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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



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.