



Departments and Job Descriptions in a Biotechnology Company:

Research & Development (Preclinical):

Discovery Research, Bioinformatics and Animal Sciences

Operations:

Process/Product Development, Manufacturing and Production and Environmental Health & Safety

Quality:

Quality Control, Quality Assurance and Validation

Clinical Research:

Clinical Research, Regulatory Affairs and Medical Affairs/ Drug Information

Finance & Administration:

Finance, Administration, Information Systems and Legal Counsel

Business Development:

Business Development and Marketing/Sales

Project Management:

Project Management for all departments in the company.

Each job description includes the required level of education and experience, and approximate compensation in Massachusetts.² Figures are projected for the 2002 to 2004 time frame. Not all companies pay at the levels shown: smaller start-up companies may pay less, but may offer employees stock options. Senior executives and managers may also receive annual bonuses that range from 10-25 percent of salary. Employers encourage continuing education, which is often part of already generous benefits packages. In other words, individuals with a strong work ethic, who demonstrate a willingness to expand their knowledge base and leadership skills, can expect to have a rewarding and stimulating career in this young and vigorous industry.

Specific Areas of Biotechnology Job Growth:

Scientific Careers:

The biotechnology industry's greatest growth areas are research and development (pre-clinical and clinical) and manufacturing. As companies search for new products, the need for research staff expands. It typically takes ten to fifteen years to bring a biotech product through clinical trials and into the marketplace. Many biotech companies formed in late 1980s and early 1990s now have products that are nearing clinical and/or commercial manufacturing. Some of the largest companies are expanding their product base, and therefore, their manufacturing capacity. Over the next two years, the demand for qualified manufacturing personnel will continue to increase. A new biomanufacturing training program for entry-level biomanufacturing technicians development is now offered at Middlesex Community College for incumbent and new workers.³

Non-Scientific Careers:

Biotechnology companies also offer non-scientific career opportunities in marketing and

sales, finance and administration, and project management. As companies mature, positions in planning, public relations, investor relations, government relations, distribution management, material planning, accounting and finance, and legal counsel become available. Other occupations needed throughout the industry include engineers; mechanics, electricians; heating, ventilation and cooling (HVAC) technicians; welders; and security guards. Glass washers and media preparation personnel, packagers, and shipping and receiving clerks are also needed to manage the influx and efflux of materials and products.

Notes:

¹ This Online Directory provides descriptions for every job in a biotechnology company in the medical therapeutics sector. Other types of biotechnology companies in different market sectors include agbio, environmental protection, human diagnostics, medical devices, scientific equipment/supplies, scientific services, and veterinary medicine.

² All compensation numbers are based on information gathered from a 2001 survey of Massachusetts companies.

³ These programs are funded by the BEST Initiative - The Building Essential Skills through Training (BEST) Initiative of the governor's office, Commonwealth Corporation, and the Massachusetts Department of Labor and Workforce Development, the Department of Education, the Division of Employment and Training, and the Department of Transitional Assistance.

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Job Descriptions

Research & Development (Preclinical):

Discovery Research, Bioinformatics and Animal Sciences

Note: The approximate salary ranges quoted here are estimates only. Salary structures within any company may vary based on company size, geographical location, labor market, level of experience, and/or educational qualifications.

Vice President of Research and Development

Job Description

Develops operating plan and develops strategic objectives that support the company's research and development strategies. Determines overall organizational structure and allocations of managerial responsibilities. Provides leadership to direct others in solving complex problems. Reviews and approves all major projects. Exercises authority to implement and initiate projects. Participates with senior management in developing and establishing organizational and company policies. Receives strategic guidance only. Make final decisions on administrative and operational matters. Directs all major functions and activities within the research area. Integrates these functions and activities with those of other major organizations. Has demonstrated management and strategic planning skills. Capable of representing the company in all related technical matters of high significance. Responsible for introduction of new technology enhancement into the research area. Responsible for the scientific and career growth of employees.

Education/Experience

Requires a PhD in a scientific discipline and 15 years' management experience.

Approximate Salary Range

\$175,000+

Scientific Director

Job Description

Responsible for directing the activities of multiple sections or an entire program area in the research department through subordinate managers. Undertakes long-term and short-term planning and supervision of projects that require interaction with business and manufacturing units. Makes decisions on work programs and monitors project and program costs. May conduct and collaborate with others on basic research relevant to long-term objectives and concerns. Collaborates on patent applications and manuscripts for publication. Develops strategies to ensure effective achievement of scientific/business objectives. Monitors and evaluates completion of tasks and projects. Develops budgets for capital expenditures, labor and contracts. Makes final decision on administrative or operational matters.

Represents the organization as prime internal and customer contact on contracts or operations. Conducts briefing and technical meetings for top management and customer representatives. Instrumental in attracting and obtaining major new company business contracts.

Education/Experience

Requires a PhD in a scientific discipline and a minimum of 12 years' experience in a research environment.

Approximate Salary Range

\$120,000 - \$175,000

Associate Scientific Director

Job Description

Responsible for planning, coordinating and managing the activities of one or more sections or projects in the research department. Undertakes long-term and short-term planning and supervision of projects, which generally require interaction with business and manufacturing units. Makes decisions on work programs and monitors project and program costs. May conduct and collaborate with others on basic research relevant to long-term objectives and concerns. Collaborates on patent applications and manuscripts for publication. Develops tactics to ensure effective achievement of scientific/business objectives. Monitors and evaluates completion of tasks and projects. Assists in developing budgets for capital expenditures, labor and contracts.

Frequent contacts with equivalent inter-organizational managers and customer representatives concerning projects, operational decisions, scheduling requirements, or contractual clarifications. Conducts briefings and technical meetings for internal and external representatives including equivalent or above management.

Education/Experience

Requires a PhD in a scientific discipline and a minimum of 10 years' experience in a research environment.

Approximate Salary Range

\$99,000 - \$143,000

Principal Scientist

Job Description

Initiates, directs and executes scientific research and development that is critical to corporate strategies and image. Investigates the feasibility of applying a wide variety of scientific principles and concepts to potential inventions, products and problems. Makes major contributions to the scientific direction of the company including initiation of research that may lead to major new programs. Participates in development of patentable technology. May be responsible for management and professional development of research group. Plans and executes laboratory research. Maintains broad knowledge of state-of-the-art principles and theory. Makes important contributions to scientific literature and conferences.

Exhibits an exceptional degree of sustained ingenuity, creativity and resourcefulness. Applies and/or develops highly advanced technologies, scientific principles, theories and concepts that may be new to the industry.

May serve as consultant to top management in long-range corporate planning concerning new or projected areas of technological research and advancements. Key spokesperson to customer personnel on corporate capabilities and future efforts. May be instrumental in attracting and obtaining major new company business contracts and/or grants. Recognized as a scientific leader within the company.

Education/Experience

Requires a PhD in a scientific discipline and a minimum of 10 years' experience in a research environment. Expert knowledge of scientific principles and concepts is also required. As an alternative, post doctorate experience may be considered if combined with a minimum of 12-15 years related experience.

Approximate Salary Range

\$99,000 - \$132,000

Senior Scientist

Job Description

Initiates, directs and executes scientific research and development that is critical to corporate strategies and image. Investigates the feasibility of applying a wide variety of scientific principles and concepts to potential inventions, projects and problems. Plans and executes laboratory research. Maintains a broad knowledge of state-of-the-art principles and theory. Makes major contributions to scientific literature and conferences. Acts as spokesperson on corporate research and development. Participates in development of patent applications. May be responsible for management and professional development of research group. Interfaces with various departments.

Projects require expert and extensive knowledge of advanced principles, theories and concepts in area of expertise. Contributes to the development of principles and concepts new to the field.

Often acts as project leader. Serves as organization consultant and spokesperson on specialized projects or programs. Acts as advisor to top management and customers on advanced technical research studies and applications.

Education/Experience

Requires a PhD in a scientific discipline and a minimum of 5-10 years' experience or MS with 8-10 years' experience in a research environment. Expert knowledge of scientific principles and concepts is also required. As an alternative, post doctorate experience may be considered if combined with a minimum of 12-15 years related experience.

Approximate Salary Range

\$85,000 - \$100,000

Scientist II

Job Description

Responsible for the initiation, design, development, execution and implementation of scientific research projects in collaboration with others, that are critical to corporate strategies and image. Investigates the feasibility of applying a wide variety of scientific principles and concepts to potential inventions and projects. Serves as in-house and outside consultant. Participates in development of patent applications. May manage and be responsible for professional development of research group. May coordinate interdepartmental activities and research efforts. Contributes to scientific literature and conferences.

Projects require expert and extensive knowledge of state-of-the-art principles and theories in area of expertise. Uses professional concepts and company procedures to solve a wide range of complex scientific problems in creative and imaginative ways.

May represent the organization as prime technical contact on contracts or projects

requiring coordination across organizational lines. Provides intra/inter-group scientific leadership and training. Often acts as mentor and may act as project leader.

Education/Experience

Requires a PhD in a scientific discipline and a minimum of 2-5 years' experience or MS with 8-10 years' experience in a research environment.

Approximate Salary Range

\$70,000 - \$90,000

Scientist I

Job Description

Designs, implements and executes scientific research and development projects in collaboration with a larger research team. Investigates the feasibility of applying a variety of scientific principles and concepts to potential inventions and products. Demonstrates potential for technical proficiency, scientific creativity, collaboration with others and independent thought. May coordinate interdepartmental activities and research efforts. Contributes to scientific literature and conferences.

Projects require substantial knowledge of state-of-the-art principles and theories in area of expertise. Uses professional concepts and procedures to solve a wide range of difficult scientific problems in imaginative ways.

