

Bio-pharmaceutical Industry Human Capital Infrastructure

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Life Science Career Alliance

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Introduction

As part of an industry partnership initiative funded by a grant from the Pennsylvania Department of Labor & Industry, the Life Science Career Alliance (LSCA) began the process of documenting career pathways in the bio-pharmaceutical industry. The LSCA, a workforce development organization dedicated to the life sciences and located in one of the nation's bio-pharmaceutical hubs, worked directly with the Pennsylvania Biotechnology Association (PABio). Together, the two organizations were able to create an industry partnership comprised of PABio member bio-pharmaceutical firms in the region. The partnership also included stakeholders from other organizations such as research institutes, educational institutions, and regional economic development organizations. With this partnership in place, the LSCA was able to draw upon the knowledge of experts at major biotechnology and pharmaceutical firms as well as professionals at smaller start-up firms to create industry-driven documentation of the bio-pharmaceutical human capital infrastructure. The documentation undertaken by the LSCA and the industry partnership was conducted in four stages:

- Research national models of workforce development in bio-pharmaceuticals
- Research key positions and job progressions in the bio-pharmaceutical industry
- Verify job progression with industry experts
- Finalize documentation of career ladders

During the initial research phase, the LSCA, working with the Council for Adult and Experiential Learning (CAEL), gathered information on national bio-pharmaceutical workforce development initiatives that promote skills enhancement and career advancement. At the same time, they researched key positions and job progressions in the bio-pharmaceutical industry. Position descriptions and prerequisite education and experience information for each position were gathered from documentation published by the U.S. Department of Labor as well as from biotechnology industry groups such as the Massachusetts Biotechnology Council, Bio-Link, and workforce development agencies including the San Diego Workforce Partnership. This information was shared with industry experts within the Southeastern Pennsylvania regional bio-

pharmaceutical partnership who customized position information and salary data to specifically reflect the state of the industry in this region.

Though previous documentation efforts undertaken by other industry groups had documented bio-pharmaceutical jobs, the young, rapidly changing bio-pharmaceutical industry did not have well-established, industry-wide career ladders. The work of the LSCA, PABio, and the regional bio-pharmaceutical partnership was unique in its goal of documenting opportunities for advancement and lateral movement between positions. The career ladders presented in the Bio-Pharmaceutical Industry Human Capital Infrastructure emerged from extensive discussion with industry professionals and reflect both the hiring practices of bio-pharmaceutical firms and the career progression of workers throughout the industry. To better illustrate this progression between jobs, positions are organized by bio-pharmaceutical job families.

The career ladders that resulted from this documentation process were then submitted to a broad panel of industry experts for verification and validation. Feedback from representatives of more than thirteen biotechnology and pharmaceutical firms was used to refine the career ladders to ensure that they accurately represented the jobs at the intersection of these two key industries. In addition, the career ladder for each job family was reviewed by an expert working in that area.

While this document presents a picture of the industry as a whole, there will be variations from company to company in the number of positions within a job family, prerequisite training and experience, and exact salary depending on the size, stage of development and area of focus of the organization. It is important to note that salaries in the bio-pharmaceutical industry are market-driven, and annual salaries recorded in this document reflect only a portion of the total compensation that an employee might receive. Annual bonuses, stock options, profit-sharing, insurance benefits, and other forms of compensation may complete the incentive package.

