years of work experience with 9 or more years of experience in operation/manufacturing environment. Direct experience with regulated environments (GMP, OSHA, EPA) required.</p>	<p>Working knowledge of pharmaceutical/biotech processes. Familiarity with validation processes, documentation in a highly regulated environment.</p> <p>Ability to operate specialized laboratory equipment and computers as appropriate.</p> <p>Ability to interpret and apply GLP and GMP. Ability to apply engineering science to production. Able to develop solutions to routine technical problems of limited scope. Comprehensive understanding of validation protocol execution requirements.</p> <p>Management of contractors and vendors.</p>

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
	depth investigation of subject area, definition of scope, selection of areas of investigation, and development of novel concepts. Plans, organizes and coordinates work of a staff of engineers and/or technicians. Leads efforts with research, manufacturing, process development, utilities, facilities, quality assurance and validation departments in developing requirements and recommendations for large and/or highly complex system/facility or process modifications.		



Manufacturing

Sr. Management

Head of Manufacturing

Middle Management

Manufacturing Manager

Lower Manager/
Sr. Professional

Manufacturing Supervisor

Sr. Supervisor/
Professional

Supervisor/
Entry Professional

Manufacturing Associate

General Staff

Cleaning Specialist

Manufacturing Operator

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Cleaning Specialist	Responsible of sanitizing the aseptic areas of manufacturing and warehouse, following the procedures established according to the applicable regulations (CGMP, OSHA, etc.)	High School Diploma.	Knowledge of SOP and GMP regulations. Knowledge of investigation and computer programs. Bilingual; to speak, read and write in English and Spanish.
Manufacturing Associate	Performs some or all of the following in strict accordance with SOP: fermentation, protein purification, solvents extractions, tissue culture, preparation of bulk solutions, non-critical aseptic fills or buffers, filling and labeling of vials under sterile and non-sterile conditions, large scale bioreactor operations, critical small or large volume sterile fills, aseptic manipulation of cell cultures. Operates with minimal supervision complex systems and equipment and optimizes their use in manufacturing in accordance with defined goals. Troubleshoots processing problems, bringing unusual problems (i.e., potential deviations) to the attention of the supervisor.	Requires an AS or equivalent with 4-8 years of related work experience or BS in Science (Biotechnology, Biology, Microbiology, Chemistry, Biochemistry and Chemical Engineering) with a minimum of 2-4 years of experience. Detailed knowledge of purification systems and familiarity with regulatory and SOP is required. Buffer and media preparation experience.	Technical experience working with GMP. Knowledge of SOP, investigation and computer programs. Bilingual; to speak, read and write in English and Spanish. Have skills in cell culture, purification, liquid chromatography and fermentation. Experience with laboratory equipment, aseptic techniques, and aseptic filtration and room classifications. Troubleshooting skills. Technical writing techniques.

Job Title	Role Description	Education/Experience	Technical Skills/Requirements
Manufacturing Manager	Administration, direction, controlling, and organization of the Manufacturing areas. Responsible for the Plant throughput, product quality, and efficiency optimization. Maintains a consistent production, keeping the manufacturing variances and the cost reduction plans within the established goals. Establishes short and long range plans for effective capital utilization. Assures full compliance with required government regulations. Prepares and controls the manufacturing department budget. Assures proper technical support and productivity increase in the manufacturing processes. Provides the necessary organization in order to achieve the overall department expectations and objectives, the Plant financial goals and supports the division sales plan.	BS in Engineering or Science. Requires 8-10 years of related experience.	Knowledge of SOP and GMP regulations. Knowledge of investigation and computer programs. Bilingual; to speak, read and write in English and Spanish.
Manufacturing Operator	Responsible for assisting manufacturing in specific product-related operations (cell culture/fermentation). Operates and maintains production equipment related to cell culture/fermentation (i.e., fermenters, bioreactors, cell harvests, others). May also assist manufacturing in production process purification and manufacturing of final products. Weighs, measures and checks raw materials to assure proper ingredients and quantities. Prepares media and buffer components. Maintains records to comply with regulatory requirements and assists with in-process testing.	Associate degree or equivalent experience, 0-2 years of experience in a manufacturing environment. A senior level position requires BS in biology or related life science and 1-4 years of working experience.	Knowledge of SOP and GMP regulations. 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
Manufacturing Supervisor	Supervises the transference of cell culture/fermentation methods from research and development to manufacturing. Supervises and maintains purification production methods, processes and operations for new or existing products. Implements and maintains production schedules and manpower requirement. Provides general supervision over a work group, assigning tasks and checking work at regular intervals. Other key responsibilities may include interacting with outside vendors and departments, scheduling validation activities, training operators and writing/approving maintenance work requests, engineering and facility change requests and purchase requisitions.	Requires a BS or equivalent with a minimum of 3-5 years of experience in all aspects of the manufacturing process in a pharmaceutical or biotechnology environment. Working knowledge of cell culture, aseptic and scale-up operations in accordance with GMP is required.	Knowledge of SOP and GMP regulations. Knowledge of investigation and computer programs. Bilingual; to speak, read and write in English and Spanish.