Involved in intra/inter-group teams regarding project design and implementation. Provides scientific guidance and training to more junior staff. May directly supervise one or more members of research group.

Education/Experience

Requires a PhD in a scientific discipline and a minimum of 0-2 years' experience or MS with 8-10 years' experience in a research environment.

Approximate Salary Range

\$60,000 - \$85,000

Principal Research Associate

Job Description

This position encompasses all the responsibilities of the Senior Research Associate, with either additional formal responsibility for supervising a distinct group, or additional technical responsibilities of a very independent nature that require the evaluation of tangible variance factors. If functioning in the more senior technical versus supervisory capacity this position would typically involve acting as the primary investigator in conducting his/her own experiments and would routinely exercise independent judgment in developing methods, techniques, and evaluation criteria for obtaining results.

Has expert understanding of and ability to apply principles, theories and concepts in specialized area of responsibility, together with working knowledge of related disciplines. Projects require a high level of familiarity with current scientific literature together with the capability to select methods and techniques of obtaining solutions including the development of new scientific techniques.

Typically leads department/project team in providing services or solutions to complex technical problems. Serves as consultant within area of expertise for other sections and/or divisions.

Education/Experience

Requires a BS/MS and 5-8 years' regulatory affairs experience in the development of biological or pharmaceutical products or 2-5 years with a Masters and demonstrated working knowledge of scientific principles. In-depth knowledge of FDA laws is desirable.

Approximate Salary Range

\$60,000 - \$70,000

Senior Research Associate**Job Description**

Responsible for performing research and development experiments for projects and products in collaboration with others. Uses professional concepts in accordance with company objectives to solve complex problems in creative and effective ways. Investigates, creates and develops new methods and technologies for project advancement. Regularly exercises technical discretion in design, execution and interpretation of experiments that contribute to project goals. Contributes to project process within scientific discipline through innovative research. Prepares technical reports, summaries, protocols and quantitative analyses. May participate in scientific conferences and make contributions to publications and patents.

Has full understanding of and ability to apply established principles, theories and concepts in area of responsibility, together with a working knowledge of related disciplines. Projects require familiarity with current scientific literature together with capability to select methods and techniques for obtaining solutions within broadly defined practices and procedures.

May be involved in teams, which include participation from other sections and/or divisions. May provide guidance to less senior personnel. May assume leading role in providing solutions to difficult, though defined, problems associated with specific projects.

Education/Experience

Requires a BS in a scientific discipline and a minimum of 5-8 years' related laboratory experience, or MS with 2-5 years' experience.

Approximate Salary Range

\$52,000 - \$60,000

Research Associate**Job Description**

Responsible for performing research and development experiments for projects and products, in collaboration with others. Regularly exercises technical discretion in the design, execution and interpretation of experiments that contribute to project goals. Contributes to project process within scientific discipline through innovative research. Prepares technical reports, summaries, protocols and quantitative analyses. May participate in external seminars and scientific conferences.

Has full understanding of and the ability to apply established principles, theories and concepts in area of responsibility. Projects may require familiarity with current scientific literature together with the capability to select methods and techniques for obtaining solutions within generally defined practices and policies.

Contacts are primarily with direct supervisors and others in section or group for guidance and regarding status of work projects. May interact with other sections/divisions on routine matters.

Education/Experience

Requires BS in a scientific discipline and a minimum of 2-5 years' related laboratory experience, or MS with 0-2 years' experience.

Approximate Salary Range

\$38,000 - \$50,000

Research Assistant

Job Description

Responsible for performing research and laboratory tasks for projects and products, in collaboration with others. Projects may require the exercise of technical discretion in the design, execution or interpretation of experiments. Makes detailed observations, analyzes data and interprets results. Prepares technical reports, summaries, protocols and quantitative analyses. Has an understanding and/or application of fundamental principles, theories and concepts in the area of responsibility. Projects require the ability to read and understand relevant scientific literature.

Contacts are primarily with direct supervisors and others in section or group for guidance and regarding status of work projects.

Education/Experience

Requires a certificate, AS/BS or equivalent in a scientific discipline and a minimum of 0-2 years' related laboratory experience.

Approximate Salary Range

\$32,000 - \$48,000

Bioinformatics Scientist/Engineer

Job Description

Develops gene discovery algorithms for integrating sequence-based/functional knowledge about genes to help scientists analyze and interpret gene-expression data. Analyzes DNA information and identifies opportunities and needs for innovative solutions for the analysis and management of biological data in relevant databases. Assists in the development of software and custom scripts to automate data retrieval, manipulation, and analysis; application of statistics, and visualization tools. May manage some of the processes involved in database design, interface design, and information processing.

Provides leadership in the development, evaluation and deployment of gene centric information systems and works closely with scientists and other experimental departments in developing statistical and probabilistic methods for gene clustering/analysis.

Other responsibilities may include the initiation and management of external relationships and collaborations with academic and commercial parties, evaluation of third party products and technologies, and management of acquisition and implementation.

Education/Experience

Requires MS or PhD in Bioinformatics, Statistics, Biochemistry, Mathematics, Molecular

Biology or Computer Science, Computational Chemistry, or related field and 1-4 years of industry experience.

Proficiency in programming languages like C/C++, Perl, SQL, HTML, and JAVA and knowledge of mixed operating systems environments (e.g. UNIX, Windows NT, Sybase, Oracle etc.) is required.

Working knowledge of public domain bioinformatics data sources, public sequence databases, sequence assembly tools and gene expression analysis software is preferred.

Approximate Salary Range

\$75,000 - \$85,000

Approximate Senior Salary Range

\$85,000 - \$100,000

Bioinformatics Analyst/Programmer

Job Description

Designs and develops software, databases, and interfaces for analyzing and manipulating genomic databases. Collaborates with Production to develop high throughput data processing and analysis capability, design and implement data queries, novel algorithms and/or visualization techniques. Maintains large-scale DNA databases and prepares data for utilization by other scientists. Monitors new data from public databases and cleans loaded data to satisfy quality control criteria. Works with the entire life science team to diagnose and fix issues with bioinformatics software. Provides direct technical and scientific customer support and helps guide, implement and maintain further improvements to Bioinformatics software.

Education/Experience

Requires an MS/PhD or equivalent experience in Molecular or Computational Biology, Computer Science, Mathematics/Statistics, Bioinformatics, or related field and 1-3 years' experience developing computational biology applications.

Fluency in at least one of the following: C/C++, Perl, SQL, HTML, and JAVA and a working knowledge of relational databases and system administration is preferred.

Familiarity with public sequence databases and standard sequence analysis tools is highly desirable.

Approximate Salary Range

\$60,000 - \$100,000

Molecular Modeler

Job Description

Provides molecular modeling support for ongoing discovery research and applies computational techniques for the identification and optimization of hit/lead compounds. Other responsibilities include scientific leadership for the molecular modeling or computational design group, interaction with scientists of varied disciplines, new methods development, ligand design, pharmacophore development, library design and analysis, model development for virtual screening, and Quantitative Structural Activity Relationships (QSAR), protein structure and molecular simulations.

Education/Experience

Requires a PhD degree in chemistry, biochemistry, computational chemistry or a related field, 5+ years of industrial experience. Expertise in all aspects of molecular modeling of small molecules in rational drug design including QSAR and Structure based design, predictive Drug Absorption, Distribution, Metabolism and Excretion (ADME), and/or library design in a drug discovery setting is preferred.

Strong familiarity with principles of medicinal chemistry and knowledge of commercial modeling software packages, database searching, docking and scoring functions are also desirable. Systems administration knowledge and programming experience is a plus.

Approximate Salary Range

TBA

Facility Manager/Supervisor (Animal Sciences)**Job Description**

Supervises all activities and staff of the animal facility. Sets and maintains a high standard of animal husbandry according to AALAC guidelines and optimizes animal handling techniques based on scientific requirements of animal projects and Good Laboratory Practices (GLP). Ensures a smooth-running animal facility including stability of the lab environment, proper functioning of all equipment, appropriate levels of all supplies, and environmental monitoring (e.g. live sentinel). Responsible for processing requests for animals to be purchased, and for allocating space, time and resources for the company's animals. Hires, develops, manages, and appraises the animal facility staff.

Education/Experience

Requires a BS in biological sciences or equivalent and a minimum 5 years experience in animal husbandry. Previous supervisory experience (3+ years) in an animal facility (biotech/pharmaceutical company) is required and AALAS certification at a technologist level is preferred.

Approximate Salary Range

\$60,000 - \$80,000

Veterinarian**Job Description**

Responsible for diagnosing, treating and monitoring laboratory animals during the research stage of new drug therapies/discoveries. Other responsibilities include observing and documenting animal behavior, testing and vaccinating animals, performing autopsies, and working closely with scientists to analyze complications during new drug treatments/applications. Veterinarians may also consult on the breeding, feeding and maintenance of animals in a controlled laboratory environment.

Education/Experience

Requires Doctor of Veterinary Medicine (DVM or VMD) degree and a license to practice. Minimum of 2-3 years laboratory, veterinary and/or animal experience in a biotechnology or clinical research environment is required.

Approximate Salary Range

\$100,000 - \$150,000

Lab Assistant

Job Description

Performs a variety of research/laboratory tasks and experiments under general supervision. Works on assignments that are moderately complex and where judgment is required in resolving problems and making routine recommendations. Maintains laboratory equipment and inventory levels of laboratory supplies. May make detailed observations, analyze data and interpret results, write experimental reports, summaries and protocols. May be responsible for limited troubleshooting and calibration of instruments and assisting in training of entry-level employees.