Bio-pharmaceutical Career Ladders

Discovery Research Job Family				
Workers in the discovery research area in bio-pharmaceutical firms seek to identify and/or create biologically active molecules and compounds that have therapeutic value. Once a promising compound has been identified as having therapeutic potential, workers in discovery research subject the compound to extensive testing to determine its mechanism of action and assess its safety for human testing. Discovery researchers also develop a dosage form of the compound.				
Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Laboratory Assistant	A	Performs research laboratory tasks and experiments under the supervision of other laboratory staff; makes and records detailed observations, analyzes data and interprets results, maintains laboratory equipment, performs inventory	High school diploma/equivalent, preferably biotechnology certificate or A.S. and 1-2 years related laboratory experience	\$24,000-\$33,000
Research Assistant	B	Performs laboratory experiments and tests in accordance with Good Laboratory Practice; works under the supervision of the Research Associate; makes detailed observations, analyzes data and interprets results	B.S./equivalent	\$30,000-\$48,000
Research Associate	C	Collaborates with co-workers on research and development; makes detailed observations, analyzes data, interprets results; prepares technical reports, summaries, protocols and quantitative analyses; maintains familiarity with current scientific literature; investigates and creates new methods and technologies for project advancement; may act as principle investigator; contributes to journals or participates in conferences	B.S. and 2-5 years related laboratory experience or M.S. and 0-2 years experience	\$35,000-\$60,000
At this point in the career progression within the Discovery Research Job Family, professionals could transition to a supervisory pathway. Positions in this track can be found at the end of this document.				
Senior Research Associate	D	Performs research and develops experiments for projects in collaboration with others; uses professional concepts in accordance with company objectives to solve complex problems in creative ways; exercises technical discretion in design, execution and interpretation of experiments contributing to project goals; contributes to project progress through innovative research; prepares technical reports	B.S. in related scientific discipline and 5-8 years related laboratory experience or M.S. and 2-5 years experience	\$45,000-\$75,000
Principal Research Associate	E	Performs all duties of Senior Research Associate as well as designing and conducting own experiments; has expert understanding of and ability to apply principles, theories and concepts in specialized area of responsibility; has working knowledge of related disciplines; maintains familiarity with current literature; leads team/department and acts as main problem solver for team	B.S./M.S. and 5-8 years related laboratory experience or M.S. and 2-5 years experience and demonstrated working knowledge of scientific principles	\$60,000-\$80,000
Scientist I	F	Works within a team to initiate, design, develop, and execute scientific research projects; possesses potential for technical proficiency, scientific creativity, collaborative work, and independent thought	Ph.D. in scientific discipline and 0-2 years experience or M.S. and 8-10 years experience in research environment	\$80,000-\$100,000
Scientist II	G	Collaborates with others to initiate, design, develop, and execute scientific research projects critical to corporate strategies and image; serves as in-house and outside consultant; contributes to scientific literature and conferences	Ph.D. in scientific discipline and 2-5 years experience or M.S. and 8-10 years experience in research environment	\$85,000-\$105,000

Discovery Research Job Family *(continued)*

Senior Scientist	H	Initiates, directs, and executes scientific research and development critical to corporate strategies and image; investigates potential applications of scientific concepts to inventions, projects, and problems; plans and executes laboratory research; maintains knowledge of state-of-the-art scientific developments; makes significant contributions to scientific literature and body of knowledge; participates in conferences	Ph.D. in scientific discipline and 5-10 years experience or M.S. and 8-10 years experience in research environment with expert understanding of scientific principles and concepts	\$90,000-\$110,000
Chief Scientific Officer	I	Responsible for the identification, development, evaluation, and/or implementation of new technologies and products that support business goals; advances the discovery, development or maintenance of significant new compounds; recommends and defends the termination of candidates in a way that supports business goals; identifies, defines, solves and/or prevents problems of a broad scope and high complexity. Must be recognized internationally as an expert in the field and have proven ability to interface with external parties internationally in a way that generates value for the company	M.D. or Ph.D. and 15+ years of scientific experience	\$150,000-\$200,000

Clinical Development Job Family

Once discovery researchers have determined that a compound may have potential as a drug and they have received approval from the Food and Drug Administration to begin testing the compound, the clinical development area of a firm begins clinical testing involving human subjects. Several distinct stages of clinical testing must be conducted beginning with small groups of healthy patients and ultimately testing the drug in groups of several thousand patients with varying degrees of the disease treated by the drug. During these trials, workers document toxicity, any adverse affects, modify dosage, monitor blood levels, determine compatibility with other medications, and determine the drug's effectiveness in treating the disease or condition. Data gathered during clinical trials is used to determine whether a drug can go to market.

Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Clinical Document Assistant	A	Works with the Document Management System with clinical development, including creation, authorship, electronic publication, review, approval, and distribution of documents; acts as liaison between clinical development and regulatory affairs in the planning and publication of submitted documents	High school diploma/equivalent, preferably biotechnology certificate or A.S. and 1-2 years related lab experience	\$24,000-\$33,000
Clinical Data Associate	C	Ensures the validity of clinical trials, formats trials for statistical purposes; responsible for setting-up databases, tracking and managing data from all clinical trial sites; works with supervisors to establish procedures for data review and entry, and assists in the review of data	B.S. and 1-3 years clinical data management experience; database management experience is helpful	\$35,000-\$60,000
At this point in the career progression within the Clinical Development Job Family, professionals could transition to a supervisory pathway. Positions in this track can be found at the end of this document.				
Biostatistics Associate	F	Provides statistical support for clinical, pre-clinical, and other designated projects within clinical development; provides accurate data to obtain timely regulatory agency approval of products	B.S. and 10 years experience or M.S. and 5-7 years experience or Ph.D. and 2 years experience	\$80,000-\$100,000

Clinical Development Job Family <i>(continued)</i>				
Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Clinical Research Associate	F	Responsible for ensuring proper study conduct at assigned sites including the collection and validation of generated data; responsible for contribution to a clean data set	B.S. and 6-8 years experience or M.S. and 5-7 years experience or R.N. and 5-7 years experience or Pharm.D. and years experience Ph.D. and 2 years experience	\$80,000-\$100,000
Medical Writer	F	Ensures high quality and timely production of all clinical documents; responsible for confirming that documented information complies with all internal and external standards	B.S. and 10 years experience or M.S. and 5-7 years experience or Ph.D. and 2 years experience	\$80,000-\$100,000
Bioinformatics Scientist	G	Develops algorithms for integrating functional knowledge about genes to help scientists analyze and interpret gene expression data; assists in developing software to automate data retrieval and analysis; works with scientists across organization to develop statistical methods for gene analysis	M.S. or Ph.D. in bioinformatics, statistics, biochemistry, computational chemistry or related field and 1-4 years industry experience	\$85,000-\$105,000
Senior Clinical Research Associate	G	Serves as an in-house expert and resource in clinical study monitoring for all clinical trials; responsible for mentoring junior Clinical Research Associates and leading all Clinical Research Associates in maintaining consistent monitoring across all clinical research sites; works with protocol development scientists to develop protocols, site instruction manuals, and case report forms	B.S. and/or R.N. and 8-12 years experience including clinical research experience and extensive experience working in a FDA regulated environment	\$85,000-\$105,000
Senior Medical Writer	G	Provides broad medical writing support for multiple simultaneous projects; responsible for overseeing writing and editing of all clinical regulatory documents including clinical study reports, protocols, investigator's brochures, briefing documents, Investigational New Drug applications, and clinical summary sections of Common Technical Documents/New Drug Applications; responsible for all stages of document production from review and revision to approval and publishing; collaborates closely with physicians, biostatisticians, clinical and regulatory affairs personnel in accordance with company Standard Operating Procedures and regulatory requirements	B.S., M.S. or Ph.D. and minimum of 3-5 years experience as a medical writer	\$85,000-\$105,000
Protocol Development Scientist	G	Responsible for the writing of protocols, case report forms and consent forms for clinical trials; develops the design of, implements and monitors clinical trials; responsible for preparation of medical reports, Investigational Device Exemptions, New Drug Applications and license applications	B.S., M.S., R.N., or Pharm.D. and 5-8 years experience	\$85,000-\$105,000
Senior Protocol Development Scientist	H	Supervises the design and writing of protocol, case report forms, and consent forms for clinical trials; directs the design, implementation, and monitoring of clinical trials; responsible for preparation of medical reports, Investigational Device Exemptions, New Drug Applications and license applications; ensures that Good Clinical Practices are followed in all trial activities and monitors all phases of clinical trial studies	M.S., R.N., or Pharm.D. and 10-12 years industry experience including extensive experience in clinical trials	\$90,000-\$110,000
Medical Expert	H	Serves as clinical project leader providing clinical expertise in area specific to clinical trials; responsible for decisions concerning monitoring safety, eligibility, enrollment, and data consistency; prepares project-specific training programs and training materials for all clinical research staff	M.D. or M.D./Ph.D. and 3-5 years experience in clinical medicine as well as previous industry clinical research experience	\$90,000-\$110,000

