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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



# 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				

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

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
<b>Biostatistician II</b>	<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>
<b>Engineer I</b>	<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>

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
	<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>		
<b>Engineer II</b>	<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>

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
<b>Engineer III</b>	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).
<b>Manufacturing Engineer</b>	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.

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
<b>Process Control / Automation Manager</b>	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.
<b>Process Control Engineer</b>	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
	<p>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.</p>		
<p><b>Process Development Associate Director</b></p>	<p>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.</p>	<p>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.</p> <p>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.</p>	<p>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.</p>

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
<b>Process Development Director</b>	<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>

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
<b>Process Development Engineer</b>	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.
<b>Principal Engineer</b>	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.

<b>Job Title</b>	<b>Role Description</b>	<b>Education/Experience</b>	<b>Technical Skills/Requirements</b>
	<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>		
<b>Senior Engineer</b>	<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>

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

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