Education/Experience

Requires a high school diploma, preferably a biotechnology certificate, AS or equivalent experience with a scientific background. A minimum work experience of 1-2 years' related laboratory experience with a high school diploma, or 1-2 years with an AS.

Approximate Salary Range

\$24,000 - \$33,000

Glasswasher**Job Description**

Responsible for washing and drying glassware and distributing it to appropriate locations within the laboratories. Maintains glass washing facility and performs routine maintenance on glass washing equipment. May sterilize glassware and other laboratory items in an autoclave. Generally works on assignments that are semi-routine in nature, and requires ability to reorganize deviation from accepted practices.

Education/Experience

Requires a high school diploma or equivalent. Should have a minimum of 0-2 years' laboratory experience.

Approximate Salary Range

\$22,000 - \$29,000

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Vice President of Operations**Job Description**

Has overall responsibility for pharmaceutical product development/technology transfer and product manufacture according to Food and Drug Administration (FDA) guidelines, Good Manufacturing Practices (GMP) and ISO 9000 requirements for clinical trials of Investigational New Drugs (IND) and approved

New Drug Applications (NDA) materials. Identifies personnel needs, trains, develops and motivates subordinates in product development, plant operations, facility maintenance, process and equipment validations. Is responsible for optimizing production of existing products manufacturing; assuring compliance with GMP and National Regulatory Commission (NRC) regulations; operations budget including capital requirements; improving productivity of the vial inspection process; facilitating technology and manufacturing process transfer; providing product for applicable clinical trials as required to support US NDA file; and supporting program development as appropriate to decisions regarding market opportunities.

Education/Experience

Requires PhD in engineering or other scientific discipline, 10-12 years' experience or MS in engineering and 15+ years' management experience.

Approximate Starting Salary Range

\$150,000+

Director of Product/Process Development

Job Description

Directs the development, planning and implementation of product and process development for new products and technologies from the laboratory through pilot plant and manufacturing scale. Provides strategic direction, tactical oversight and technical expertise for all activities within the Product/Process Development area. Oversees production schedules, materials, equipment and manpower requirements. Formulates and recommends manufacturing policies and programs to maximize yields and reduce costs. Develops budgets for labor and capital expenditures. Represents departmental activities as needed, including project teams, task forces, audits and business or technical meetings with outside groups.

Education/Experience

Requires PhD in Chemistry, Biochemical Engineering, Biochemistry, Microbiology, or a related discipline with 7-10 years in all aspects of process/product development, or BS/MS degree with 12+ years of relevant experience. Experience with cGMP, GLP, process development/scale-up and methods/process validation is preferred.

Approximate Salary Range

\$85,000 - \$159,000

Process Development Supervisor

Job Description

Supervises one or more of the functional areas (such as fermentation or purification) within process development with responsibility for designing and scaling-up production processes 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. May act as liaison with Research and Manufacturing to ensure processes and designs are compatible.

Education/Experience

Requires a BS/MS and 5-8+ years of experience implementing scale-up processes.

Approximate Salary Range

\$49,000 - \$85,000

Process Development Associate

Job Description

Responsible for evaluating, improving and scaling-up manufacturing processes in order to improve product yield and reduce overall costs of production. Executes small-to-medium scale production work, which may involve cell culture, fermentation, purification and/or chromatography. Additionally, assists with maintenance of production equipment. May research and implement new methods and technologies to enhance operations and may assist in validation of production processes.

Education/Experience

Requires a BS/MS degree in a scientific discipline or equivalent. A minimum of 2-5 years experience in the development and optimization of manufacturing processes is required with a Bachelors or 0-2 years relevant experience with a Masters.

Approximate Salary Range

\$35,000 - \$65,000

Process Development Technician

Job Description

Responsible for the definition, development and optimization of processes and equipment from the laboratory through pilot plant and manufacturing scale. Identifies and resolves issues with materials, processes, or equipment. Mixes compounds, prepares test samples, maintains inventory of materials on a regular basis and operates equipment as required. Executes process validation/equipment qualification processes and maintains files of lab tests, work procedures, formulations, calculations and assembly methods. Responsible for routine maintenance on all equipment used. Maintains records to comply with regulatory requirements, GMPs and standard operating procedures and assists in writing production procedures as necessary.

Education/Experience

Requires BS or equivalent in engineering or related discipline and a minimum of 2-5 years experience in process/product development preferably in a pharmaceutical or research development environment. Prior work experience with computerized instrumentation and micro measurement equipment is desirable.

Approximate Salary Range

\$30,000 - \$43,000

Director of Manufacturing**Job Description**

Responsible for the development, implementation, and ongoing support of manufacturing business systems including clinical and commercial production activities. Ensures plans and resources (people, facilities, supplies etc.) are efficiently utilized to ensure uninterrupted supply of products produced. Oversees the hiring, development, retention and optimal performance of staff for the leadership and execution of manufacturing operations. Develops comprehensive operating plans and budgets and monitors achievement of business and financial goals. Responsible for the development of effective working relationships with both internal and external partners.

Education/Experience

Requires a BS in the sciences; MS is preferred and a minimum of 8+ years of experience in all aspects of the manufacturing process in a pharmaceutical or biotechnology environment. Previous management or project experience is required and knowledge of GMP and GLP is preferred.

Approximate Salary Range

\$93,000 - \$159,000

Manufacturing Manager**Job Description**

Responsible for the production operations associated with the manufacture of all GMP products. Develops weekly/monthly goals and schedules for supervisors and manages activities through shift or unit supervisors. Oversees progress of supervisors' daily schedules to ensure safe and timely completion of releasable products. Point person for technical and compliance issues and liaisons with internal groups (QA, QC, Regulatory etc.) to facilitate issue resolution. Ensures functional unit's compliance with GMP and all its related elements such as facilities, documentation (SOPs and validation protocols etc.), training, reports and records. May be required to negotiate process-manufacturing agreements or manage external manufacturing contracts.

Education/Experience

Requires BS in a relevant science or engineering discipline and a minimum of 5-8 years experience in a biotechnology manufacturing/quality/development environment. Thorough knowledge and understanding of cGMPs and familiarity with FDA guidelines is required.

Approximate Salary Range

\$60,000 - \$93,000

Manufacturing Supervisor**Job Description**

In small to medium size companies 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. Directly provides guidance to employees to ensure operations meet GMPs. 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.

In large companies, separate supervisors will be used for cell culture/fermentation and purification processes.

Education/Experience

Requires BS and a minimum of 3-5 years' 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 cGMPs is required.

Approximate Salary Range

\$46,000 - \$68,000

Manufacturing Associate

Job Description

Performs a variety of complex tasks under general guidance and in accordance with current GMPs. Plays a role in implementing new technology into the manufacturing process or in starting up a new manufacturing area. Performs some or all of the following in strict accordance with Standard Operating Procedures (SOPs): fermentation, protein purification, solvent extraction, tissue culture, preparation of bulk solutions, non-critical aseptic fills of 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. May participate in plant trials for evaluating process modifications. Troubleshoots processing problems, bringing unusual problems (i.e., potential deviations) to the attention of the supervisor. Assists in the implementation of production procedures to optimize manufacturing processes. Monitors processes and results and suggests methods to ensure process success. May attend research meetings related to the transfer process of new products. Organizes own daily workload schedule and relevant resource requirements. May provide training to new personnel in a specific technical process. Participates in authoring complex, explicit documentation for manufacturing operations.

Education/Experience

Requires AS with 4-7 years' related work experience or BS in biology or related life science and a minimum of 2-3 years' experience. Detailed knowledge of purification systems and familiarity with regulatory and Standard Operating Procedures is required.

Approximate Salary Range

\$35,000 - \$60,000

Manufacturing Technician

Job Description

Responsible for assisting manufacturing in specific product-related operations in cell culture/fermentation. Operates and maintains production equipment as it relates to cell culture/fermentation (i.e., fermenters, bioreactors, cell harvests and separation operations). May also assist manufacturing in production-scale protein 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.

Education/Experience

An entry-level position requires a high school diploma, certificate in biomanufacturing, AS degree or equivalent experience plus a minimum of 0-2 years' related work experience in a manufacturing environment.

A senior-level position requires BS in biology or related life science and 1-4 years' experience.

Approximate Salary Range

\$28,000 - \$44,000

Manufacturing Instrumentation / Calibration Technician

Job Description

Maintains, tests, troubleshoots and repairs a variety of circuits, components, analytical equipment and instrumentation. Calibrates instrumentation and performs validation studies. Specifies and requests purchase of components. Analyzes results and may develop test specifications and electrical schematics. Performs continuous monitoring of equipment status, condition and location. Prepares required documentation for the recording and notification of events and changes related to equipment such as calibration certificates, deviations, out of tolerances and installation reports.

Education/Experience

Requires an AS in electronics technology or equivalent technical training related to mechanics or instrumentation and a minimum of 2-4 years' experience with instrumentation, problem diagnosis and repair. Knowledge and understanding of measurement parameters and experience working in a GMP environment is preferred.

Approximate Salary Range

\$35,000 - \$60,000

Material Handler**Job Description**

Responsible for the collection and distribution of materials between departments and the shipping department. Wraps and protects materials for safe transportation or warehouse storage. Loads and unloads materials on/ from freight vehicles, and stacks items in inventory. Other responsibilities may include lifting heavy loads (in excess of 70 lbs), operating a forklift, inspecting received goods, performing inventory reconciliation, updating inventory databases, weighing and dispensing materials for manufacturing.

Education/Experience

Requires a high school diploma or equivalent and a valid driver's license. Forklift experience and the ability to lift heavy loads is desirable.