Clinical Development Job Family <i>(continued)</i>				
Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Senior Medical Expert	J	Acts as medical and safety consultant to Clinical Development team in specific medical area relevant to clinical development activities; serves as medical consultant to marketing team and regulatory agencies when requested; provides oversight of clinical trials for company products under development	M.D. or M.D./Ph.D. and 7-10 years clinical experience in a specific therapeutic area; board certification in area of medical specialty	\$180,000-\$220,000
Director of Clinical Research/Development	I	Responsible for all aspects of clinical research programs including planning, implementation, coordination and completion of research project according to Food and Drug Administration regulations, internal policies and procedures, and within the bounds of good scientific and ethical conduct; assures that all pre-clinical and clinical studies are conducted according to protocol and that data reported is accurate and acceptable to internal and external audits; assures that proper statistical analyses are performed; responsible for medical writing; supports medical reports, registration dossiers, and manuscripts	M.D. or M.D./Ph.D. and 10-15 years experience in a specific therapeutic area or across multiple therapeutic areas; board certification in one area of medical specialty	\$150,000-\$200,000
Director of Medical Affairs	I	Provides both ethical and consumer medical support services for marketed products including prompt, factual, concise and pertinent responses to product inquiries from lay and professional sources both inside and outside the company; promptly reports all adverse experiences with products to designated personnel for proper processing in accordance with Good Manufacturing Practice and Food and Drug Administration regulations and maintains documentation of same to protect corporate liability; collaborates with sales and marketing personnel in the development of promotional and educational materials; reviews and approves medical and technical content in marketing materials; provides medical lecture content for initial and advanced sales training programs; provides input and appropriate modifications to product labeling and package inserts; reviews and approves protocols and case report forms for Phase IV clinical trails and all subsequent publications	M.D. or M.D./Ph.D. and 10-15 years industry experience in medical affairs; experience spanning multiple therapeutic areas	\$150,000-\$200,000



Regulatory Job Family				
<p>Every stage of the drug and therapeutic product development process is highly regulated. The regulatory affairs department in bio-pharmaceutical firms acts as the link between the company and agencies such as the Food and Drug Administration. Workers in the regulatory affairs area apply an understanding of the chemistry of drug behavior and knowledge of the regulatory requirements to the preparation and submission of all required paperwork during the process of drug development and testing to ensure that a firm complies with all Food and Drug Administration requirements.</p>				
Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Documentation Specialist	C	Coordinates all activities related to providing required documentation and implementing documentation systems; coordinates review and revision of procedures, specifications, and forms	B.S. in related field/equivalent and 2-4 years related experience in documentation, quality assurance.	\$35,000-\$60,000
Regulatory Affairs Associate	D	Ensures that company products meet regulatory requirements; coordinates and prepares document packages for submission to regulatory agencies, internal audits and inspections	B.S./M.S. and 2-4 years experience in research and development and 0-4 years experience in regulatory affairs	\$45,000-\$75,000
Labeling Associate	D	Labels products; acts as liaison between domestic and international regulatory authorities regarding labeling issues; works on design and development of labeling policies and practices	B.S./M.S. and 2-4 years experience in research and development and 0-4 years experience in regulatory affairs	\$45,000-\$75,000
Dossier Management Associate	D	Responsible for dossier management priorities, workflow, and resources to meet regulatory submission target dates for both electronic and paper submissions	B.S./M.S., 2-4 years experience in research and development and 0-4 years experience in regulatory affairs	\$45,000-\$75,000
Senior Regulatory Affairs Associate	E	Responsible for maintaining current regulatory knowledge and awareness of changes in regulatory procedures; provides guidance to regulatory team staff and oversees the development and submission of documents to regulatory agencies	B.S./M.S. and 5-8 years experience in regulatory affairs	\$60,000-\$80,000
<p>At this point in the career progression within the Research Job Family, professionals could transition to a supervisory pathway. Positions in this track can be found at the end of this document.</p>				
Manager Regulatory Affairs	F	Manages the integrated development process by coordinating project team activities, installing and monitoring project planning functions, and reporting to management; assists in the development of regulatory strategies for projects to ensure multinational registrations consistent with strategic objectives and world-wide regulatory requirements	B.S./M.S. in scientific discipline and 5-7 years experience	\$80,000-\$100,000
Director of Regulatory Affairs	I	Plans and directs long and short-term regulatory activities; develops and implements strategies for approval of regulatory submission; negotiates with outside agencies to resolve regulatory issues; stays current with changes in regulatory requirements	B.S./M.S. in scientific discipline with Ph.D. preferred and 10 years experience	\$150,000-\$200,000

