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## **Biotechnology Job Catalog**

Pharmaceutical Industry Association

2006 Edition

## About This Material

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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



## 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

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
<b>Biologic Operator</b>	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.
<b>Cell Culture Scientist</b>	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.
<b>Mgr. Mfg./ Tech Services</b>	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.

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
<b>Purification/Formulation Supervisor</b>	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.
<b>QA Analyst / Scientist</b>	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.
<b>Research Scientist</b>	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.
<b>Scientist</b>	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.

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
	application of sound professional judgment. May supervise or coordinate the work of the Technicians and is assisted by lower level scientists.		
<b>Sr. Scientist</b>	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.
<b>Technical Operations Manager</b>	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.

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
<b>Technician</b>	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.