Approximate Hourly Rate Range

\$10.50 - \$12.00

Purchasing Agent / Buyer**Job Description**

Responsible for planning, organizing, directing and controlling purchasing activity for all production and non-production related goods and services required to support the manufacturing plant. Purchasing activities include supplier selection and the negotiations with suppliers for price, quality, timeliness of delivery, specifications, value improvement programs, contract administration, requisition review, and purchase order execution. Other responsibilities include maintaining knowledge of market conditions and advising management on purchasing alternatives to assure a continued flow of materials to meet production and sales requirements.

Education/Experience

Requires BS in Business, Material Management or related field with a minimum of 3 years experience in a purchasing and/or materials environment. Effective negotiation, persuasion and communication skills are also required.

Approximate Salary Range

\$35,000 - \$55,000

Aseptic Fill Supervisor**Job Description**

Supervises all aseptic filling activities in accordance with GMPs, GLPs and SOPs regulations. Areas of responsibility include equipment/component preparation, sterilization and sanitation of aseptic filling rooms. Manages work group, assigns tasks and checks work. Reviews and processes Batch Production Records. Additional responsibilities include hiring, developing, and overseeing the training of new employees.

Education/Experience

Requires BS in Biology, Chemistry, or related area plus a minimum of 3-5 years of supervisory experience in a pharmaceutical environment preferably in aseptic

filling.

Approximate Salary Range

\$46,000 - \$68,000

Aseptic Fill Research Associate

Job Description

Implement production procedures to optimize the aseptic fill manufacturing processes in accordance with GMP regulations. May assist process development in developing scalable processes to improve yield and reduce cost for aseptic fill manufacturing systems. Other responsibilities may include filling, labeling and packaging of products, or the operation/maintenance of production equipment.

Education/Experience

Requires BS in a scientific discipline or equivalent and a minimum of 0-2 years' experience in an aseptic fill, manufacturing environment.

Approximate Salary Range

\$31,000 - \$44,000

Aseptic Fill Technician

Job Description

Assists in the operation and maintenance of production systems. Other responsibilities may include setting up, changing-over and operating labeling and packaging equipment.

Education/Experience

Requires a BS in a scientific discipline for senior-level positions or an AS or certificate in Biomanufacturing for entry-level positions and a minimum of 0-2 years' work experience in an aseptic fill manufacturing environment. Knowledge of manufacturing procedures and federal regulations pertaining to manufacturing processes is preferred.

Approximate Salary Range

\$28,000 - \$44,000

Facilities Manager

Job Description

Manages the design, planning construction and maintenance of equipment, machinery, buildings and other facilities. May have responsibility for health and safety standards. Plans, budgets and schedules facility modifications including estimates on equipment, labor, materials and other related costs. Oversees the coordination of building space allocation and layout, communication services and facilities expansion.

Education/Experience

Requires BS or equivalent and a minimum of 5 years' experience in maintenance trades and knowledge of building codes.

Approximate Salary Range

\$60,000 - \$88,000

Facilities Technician**Job Description**

Performs daily monitoring, repair, and preventative maintenance activities on critical systems and facility equipment. Also troubleshoots, install and modernizes new and existing systems, including refrigeration equipment, water systems, HVAC systems, and electrical systems. Documents repairs, adjustments, and replacement of equipment and/or components per GMP standards. May also provide input and corrections to Standard Operation Procedures (SOPs) and assist engineering in the evaluation of new equipment or technology.

Education/Experience

Requires an AA/AS or Certificate of Completion at a 2-year technical school in the mechanical/electrical field or a high school diploma with 5+ years of experience in GMP maintenance. Knowledge of major trades, such as carpentry, electrical, plumbing, and HVAC/refrigeration including the ability interpret blueprints, technical manuals and specifications are required. Experience in a pharmaceutical or bio pharmaceutical environment is preferred.

Approximate Salary Range

\$25,000 - \$46,000

Shipper/Receiver**Job Description**

Responsible for loading or unloading, checking, storing, moving and recording the movement of supplies, raw materials, equipment and products to and from internal departments, external suppliers and/or customers. Other responsibilities include preparing bills of lading, invoices, requisitions and other documents, routing shipments, reviewing receipt of all materials and verifying quantities, and ensuring outgoing shipments are packaged according to specification.

Education/Experience

Requires a high school diploma or equivalent. Previous experience and knowledge of shipping and couriers is a plus. A valid driver's license may be required for some positions.

Approximate Salary Range

\$25,000 - \$40,000

Toxicologist**Job Description**

Designs and oversees regulatory and investigative toxicology studies in support of product registration based on innovative drug delivery technologies. Participates in the review and assessment of products and initiates any needed testing. Provides interpretation and consultation in regard to safety data, and direction and guidance for managing risk assessment support programs. Prepares toxicological/human safety assessments pertaining to occupational, consumer and environmental exposures derived from manufacturing processes and product usage. Participates on internal committees/teams on product

stewardship, product risk characterization and regulatory affairs matters. Tracks and monitors existing and pending legislation/regulations and serves as a representative on external trade and scientific associations.

Education/Experience

Requires an MS or Doctorate (PhD, MD or equivalent) in toxicology, biological sciences, or related health science field, and a minimum of 1-5 experience in toxicology studies. Working knowledge of US EPA regulations, international regulatory toxicology operations and a broad knowledge base in pharmacology of biotechnology products is highly desirable.

Approximate Salary Range

\$70,000 - \$140,000

Approximate Starting Salary Range for Director/Head of Toxicology

\$140,000+

Environmental Engineer

Job Description

Responsible for the research, coordination, implementation, and management of environmental issues including waste disposal, air/water quality, pollution control, hazardous waste, and land management. Prepares permit applications and performs environmental regulatory reviews. Performs periodic inspections of facility operations, participates in reviews of other facilities' environmental activities and participates in environmental audits. Develops and maintains appropriate documentation to assure compliance with governmental regulations. Additional duties include the development and management of programs to meet regulatory requirements, including corrective actions, monitoring and reporting to environmental agencies when required.

Education/Experience

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. Thorough knowledge of engineering documentation including expertise in permitting, pollution prevention, environmental regulatory compliance, training and reporting is required. Experience working in a GMP facility is desirable.

Approximate Salary Range

\$33,000 - \$66,000

Environmental Technician

Job Description

Responsible for water and air sampling and monitoring, processing permits, calibration and maintenance of scientific monitoring, data collection, and routine analysis. Installs and services recording instruments; maintains physical stations where data is collected, inspects stations records to ensure quality assurance and preventative maintenance procedures are conducted properly. May conduct special studies such as toxic water monitoring, biological monitoring, and air/water pollutant investigations and recommend corrective actions. Records

and maintains periodic data logs and information files. Typically works from drawings, specifications, diagrams, schematics and specific verbal and written instructions.

Education/Experience

Requires a high school diploma with some specialized or technical training in environmental sciences, chemistry, math, hydrology, ecology, toxicology or a related field. A two or three year community college program in environmental technology is preferred. Working knowledge in sampling, data collection and analysis, pollution complaint investigations, instrument calibration, environmental law or experience in assessing environmental conditions is desirable.

Approximate Hourly Rate Range

\$14.00 - \$24.00

Job Descriptions

Quality:

Quality Control, Quality Assurance and Validation

Note: The approximate salary ranges quoted here are estimates only. Salary structures within any company may vary based on company size, geographical location, labor market, level of experience, and/or educational qualifications.

Director of Quality

Job Description

Responsible for short and long term goals of quality control (QC) laboratory efforts in support of IND, NDA and commercial products and other milestones. Formulates and recommends quality assurance (QA) policies and programs. Develops departmental budget for quality assurance and quality control, including defining materials, equipment and personnel needs. Directs QC staff and daily operations to include: release and stability testing, in-process testing, QC inspections and audits, QC documentation, equipment maintenance and calibration and QC laboratory design and maintenance. Manages GMP material control program to include: QC materials management including labeling and storage, QC materials inventory and use and materials lot control. Oversees component and finished product stability program, transfer of validated methods to routine use, and participation of QC staff in support of validation of methods and equipment. Establishes and directs QC control programs and GMP training programs. Reviews and approves reports and other documentation prepared by QA and QC for regulatory submissions/inspections. Assures finished products conform to government and company standards and satisfies GMP regulations.

Education/Experience

Require BS or MS in chemistry or equivalent science and 6-10 years plus in chemistry, quality control and/or laboratory management positions plus experience in GMPs/GLPs.

Approximate Salary Range

\$93,000 - \$170,000

Quality Control (QC) Manager/Supervisor**Job Description**

Supervises the development, implementation and maintenance of quality control systems and activities. Oversees development and implementation of standards, methods and procedures for inspecting, testing and evaluating the precision, accuracy, efficacy and reliability of products. Coordinates interdepartmental activities. Develops budgets and monitor expenditures. Provides guidance to employees and supervises the work group. Responsible for regulatory inspections and findings including all follow-up.

Education/Experience

Requires BS/MS in a related discipline or equivalent and a minimum of 3-5 years' experience with documentation and implementation of quality control systems.

Approximate QC Supervisor Salary Range

\$47,000 - \$65,000

Approximate QC Manager Salary Range

\$67,000 - \$90,000

Quality Control (QC) Analyst**Job Description**

Conducts routine and non-routine analysis of raw materials, in-process and finished formulations under supervision and according to Standard Operating Procedures (SOPs). Compiles data for documentation of test procedures and prepares reports. Calibrates and maintains lab equipment. Reviews data obtained for compliance to specifications and reports abnormalities. Revises and updates SOPs. May perform special projects on analytical and instrument problem solving.