Quality Job Family

As a bio-pharmaceutical firm manufactures a product, it is essential that it has a system for determining that the manufacturing process is progressing as it should. Professionals within the quality job family work to develop in-house standards that comply with regulatory requirements. They conduct audits, testing product composition, environmental conditions, and the functionality of equipment to ensure that all components of the manufacturing process are performing in compliance with established standards.

Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Quality Assurance Documentation Administrator	B	Provides clerical and administrative support related to documentation system maintenance; audits documentation to ensure accuracy; maintains filing of Quality Control documentation	High school diploma or Biotech Certificate or A.S./equivalent and 2-4 years experience, preferably in documentation or quality control/quality assurance; must be familiar with industry regulatory requirements and Good Laboratory/Manufacturing Practice	\$30,000-\$48,000
Quality Control Technician	B	Performs inspections, checks, tests and sampling procedures according to Standard Operating Procedures; performs in-process inspection and documents results	High school diploma or biotech certificate or A.S./equivalent and 0-5 years experience in quality assurance; must be familiar with industry regulatory requirements and Good Laboratory/Manufacturing Practice	\$30,000-\$48,000
Quality Assurance Documentation Specialist	C	Coordinates all documentation and documentation systems; coordinates review and revision of procedures, specifications and forms	B.S./M.S. in related field and 2-5 years experience in Good Manufacturing Practice documentation, and quality assurance	\$35,000-\$60,000
Quality Control Analyst	C	Conducts analysis of raw materials, in-process samples and finished formulations according to Standard Operating Procedures; calibrates and maintains chemistry and microbiology lab equipment; compiles and analyzes data for test procedure documentation	B.S. in scientific discipline/equivalent and 0-4 years experience in quality control systems; must be familiar with industry regulatory requirements and Good Laboratory/Manufacturing Practice	\$35,000-\$60,000
Validation Specialist	C	Develops, installs, and revises test validation protocols to ensure that manufacturing practices meet in-house, industry and federal standards; compiles and analyzes validation data; prepares reports and recommends improvements	B.S. in scientific, engineering, or related technical field and 3 years experience in a regulated industry; knowledge of current industry practices, and current Good Manufacturing Practice	\$35,000-\$60,000
Quality Assurance Manager	D	Assures that products, processes, facilities and systems conform to quality standards and governmental regulations; performs audits of raw materials; reviews and approves Standard Operating Procedures; develops budgets and monitors expenditures	B.S. in biological science and 3-5 years experience in quality control/quality assurance; must be familiar with industry regulatory requirements and Good Laboratory/Manufacturing Practice	\$45,000-\$75,000
Quality Control Engineer/Supervisor	D	Develops, applies, revises, and maintains quality standards for processing materials into products; designs and implements inspection, testing, and evaluation procedures; prepares documentation for inspection testing procedures	B.S./M.S. in related discipline/equivalent and 3-5 years experience with documentation and implementation of quality control systems	\$45,000-\$75,000
Validation Manager	D	Manages, develops and implements validation protocols and test procedures; ensures that products meet regulatory requirements, company standards and industry current practices; oversees and reviews validation area processes and procedures	B.S./M.S. in scientific discipline and 5-7 years experience in Good Laboratory/Manufacturing Practice environment and industry regulatory requirements	\$45,000-\$75,000