Education/Experience

Requires BS in a scientific discipline or equivalent and a minimum of 0-4 years' experience. Senior positions require BS/MS with 3-7 years relevant experience. Previous experience in microbiology, chemistry or biochemistry is required.

Approximate QC Analyst Salary Range

\$40,000 - \$48,000

Approximate Senior QC Analyst Salary Range

\$47,000 - \$60,000

Quality Control (QC) Technician**Job Description**

Performs a wide variety of inspections, checks, tests and sampling procedures for 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.

Education/Experience

Requires a high school diploma, Biotech Certificate, AS degree or equivalent experience with a scientific background and a minimum of 0-5 years in quality control systems with knowledge of good manufacturing practices (GMPs). Entry-level positions require 0-2 years relevant experience. More experienced positions require a minimum of 2-5 years experience.

Approximate Entry-Level QC Technician Salary Range

\$31,000 - \$38,000

Approximate Experienced QC Technician Salary Range

\$35,000 - \$43,000

Quality Assurance (QA) Manager/Supervisor

Job Description

Assures that products, processes, facilities and systems conform to quality standards and governmental regulations; conducts internal audits to monitor processes, facilities and systems. Conducts raw materials audits. Reviews and approves operating procedures in Manufacturing and Quality Control departments. Assures that the Equipment Calibration Program complies with the GMPs requirements. Coordinates interdepartmental activities. Develops budgets and monitors expenditures.

Education/Experience

QA supervisory positions require BS in biological science and a minimum of 3-5 years' related experience in quality assurance and/or quality control. Managerial positions require BS/MS in a biological science with a minimum of 5-8 years plus related experience.

Approximate QA Supervisor Salary Range

\$47,000 - \$65,000

Approximate QA Manager Salary Range

\$67,000 - \$90,000

Quality Assurance (QA) Documentation Specialist

Job Description

Provides required documentation and implements documentation systems. Ensures the accuracy and completeness of the QA document system, performs daily filing, organizes contents and revises the table of contents. Processes, dates, issues and tracks batch record and other documentation. Maintains and updates the document control and tracking databases. Coordinates the review and revision of procedures, specifications and forms. Issues, distributes and updates controlled manuals. Assists in the compilation of regulatory filing documents and maintains computerized files to support all documentation systems. May assist the QA Manager in the training and orientation of Junior Documentation Specialists.

Education/Experience

Requires BS/MS in a related field and a minimum of 2 -5 years' experience in GMP Documentation Control documentation, quality assurance, or equivalent.

Approximate Salary Range

\$36,000 - \$52,000

Quality Assurance (QA) Documentation Coordinator/Associate

Job Description

Responsible for providing clerical and administrative support related to documentation system requirements/maintenance. Audits all documentation manuals to assure they are accurate and up-to-date, and available to appropriate personnel. Maintains filing of all master documents and assists in all microfilming and archiving activities.

Education/Experience

Requires a high school diploma, Biotech Certificate, AS or equivalent experience and a minimum of 2-4 years' experience, preferably in documentation or quality control/assurance.

Approximate Salary Range

\$28,000 - \$39,000

Validation Manager

Job Description

Is responsible for managing, developing and implementing validation protocols and test procedures to ensure products meet with appropriate regulatory agency validation requirements, internal company standards and industry current practices. Oversees and reviews validation area processes and procedures. Make recommendations for changes and improvements. May manage through subordinate supervisors the coordination of the activities of a section or department with responsibility for results in terms of costs, methods and employees.

Education/Experience

Requires BS/MS in a scientific discipline with 5-7 years' experience.

Approximate Manager Salary Range

\$70,000 - \$90,000

Approximate Director Level Salary Range

\$90,000 - \$115,000

Validation Specialist

Job Description

Responsible for developing and recommending validation strategies and designing studies for the purpose of providing documented evidence that a system, equipment, method, or process has been validated. Conducts and processes qualifications programs, writes detailed protocols and reports to document the validation of systems/ equipment and provides validation support for facility and utility expansion, compliance upgrades, etc. Develops and

implements solutions to validation issues.

Education/Experience

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 cGMP requirements related to validation tasks is required.

Approximate Entry-Level Salary Range

\$45,000 - \$60,000

Approximate Senior Level Salary Range

\$55,000 - \$82,000

Job Descriptions

Clinical Research:

Clinical Research, Regulatory Affairs and Medical Affairs/ Drug Information

Note: The approximate salary ranges quoted here are estimates only. Salary structures within any company may vary based on company size, geographical location, labor market, level of experience, and/or educational qualifications.

Medical Director/Associate Medical Director

Job Description

Designs, implements and monitors clinical studies of compounds designated for clinical development. Develops protocols and case report forms, which will provide adequate efficacy and safety information for Phases 1 to 3 of clinical trials. Interacts with data management personnel to plan data entry and analysis; recruits/screens/selects competent investigators; organizes investigators' meetings; assures that Good Clinical Practices (GCPs) are followed; assures timely completion of studies; monitors data for safety and efficacy trends by reviewing clinical data; and writes clinical reports upon completion or termination of studies (in cooperation with statistical staff). Reviews requests for results of Investigational New Drugs (IND) studies, and provides input for pharmacokinetics and pre-clinical studies. Prepares clinical portions of INDs, New Drug Applications (NDAs) and Biological License Applications (BLAs), including protocols, investigator brochures, medical reports, efficacy and safety summaries, scientific rationales and benefit/risk ratios.

Plans clinical programs and develops a timetable, budget and resource analysis for clinical programs and personnel administration. Establishes and maintains relationships with alliance partners, external companies, investigators and opinion leaders to optimize performance on clinical trial activities. Prepares manuscripts for technical journals and makes presentations at scientific meetings

Education/Experience

Medical Directors require a MD/PhD in a relevant scientific discipline and a minimum of 5-8 years' experience in clinical research. Associate Medical

Directors require a MD/PhD and 0-3 years' clinical research experience. Pharmaceutical experience is desirable.

Approximate Medical Director Salary Range

\$150,000 - \$240,000

Approximate Associate Medical Director Salary Range

\$125,000 - \$165,000

Clinical Research Manager

Job Description

Supervises design and writing of protocols, case report forms and informed consent forms for clinical trials. Supervises and directs the design, implementation and monitoring of clinical trials, preparation of integrated medical reports, INDs, Investigational Device Exemptions (IDE), periodic reports New Drug Applications (NDAs) and Biological License Applications (BLAs), etc. Makes decisions on recruitment/selection of new investigators, contract research organizations and outside vendors. Directs planning and implements all activities required to conduct and monitor complex clinical trials and ensures that Good Clinical Practices (GCP) are followed. Monitors site visits pre-study, at study initiation, at regular intervals during the study and at study closeout. Directs investigator performance and adherence to protocol, and proactively addresses conduct issues and enrollment problems, as necessary. Ensures that Case Report Forms (CRF) are reviewed in a timely fashion and submitted to the data management group. Monitors the compilation/writing of integrated medical reports and clinical sections of INDs, IDEs, New Drug Applications (NDAs) and Biological License Applications (BLAs), etc. Prepares manuscripts for technical journals and makes presentations at scientific meetings.

Education/Experience

Requires a BS or MS in a scientific or health care field (e.g., nursing, pharmacy, physician's assistant) and 5-8 years plus experience in the pharmaceutical or device industry including relevant clinical research experience.

Approximate Salary Range

\$75,000 - \$110,000

Clinical Research Associate

Job Description

Is key participant in the design, implementation and monitoring of clinical trials, preparation of integrated medical reports, INDs, Investigational Device Exemptions (IDE), periodic reports, New Drug Applications (NDAs) and Biological License Applications (BLAs), etc. Participates in design and writing of protocols, case report forms and informed consent forms for clinical trials. Productive in recruitment/selection of new investigators, contract research organizations and outside vendors. Responsible for planning and implementing all activities required to conduct and monitor complex clinical trials and ensures that Good Clinical Practices (GCP) are followed. Conducts site visits pre-study, at study initiation, at regular intervals during the study and at study closeout.

Monitors investigator performance and adherence to protocol, and proactively addresses conduct issues and enrollment problems, as necessary. Ensures that Case Report Forms (CRF) are reviewed in a timely fashion and submitted to the data management group. Involved in the compilation/writing of integrated medical reports and clinical sections of INDs, IDEs, New Drug Applications (NDAs) and Biological License Applications (BLAs)), etc. Assists in preparation of presentations and manuscripts of scientific meetings and technical journals. Attends scientific/professional meetings and training courses as appropriate.

Education/Experience

Senior positions require BS in a scientific, health care field (e.g., nursing, pharmacy, physician's assistant), or related field and 5-8 years' experience in the pharmaceutical or device industry including relevant clinical research experience.

Intermediate positions require BS in scientific field and 2-4 years related experience.

Knowledge of FDA regulatory requirements is preferred for both Senior and Intermediate levels.

Approximate Senior Clinical Research Associate Salary

\$55,000 - \$95,000

Approximate Intermediate Clinical Research Associate Salary Range

\$40,000 - \$65,000

Biostatistician

Job Description

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 (NDAs) and Biological License Applications (BLAs) submissions. Maintains and improves professional knowledge of technological advancements in data manipulation and statistical analyses.

Education/Experience

Senior positions require an MS, a PhD is preferred and 4-8 plus years' 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 BS/MS and 2-5 years' related experience.

Both levels require good communication and interpersonal skills and a background in SAS and other programming skills. Application of these skills in a pharmaceutical environment is preferred.

Approximate Senior Biostatistician Salary Range

\$70,000 - \$115,000

Approximate Intermediate Biostatistician Salary Range

\$55,000 - \$90,000

Clinical Data Manager/Associate**Job Description**

Primary responsibility is to ensure the validity of clinical trials and format them for statistical purposes. Also designs collection instruments, sets up databases and tracks and manages the flow of data to and from the investigative sites. With supervision, establishes protocol-specific data review and entry guidelines to document data validation and formatting procedures and defines batch-ending programs. Monitors timely data entry. Reviews data discrepancies resolutions provided by the investigative sites and enters corrections in the database, as appropriate. Assists in the review of interim/final data listings prior to transmission to other groups or inclusion in interim/final reports. Is familiar with database management systems and the principles, organization and content of standard Case Report Form (CRF) libraries. Ensures that incoming CRFs are tracked in a timely manner prior to safety review and upon manual review. Is familiar with data coding of Standard Operating Practices (SOP) and coding dictionaries. Conducts database audits according to established SOPs and is familiar with the implementation of GCPs.

Education/Experience

Entry-level positions require a high school diploma or Biotech Certificate and 2-5 years' experience in clinical data management or a BS with 0-2 years related experience.

Intermediate positions require a BS and 1-3 years clinical data management experience, senior positions require a BS/MS with 3-6 years related experience.

Managerial positions require a BS/MS with 5-8 years clinical data management experience.

Experience with use of a personal computer and a range of software applications is necessary. Database management experience is helpful.

Approximate Clinical Data Manager Salary Range

\$65,000 - \$105,000

Approximate Senior Clinical Data Associate Salary Range

\$45,000 - \$80,000

Approximate Intermediate Clinical Data Associate Salary Range

\$35,000 - \$60,000

Approximate Entry-level Clinical Data Associate Hourly Rate

\$13.20

Clinical Database Manager/Programmer Analyst

Job Description

Works as part of a project team, or possibly as a team manager, to design and implement applications in support of clinical research and biostatistics. Leads the analysis, design and implementation of client-server applications such as Oracle, SQL and forms of GUI-based products. Develops forms, menus and reports based on functional and design specifications. Documents all work fully according to Clinical Information Systems (CIS) standards. Actively promotes standards for the development and acquisition of systems. Participates in the evaluation and implementation of packaged systems. Communicates with the end-users.

Education/Experience

Programmer/Analyst positions require BS in computer science or related field and 0-3 years' programming experience, preferably in the pharmaceutical or health care industry.

Senior Programmer/Analyst positions require BS/MS in computer science or related field and 2-5 years related programming experience.

Managerial positions require BS/MS in computer science or related field and 5-8 years related experience.

Approximate Clinical Database Manager Salary Range

\$70,000 - \$115,000

Approximate Senior Programmer Analyst Salary Range

\$55,000 - \$90,000

Approximate Programmer Analyst Salary Range

\$42,000 - \$70,000

Medical Writer**Job Description**

Responsible for the timely preparation, production and quality control of regulatory documents, including coordinating with regulatory project teams, creating editorial timelines and work flow specifications, scheduling and tracking documents, assessing documentation staffing needs, participating in "round-table" review of documents, establishing project-specific style guidelines, editing at various levels, writing and proofreading. Develops and updates specifications for the design, format production elements, tracking of regulatory documents and artwork used in regulatory documents. Hires, trains and supervises editorial temporaries and coordinates their work. Develops and updates departmental editorial style standards by preparing and revising a style guide. Provides guidance on writing to authors of regulatory submissions, and develops and updates general writing guidelines by preparing and revising an author's guide. Participates in Computer Application for New Drug Application/Computer Application for Product License Application (CANDA/CAPLA) planning pertaining to document structures.

Education/Experience

Senior positions require BA/BS/MS and 5-8 years plus publications experience, including at least 3 years in a scientific or technical publishing environment.

Intermediate positions require BA/BS and 3-5 years' related experience.

Direct experience in FDA regulatory documentation is desirable for both levels.

Approximate Senior Medical Writer Salary Range

\$60,000 - \$105,000

Approximate Medical Writer Salary Range

\$40,000 - \$75,000

Director/Manager of Regulatory Affairs**Job Description**

Responsible for long- and short-term planning and directing of regulatory activities. Interprets corporate policy, develops and implements strategies for the earliest possible approval of regulatory submission, advises and manages the regulatory teams, and reviews ongoing projects. Plans, schedules and directs activities and programs through regulatory staff. Negotiates with outside agencies (national and international) as needed to resolve key regulatory issues and expedite approvals of product and services. Reviews and prepares responses to inquiries from regulatory authorities relating to product registrations. Monitors and updates national and international registration requirements through reviews of publications, seminars, and direct communication with outside regulatory personnel. Communicates pertinent changes and updates to regulatory staff and senior management. Oversees the preparation and submission of applications and routine reports/renewals, including the preparation and submission of supplements and amendments as required by internal department (Manufacturing, QA/QC, Medical, etc.) to update registered product information. Provides input on budget requirements, and monitors project and program costs. May hire, train and develop regulatory staff and provide input on associated compensation and department structure decisions.

Education/Experience

Director levels require a BS/MS in a scientific discipline, a PhD is preferred and 10 years' experience.

Managerial levels require a BS/MS in a scientific field and 8 years' experience.

Approximate Director Salary Range

\$90,000 - \$160,000

Approximate Manager Salary Range

\$65,000 - \$110,000

Regulatory Affairs Associate**Job Description**

Ensures all company products meet worldwide regulatory requirements by

supporting all assigned regulatory aspects of product approval and post-marketing compliance. Responsible for the coordination and preparation of document packages for regulatory submissions ensuring compliance with the Food and Drug Administration (FDA) and international regulations/interpretations. This may include the review, evaluation, and compilation of files and reports for submissions. Provides project team representation and direction in managing information from/to other departments (including R&D, Manufacturing, Quality Assurance, Quality Control, Medical Affairs, Marketing, and Clinical Affairs) regarding Regulatory submissions. This may include the preparation of outlines, summaries, status reports, graphs, charts, tables and slides for distribution and communication to other departments. Reviews technical and clinical documentation and recommends changes for labeling, manufacturing, marketing, and clinical protocol for regulatory compliance. Researches and analyzes regulatory information and determines acceptability of data, procedures, and other product-related documentation presented in support of product registration. Is responsible for the timely completion of regulatory projects and submission of documentation to regulatory agencies. Develops and maintains current regulatory knowledge and keeps abreast of regulatory procedures and changes. May provide regulatory guidance to project teams and junior staff.

Education/Experience

Senior positions require BS/MS and 5-8 years plus regulatory affairs experience in the development of biological or pharmaceutical products.

Entry-level and intermediate positions require a BS/MS and 0-4 years' related experience.

In-depth knowledge of FDA laws is desirable for both levels.

Approximate Senior Regulatory Affairs Associate Salary Range

\$55,000 - \$95,000

Approximate Regulatory Affairs Associate Salary Range

\$40,000 - \$75,000

Documentation Associate/Assistant

Job Description

Responsible for coordination and administration of document production procedures, including planning and scheduling of word processing and production resources. Coordinates with project teams in the development of timelines for documentation phase of regulatory submissions. Is responsible for management of electronic files. Coordinates with scientific editor to develop and update specifications and procedures for design and format of documents and artwork policy and procedures. Oversees reference collection, archive system, and produces monthly and annual reports of regulatory submissions. As Local Area Network (LAN) administrator is liaison with bioinformatics and information systems departments and is responsible for computer hardware and software

setups and maintenance. Participates in capital budgeting and in planning regarding CANDA/CAPLA systems.

Education/Experience

Intermediate positions require a BS and 2-4 years related experience in a scientific or regulatory environment and senior positions require a BS/MS and 5-8 years related experience.

Entry-level positions require a high school diploma or Biotech Certificate and 1-3 years' experience with computers and a LAN in a scientific or regulatory environment or a BS with 0-2 years related experience.

Approximate Senior Documentation Assistant/Associate Salary Range

\$47,000 - \$85,000

Approximate Documentation Assistant/Associate Salary Range

\$35,000 - \$65,000

Approximate Entry-Level Documentation Assistant/Associate Hourly Rate

\$13.20

Medical Affairs Director Oversees the management of Medical Affairs Department including, updates of operating SOPs, attainment of quality and financial standards, budget preparation, personnel training and development, and overall coordination of medical monitoring operations. Responsible for providing medical monitoring for ongoing clinical trials; communicating with investigators, sponsors, and clinical research personnel. Resolves medical issues, provides medical input for medical documents, supports business development activities and provides Serious Adverse Event (SAE) consultation. Maintains professional knowledge and skills, particularly in the areas of FDA/ICH guidelines and regulations.

Education/Experience

Requires an MD with a minimum of 5 years medical experience and 3 years experience in the pharmaceutical or contract research industries.

Approximate Senior Director Level Salary Range

\$200,000+

Approximate Director Level Salary Range

\$175,000 - \$200,000

Job Descriptions

Finance & Administration:

Finance, Administration, Information Systems and Legal Counsel

Note: The approximate salary ranges quoted here are estimates only. Salary structures within any company may vary based on company size, geographical location, labor market, level of experience, and/or educational qualifications.