Quality Job Family <i>(continued)</i>				
Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Director of Quality	I	Responsible for short and long term goals of quality control; formulates and recommends quality assurance policies and programs; develops quality control and quality assurance budgets; directs quality control staff and daily operations, manages Good Manufacturing Practice program; establishes and directs Good Manufacturing Practice training; assures that finished products comply with government and company standards	B.S. or M.S. in chemistry or equivalent science, Ph.D. preferred and 6-10+ years experience in chemistry, quality control and/or laboratory management positions with experience in Good Manufacturing Practice/Good Laboratory Practice and full understanding of industry regulatory requirements	\$150,000-\$200,000



Product/Process Development Job Family

Once scientists have identified a potential new drug a bio-pharmaceutical firm must develop a process for the manufacture of quantities large enough to use in clinical trials. Workers in product and process development jobs seek ways to scale-up a potential product and improve the efficiency of its manufacturing process.

Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Process Development Operator	A	Implements production procedures to optimize manufacturing processes and meet regulatory requirements; may be involved in packaging and distribution and/or maintenance of production equipment	A.S. in scientific discipline and 2-5 years of experience in industry or B.S. in scientific discipline/ equivalent and 0-2 years experience	\$24,000-\$33,000
Process Development Technician	B	Contributes to commercial-scale manufacture of active pharmaceutical ingredient: handles raw materials, maintains batch records, operates and maintains production and separation equipment; works within structure of Good Manufacturing Practice and Standard Operating Procedures	B.S./equivalent in engineering or related discipline and 2-5 years experience	\$30,000-\$48,000
Process Development Associate	C	Evaluates, improves, and scales-up manufacturing processes to improve product yield and reduce costs; executes small-medium scale production work. Tasks may involve cell culture, fermentation, purification, and/or chromatography; carries out designated tasks under the direction of the Process Development Supervisor but operates with a degree of scientific independence	B.S./M.S. in a scientific discipline/ equivalent and 0-5 years experience	\$35,000-\$60,000
Process Development Scientist	F	Works within team to initiate, design, develop, and execute scale-up production processes; exercises significant degree of scientific independence	Ph.D. in scientific discipline and 0-2 years experience or M.S. and 8-10 years experience in research environment	\$80,000-\$100,000
Process Development Supervisor	G	Supervises one functional area within process development (such as fermentation or purification) with responsibility for initiating and directing design and scale-up production processes from lab scale through pilot plant scale; assists in technology transfer to manufacturing department; responsible for development and implementation of new process formulas; acts as liaison with both research and manufacturing	Ph.D. in scientific discipline and 5-8+ years experience implementing scale-up processes	\$85,000-\$105,000
Director of Product/ Process Development	I	Directs all stages of product and process development for new products and technologies from laboratory through pilot plant and manufacturing scale including managing development, implementation, and maintenance of process methods and equipment for the production of process formulas, technologies, and products; oversees production schedules and recommends manufacturing policies	Ph.D. in biochemical engineering, chemistry, microbiology or related area and 7-10 years experience in product development or B.S./M.S. with 12+ years experience in product development. Experience working with current Good Manufacturing Practice, Good Laboratory Practice, process development, and scale-up preferred	\$150,000-\$200,000