Vice President of Finance & Administration

Job Description

Responsible for all long-range financial matters and establishment of company-wide financial and administrative objectives, policies, and practices. Establishes and executes programs for the provision of the capital required by the business, including negotiating the procurement of capital and maintaining the required financial arrangements. Manages the cash-flow position of the company. This includes authority to establish credit and collections and purchasing policies and to establish schedules for the payment of bills and financial obligations. Approves all agreements concerning financial obligations, such as contracts for products or services and other actions requiring a commitment of financial resources. Maintains relationships with financial institutions in conjunction with the President and administers banking arrangements and loan agreements, receives, has custody of and disburses the company's monies and securities. Establishes and maintains a market for the company's securities and liaisons with investment bankers, financial analysts and shareholders in conjunction with the President. Administers all incentive stock option plans. Maintains sources for the company's current borrowings from commercial banks and other lending institutions and invests the company's funds.

Responsible for the financial aspects of real estate transactions, and executes bids, contracts and leases. Oversees the granting of credit and the collection of accounts due the company, including supervision of required special arrangements for financing sales, such as time payments and leasing plans. Analyzes company shareholder relations policies and information program including the annual and interim reports to shareholders and recommends to the President new or revised policies or programs when needed. Provides advice on all matters to the President and assists the President in the formulation of overall corporate objectives.

Departmental responsibilities include the management of Finance, Accounting, Administration, Information Systems and Legal teams including benefit administration, insurance relationships and programs, and banking and lending relationships.

Education/Experience

Requires BS in Accounting or Finance, CPA and/or MBA preferred, and a minimum of 7-10 years senior financial management experience preferably at the Director or VP of Finance level. A background in a biotechnology/pharmaceutical environment is highly desirable.

Approximate Salary Range

\$155,000 - \$275,000

Chief Financial Officer**Job Description**

Oversees all financial activities of the company including internal and external reporting, accounting, treasury and tax matters, as well as financial planning,

budgeting and analysis. Key responsibilities include advising Senior Management and the Board of Directors on the potential impact of investments, purchases, commitments and contracts on the profitability and return-on-investment performance of the company. Other duties include evaluating and determining the financial impact of product development, capital spending, inventory investments, changes in product line and/or manufacturing methods, sourcing/outsourcing alternatives and contracts and advising management. Creates, reviews and approves periodic budgets and financial statements. Leads the development, interpretation, and reporting of operating financial information. Establishes accounting and finance practices and procedures in accordance with company policy. Serves as a key participant in the development of the company's strategic plan. Responsible for coordinating and creating the operating and capital budget. Participates in presenting strategic and financial plans. Manages relationships with senior management, outside auditors, board of directors, corporation counsel and financial institutions. May also lead the financial review aspects of due diligence analysis in conjunction with the review of new business acquisitions, divestitures, and downsizing initiatives as needed.

Education/Experience

Requires BS in Accounting or Finance with an MBA, CPA or equivalent postgraduate qualification and a minimum of 10 years of demonstrated financial management experience. Prior experience in Capital Formation, and/or Mergers & Acquisitions is highly desirable. Proven ability in presenting the financial and operational results and strategic plans of the organization to a variety of audiences including employee groups, finance community, Board Members and the Corporate CEO is essential.

Approximate Salary Range

\$133,000 - \$235,000 (may vary based on company size)

Director of Finance

Job Description

Oversees the company's financial and accounting operations. Responsible for month-end closes, preparation of monthly consolidations for management, budgeting, forecasting, and evaluating and enforcing contracts, accounting polices and procedures. Establishes internal controls, operating policies and procedures. Prepares and maintains company's financial statements. Prepares SEC quarterly and annual filings. Manages fiscal growth and expenditures. Assists in debt and equity financings and financial due diligence. Coordinates annual audit and quarterly reviews. Tracks and analyzes new rules and regulations related to financial reporting and consolidations. Performs research, analysis and other technical support for deal structuring, M & A, and other special projects. Manages relationships with investors and financial institutions. Duties may also include the management of employee benefits programs and other human resources administration, asset/vendor management, and support for internal and external financial presentations and other ad-hoc requests and projects.

Education/Experience

Requires BS in Accounting, Business Administration or Finance, MBA and CPA preferred, and a minimum of 7-10 years financial analysis/planning experience. Extensive knowledge of accounting, financial statement preparation, and SEC reporting is required. Managerial experience is strongly preferred.

Approximate Salary Range

\$76,000 - \$115,000 (may vary based on company size)

Accounting Manager**Job Description**

Manages and performs a variety of technical accounting and auditing functions. Audits, analyzes, compiles and reconciles company's financial transactions. Maintains, analyzes and reconciles general ledger accounts; performs detailed quarterly audit and year-end functions; prepares monthly and year-end revenue and expenditure accruals; adjusts and closes journal entries; reconciles bank accounts. Prepares/reviews payroll, accounts payable, accounts receivable, cash receipts, employee benefit forms and claim reports; assists in the annual operating budget; maintains the fixed asset accounting system(s); performs internal audits of investments, revenues and expenditures; develops, plans and implements accounting procedures within the accounting/financial unit. Manages the accounting staff and assists in the interviewing, hiring and training of new staff.

Education/Experience

Requires BS in Accounting, Finance, or related field, with a minimum of 5-8 years accounting/general ledger experience. Extensive knowledge of the auditing, analysis, compilation and reconciliation methods used in processing financial and accounting transactions is essential.

Approximate Salary Range

\$57,000 - \$120,000 (may vary based on company size)

Accounting Clerk**Job Description**

Assists with the planning and execution of various financial processes including routine calculations, posting and verification duties, account analysis, ad-hoc reporting, and other basic accounting functions. Reviews and examines financial transaction documents for accuracy and prepares the necessary corrections. Audits ledgers for accuracy and assists in the preparation of ad-hoc requests for account analysis. Performs posting of cash receipts, expenses, or other transactions to journals or ledgers. Prepares statements, invoices and vouchers. Other duties may include data discrepancy investigation and/or resolution, inter-departmental correspondence, and the maintenance and distribution of financial documentation.

Education/Experience

Requires a high school diploma, 2 or 4 year Accounting degree is preferred, and a minimum 2-5 years accounting experience. Knowledge of bookkeeping

procedures and basic accounting principles is required. Intermediate computing skills are highly desirable.

Approximate Salary Range

\$27,000 - \$34,000

Payroll Clerk

Job Description

Assists in the verification, compilation and maintenance of payroll data. Receives and verifies time sheets. Prepares, inputs and electronically transmits payroll data. Audits and corrects payroll processing reports errors. Assumes responsibility for all tax forms relating to payroll, including W-2. Posts bi-weekly and monthly payroll adjustments as needed including changes affecting net wages, such as exemptions, insurance coverage, and loan payments. Depending on the size of the company, the clerk may prepare, issue and distribute paychecks and pay advice forms. Interfaces with Human Resources personnel to record all data on hiring, termination and employee transfers. Responds to requests from employees and external agencies on matters relating to payroll and may prepare periodic reports of earnings, taxes, and deductions as needed. Other duties may include the preparation and distribution of employee lists and staff leave/vacation reports.

Education/Experience

Requires a high school diploma with a minimum of 1-3 years' payroll or related experience. Practical knowledge of payroll accounting and working knowledge of computers is preferred.

Approximate Salary Range

\$30,000 - \$35,000

Public/Investor Relations Manager

Job Description

Responsible for the management of P/R strategies in the area of press releases and industry articles, press tours, and promotional programs. Works with external public relations and investor relations agencies to ensure company communication objectives are met on time and within budget. Produces news releases, corporate backgrounders, product launch kits, presentations, and drives the release process. Responds to all media requests, inquiries and concerns. Conceptualizes and employs proactive story angles and campaigns to secure desired PR coverage. Works with national and international PR agencies to ensure consistency and accuracy of worldwide news coverage. Exploits opportunities for product awards and sponsorships. Selects, prioritizes and oversees publicity events and media/analyst tours.

Participates at investor conferences and organizes analyst briefings. Works with Marketing and Product Development to identify and communicate the company's value propositions, and build brand image. Identifies and develops relationships with key press contacts, editors, industry analysts, and key investors. Manages

company press clippings, publication library, and contact database. Organizes and maintains a master calendar of all PR, media events and product reviews. Develops, executes, and tracks industry analyst plans. Participates in the planning and organizing of a corporate crisis management program and process to ensure effective response(s) to unforeseen issues. Provides advice to senior management on corporate positioning within the marketplace and works with cross-functional teams to create long term strategies that build value for the company.

Education/Experience

Requires BS in Marketing, Communication, Journalism or related field and a minimum of 2-3 years corporate and/or public relations experience preferably in a biotechnology or pharmaceutical environment. Strong written and oral communications skills are a necessity. Knowledge of basic design/layout/graphic principles and corresponding software programs is preferred. Extensive knowledge of top business publications and their editorial needs is highly desirable.

Approximate Salary Range

TBA

Government Relations Manager

Job Description

Responsible for a variety of activities involving community and government relations, public policy and communications including major, high profile projects with emphasis on community benefit investments, implementing legislation and new community programs. Activities include public speaking engagements, active involvement in community-based organizations, and maintaining various relationships in the community. Serves as a corporate liaison between the news media and government agencies in support of political action committees and key industry associations, special events coordination for Government Affairs and political fundraisers, and internal & external fundraising. Tracks and monitors lobbying activities and legislation, and assists in the management of government affairs issues.

Keeps the public informed about the activities of government agencies and officials. Prepares and distributes internal communication for public awareness campaigns, to ensure consistent corporate image and message. Maintains database of key government and media contacts used for external communication efforts. May assist with media relations programs, including research and development of press releases, media kits, and special interest stories.

Education/Experience

Requires BS (or equivalent) in English, Journalism, Public Relations, or Communications and 3-4 years experience in corporate communications, public relations, legislative and/or public policy analysis preferably in a biotechnology or pharmaceutical environment. A thorough understanding of corporate political

action committee administration and the political process is required. Strong verbal and written communication skills are a necessity. Experience working with elected officials, staff and governmental agencies is highly desirable. Experience with political action committees and fundraising including special event planning/execution is preferred.