Manufacturing Job Family				
<p>For most bio-pharmaceutical firms, the manufacturing of a new product is a step that occurs late in the process which begins with identification of a compound that could be clinically useful and proceeds through lengthy clinical testing of that compound and intensive review of both the process of developing the compound and the clinical trial by the Food and Drug Administration. If a product is to be distributed commercially following approval, the firm must have a large supply of the new product ready to meet demand. Workers in the manufacturing job family use the processes developed by product and process development workers to produce large batches of the desired product.</p>				
Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Material Handler	A	Collects and distributes materials between departments and shipping department; wraps and protects materials for safe transport; loads and unloads materials from freight vehicles, stacks items in inventory, operates forklift, lifts heavy loads	High school diploma/equivalent, valid driver's license and 0-2 years related experience	\$24,000-\$33,000
Packaging Technician	A	Uses manual/automated packaging systems to label, inspect and package finished product; performs data entry, complies with Good Manufacturing Practice, Standard Operating Procedures	High school diploma/equivalent and 0-2 years related experience	\$24,000-\$33,000
Aseptic Fill Technician	B	Responsible for preparing the finished product from the purified active pharmaceutical ingredient; operates and maintains equipment; maintains records; complies with Good Manufacturing Practice and Standard Operating Procedures	A.S. or biomanufacturing certificate/ equivalent and 0-2 years experience	\$30,000-\$48,000
Manufacturing Technician	B	Assists manufacturing staff in specific product-related operations; operates and maintains production equipment; assists in manufacturing production-scale product; prepares glassware, reagents, and media; maintains records required by Good Manufacturing Practice; assists with in-process testing	High school diploma or biomanufacturing certificate or A.S./equivalent and 0-2 years experience in manufacturing environment	\$30,000-\$48,000
Purchasing Agent/Buyer	B	Plans, organizes, directs and controls purchasing actions for production and non-production related goods; maintains knowledge of and relationships with vendors; advises management on purchasing alternatives to assure continued flow of materials to meet production requirements	B.S. in business, materials management or related field and 3 years experience in purchasing/ materials environment	\$30,000-\$48,000
Assay Analyst	C	Follows Standard Operating Procedures to perform assays on in-process and final product test samples; participates in modification of assay procedures	A.S. degree and 2 years experience in biomanufacturing or B.S. degree in scientific discipline	\$35,000-\$60,000
Aseptic Fill Research Associate	C	Implements production procedures to optimize aseptic fill manufacturing processes; assists in development of processes to improve yield or reduce cost for aseptic manufacturing systems	A.S. and 4-7 years related work experience or B.S. in biology or related science and 2-3 years experience	\$35,000-\$60,000
Manufacturing Associate	C	Performs complex tasks under general guidance and in accordance with current Good Manufacturing Practice; participates in integration of new technology into the manufacturing process and the initiation of new manufacturing areas; operates within Standard Operating Procedures; with minimal supervision operates complex systems and equipment, and optimizes their use in manufacturing	A.S. and 4-7 years related work experience or B.S. in biology or related science and 2-3 years experience	\$35,000-\$60,000

Manufacturing Job Family <i>(continued)</i>				
Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Manufacturing Instrumentation/ Calibration Associate	C	Performs maintenance, testing, troubleshooting, calibration and repairs on analytical equipment and instrumentation; performs validation studies and analyzes results; maintains spare parts inventory	A.S. and 4-7 years related work experience or B.S. in Biology or related science and 2-3 years experience	\$35,000-\$60,000
Aseptic Fill Supervisor	D	Oversees aseptic filling procedures, ensures that they are in accordance with Good Manufacturing Practice, Good Laboratory Practice, and Standard Operating Procedures; responsible for equipment preparation and sterilization, and sanitation of aseptic filling rooms; manages work group; reviews and processes batch records	B.S. in Biology, Chemistry or related area and 3-5 years supervisory experience in pharmaceutical environment	\$45,000-\$75,000
Manufacturing Supervisor	D	Supervises the transfer 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; provides guidance to employees to ensure that operations meet Good Manufacturing Practice	B.S. and 3-5 years experience working knowledge of cell culture, aseptic techniques, and scale-up operations in accordance with current Good Manufacturing Practice	\$45,000-\$75,000
Biochemical Development Engineer	E	Responsible for design and scale-up of processes, instruments and equipment from laboratory through pilot plant and manufacturing process; develops new process formulas and techniques	B.S. in biological, chemical or pharmaceutical engineering and 0-2 years experience in pharmaceutical process/research product development; must have strong problem-solving skills	\$60,000-\$80,000
Director of Manufacturing	I	Responsible for the development, implementation, and support of manufacturing business systems including clinical and commercial production activities; ensures plans and resources are efficiently utilized to ensure uninterrupted supply of company products; oversees hiring, development and retention of manufacturing staff; develops operating plans and budgets as well as working relationships with internal and external partners	B.S. in sciences, M.S. preferred and 10+ years experience in all aspects of manufacturing, processing in pharmaceutical/biotechnology environment; previous management or project experience, knowledge of Good Manufacturing Practice, Good Laboratory Practice	\$150,000-\$200,000



Facilities Job Family				
<p>Facilities departments at bio-pharmaceutical firms are responsible for the design and maintenance of all laboratory, manufacturing, and administrative facilities operated by the firm as well as the upkeep of key pieces of equipment. Facilities staff must work with Quality Assurance staff to apply Good Laboratory Practice and/or Good Manufacturing Practice regulations to the operations of the firm as well as ensuring that the physical plant and equipment remain in compliance with those regulations. Facilities staff is also responsible for the maintenance of the heating, ventilating and air-conditioning (HVAC) systems, water systems, and critical and non-critical utilities as well as for the development of emergency procedures for the company.</p>				
Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Facilities Technician	A	Performs daily monitoring, repair and maintenance of critical systems and facility equipment; installs and modernizes new and existing systems; documents repairs, adjustments, and replacements to equipment; provides input and corrections to Standard Operating Procedures	A.A./A.S. or certificate of completion from 2-year technical program in mechanical/electrical field	\$24,000-\$33,000
Instrumentation/ Calibration Technician	C	Maintains, tests, troubleshoots, repairs, and validates circuits, components, analytical equipment and instrumentation; monitors equipment performance and status on an ongoing basis and makes adjustments as necessary; documents calibration as well as deviations from equipment specifications	B.S./equivalent in electronics technology with knowledge of mechanics and instrumentation and minimum of 2-4 years experience in instrumentation problem diagnosis and repair and experience working in a Good Manufacturing Practice environment	\$35,000-\$60,000
Facilities Manager	D	Manages design, planning, construction and maintenance of equipment, machinery, and buildings; ensures that facility meets health and safety standards; plans, budgets, and oversees facility repairs and modifications; oversees the coordination of building space allocation and layout, communication services, and facilities expansion	B.S./equivalent and 5 years experience in maintenance knowledge of building codes	\$45,000-\$75,000



Supervisory Pathway

Within each job family, workers may have the opportunity to progress along a career ladder. Within certain job families this progression may provide the opportunity for a professional to choose to continue along a progression of scientific jobs or to follow a supervisory pathway. The descriptions below refer to a general supervisory pathway which may be applicable to any of the job families.

Position	Level	Description	Prerequisite Education and Experience	Typical Salary Range*
Supervisor	D	Responsible for the day-to-day supervision of a group of employees within a specific unit	B.S. and 3-5 years experience	\$45,000-\$75,000
Manager	F	Responsible for planning and coordinating the work of at least one supervised unit; has hiring/firing as well as budgetary monitoring responsibilities	B.S. and 5-8 years experience	\$80,000-\$100,000
Director	H	Responsible for the development, implementation, and support of a number of activities, systems, and processes; ensures plans are efficiently utilized; oversees hiring, development, and retention of staff; develops budgets and plans	B.S. and 8-12 years experience	\$90,000-\$110,000
Senior Director	I	Responsible for the development, implementation, and support of a number of diverse activities, systems, and processes; ensures that plans are efficiently implemented; oversees hiring, development, and retention of management staff	B.S. and 12-15 years experience or M.S. and 8-10 years experience or M.D./Ph.D. and 5-8 years experience	\$150,000-\$200,000
Vice President	J	Responsible for the identification, evaluation, and development/implementation of new technologies, programs, or strategies that support business goals; directs director-level personnel across diverse activities, programs, or systems	B.S. or advanced degree and 15 years experience	\$180,000-\$220,000

* As indicated by the average salary ranges provided for each position, salaries vary by firm. Salaries in the bio-pharmaceutical industries are market-driven and annual salaries recorded reflect only a portion of the total compensation that an employee might receive. Applicable annual bonuses, stock options, profit-sharing, insurance benefits, etc., combined with annual salary comprise the complete incentive package. Salary structures within individual firms vary by company size, level of experience, and/or educational qualifications.

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