Approximate Salary Range

TBA

Director of Human Resources

Job Description

Directs the activities and staff involved in developing and maintaining Human Resources (HR) activities, policies and procedures. Identifies legal requirements and government reporting regulations affecting HR and directs the preparation of information requested for compliance. Acts as a primary contact with labor counsel and outside government agencies. Directs organizational planning process including the organizational structure, succession planning, job design, and manpower forecasting. Oversees the development and management of wage and salary structures, pay policies, performance appraisal programs, disciplinary actions, employee benefit program and services, and company health and safety programs. Selects and coordinates use of insurance brokers, insurance carriers, pension administrators, training specialists, labor counsel, and other outside resources. Advises senior management on all HR related issues including recruitment practices/procedures, career development, promotions, transfers, retention, continuing education/training, compensation reviews, hiring/firing decisions, exit interviews, conflict resolutions, and employee relations.

Education/Experience

Requires BA/BS in Business, Liberal Arts, a graduate degree is preferred, and a minimum of 10-15 years HR management experience. Thorough knowledge of HR functions, particularly in the areas of organizational development, compensation, and employee relations is essential.

Approximate Salary Range

\$110,000 - \$128,000

Human Resources Representative

Job Description

Administers one or more Human Resources programs including salary administration, recruitment, staffing and retention, diversity, benefits administration, workers compensation, training, and employee relations. Provides counsel and assistance with performance management issues, workplace concerns, employment legislation, discipline, and terminations. Insures compliance with all government programs including affirmative action, anti-discrimination, ADA, OSHA, FMLA, and wage and hour regulations. Advises new and existing employees on benefit eligibility, amounts of coverage, and claim procedures. Oversees the maintenance of benefit records and ensures the

necessary documentation is processed to implement desired benefit coverage. Handles all Workers' Compensation claims and manages the annual benefit open enrollment process.

Provides administrative support to the HR department, including data entry, photocopying, data collection, and filing. Maintains and updates employee information. Codes and distributes resumes, creates new hire offer packages, post jobs internally and externally, types job descriptions, and creates and distributes interview schedules. Administers new hire orientations and exit interviews and processes all associated paperwork. Collates recruitment and benefit packets as well as other written materials. Plans and organizes meetings, conferences, employment interviews, and training sessions. Coordinates various human resource metrics including headcount, turnover, and overtime to create, maintain and/or update regular management reports.

Education/Experience

Requires BA/BS in Business, HR, Psychology or related field, and a minimum of 3-5 years experience in benefits administrations, payroll, labor relations or equivalent HR experience in a biotechnology or pharmaceutical environment. Capability and willingness to maintain confidentiality is essential. Excellent verbal and written communication skills are required. Previous recruitment experience is preferred.

Approximate Salary Range

\$40,000 - \$60,000 (may vary based on company size and/or person's level of experience)

Safety Manager

Job Description

Responsible for the development, implementation and management of company-wide safety programs in compliance with OSHA and other relevant regulations to ensure the safety and security of employees and facilities. Establishes risk management and business contingency programs. Maintains Right-to-Know documentation and provides regular, required training to security employees. Acts as first contact response for emergency situations, notifies emergency personnel and performs security investigations throughout the company on a case-by-case basis.

Administers procedures for proper reaction to abnormal and emergency conditions that threaten company personnel, tenants and or property. Coordinates the implementation of safety systems including fire, intrusion, monitoring devices, vehicle/visitor inspection, company identification cards and key issue and control programs. Maintains safety policy procedures and ensures compliance and consistency with company safety policies. Serves as chief liaison with local, state, federal law-enforcement agencies. Hires, trains, and manages security staff. Develops and maintains security officer shift schedules and changeover procedures.

Education/Experience

Requires a high school diploma, BS in business administration preferred, and a minimum of 3-5 years' experience in law enforcement or security management. Prior supervisory experience and a broad knowledge of security matters encompassing legal principles, fire and safety rules and regulations, electronic security and alarm systems, fire fighting, exposure to firearms, and communications and other related security devices is preferred. Must be certified in CPR and qualified in Basic First Aid. Certified Protection Professional (CPP) certification is a plus.

Approximate Salary Range

\$55,000 - \$70,000 (may vary based on company size and/or person's level of experience)

Receptionist**Job Description**

Manages switchboard and front desk operations. Answers and redirects telephone calls. Meets and greets customers. Opens, sorts and distributes incoming mail and processes outgoing mail. Processes repetitive documents and exercises editing responsibility for correct spelling, punctuation and language. Updates and maintains Master Schedule for staff members' weekly schedules.

Responsible for organizing, maintaining inventory, receiving and dispersing office supplies. Maintains professional appearance of front office, kitchen, conference rooms, and other public areas. Monitors office equipment and coordinates servicing. Assists other departments as needed, performing clerical tasks as assigned (copying, faxing, filing, ordering supplies etc.).

Education/Experience

Requires a high school diploma and a minimum of 1-2 years' varied administrative support and receptionist experience. Other equivalent combinations and education including completion of administrative support or business courses may be considered. Good written and verbal communication skills are required.

Approximate Salary Range

\$25,000 - \$30,000

Administrative Assistant**Job Description**

Responsible for a wide variety of general administrative duties including filing, faxing, photocopying, preparing correspondence, maintaining calendars, coordinating video conferencing and teleconferencing, making travel arrangements and managing itineraries. Manages and prioritizes internal and external communications (including Email, as necessary). Arranges and provides support for large internal/external meetings including taking minutes, and the distribution of pre and post meeting agendas, programs, presentations/briefing documents. Designs and prepares presentations, assists in specialized projects,

and coordinates on and off-site meetings as needed.

Education/Experience

Requires a high school diploma, a BA/BS is preferred, and a minimum of 1-3 years administrative experience. Strong initiative, communication, interpersonal, organizational and computing skills are required.

Approximate Salary Range

\$35,000 - \$55,000 (varies based on level of management supported and/or person's level of experience)

Manager of Information Systems

Job Description

Manages information systems and computer resources for the entire organization. Oversees the organization's Computer Operations, Systems and Programming, Technical Support Services, Communication Network and User services. Acts as a liaison between senior management and the computer staff (data processing, information systems, network services etc.). Manages the department's budget. Develops disaster recovery plans and manages back-up and security systems. Hires, trains, and supervises information systems staff. Manages user requirement definition and development, application development, system configuration and testing, installation, implementation of ongoing support, system enhancements/upgrades and bug fixes. Responsible for the introduction of new systems and hardware/software rollouts.

Education/Experience

Requires BS in Computer Science or Business Administration, an MS or MBA may be required for senior level positions in larger companies, and a minimum 5-8 years MIS management experience. Knowledge and experience of process modeling, reengineering and systems analysis is preferred.

Approximate Salary Range

\$80,000 - \$90,000

Systems Analyst

Job Description

Designs, customizes, and implements new software and supports existing legacy and packaged software systems. Interprets business needs into functional requirements and program specifications, defines business process flows, develops prototype screens and reports for new/existing system enhancements, and builds test plans, test criteria and scenarios. Collaborates with Analysts/Programmers to drive and oversee the development and implementation process. Supports all phases of system testing, user training and system deployment, and assists in creation of related documentation. Provides on-going application support, research and diagnostics on all production systems and manages the entire lifecycle for IT deliverables. Provides strategic advice to business units by defining and/or developing business processes/procedures and researching and identifying enabling systems/technologies. Provides technical support to business unit by analyzing new software programs and hardware

equipment and conducting cost/benefit analysis.

Education/Experience

Requires BA/BS in Computer Science and a minimum of 3-5 years business/systems analysis experience preferably in a biotechnology or pharmaceutical environment. Demonstrated success implementing packaged software and strong knowledge of the full 'Systems Development Life Cycle' is essential. Strong analytical and problem-solving skills are also required. A broad understanding of technology and a solid understanding of the appropriate application of various technologies is preferred.

Approximate Salary Range

TBA

Analyst/Programmer

Job Description

Designs, develops, codes, tests, debugs, and documents programming applications to satisfy requirements of one or more user areas. Typically provides 24-hour daily production and technical support to assigned systems. Provides comprehensive consultation to business units, business analysts and IT management and staffs at the highest technical level. Provide programming and proper usage support to users of Business systems. Assists with the creation and modification of custom reports, specified by users and is involved in all aspects of application development, system configuration, system testing, installation, and implementation of system enhancements/upgrades and bug fixes. Other duties may include User Acceptance Testing and End User training.

Education/Experience

Requires BS in Computer Science or related area, and a minimum of 3 years programming experience in a scientific or technical environment. Proficiency in programming languages like C/C++, Perl, SQL, HTML, and JAVA and knowledge of mixed operating systems environments (e.g. UNIX, Windows NT, Sybase, Oracle etc.) is required. Structured programming skills, problem-solving abilities, and strong diagnostic capabilities are essential. Extensive knowledge of relational databases, commercial report writers, and proficiency in PC software is preferred.

Approximate Salary Range

\$65,000 - \$75,000

Librarian

Job Description

Assists the Library Services Manager in all library operations including acquisition and organization of print and electronic resources, references services, long range planning for the library, and staff orientation in the use of electronic information resources including integrated library systems, web browsers, and search engines. Conducts statistical, financial, scientific, patent and/or business information searches in support of the organization's research and development efforts as needed.

Software management related duties (if applicable) focus on the migration of source code and files to production systems, management and maintenance of version control, release and migration documentation, access authorization for developers, testers, etc. and deployment of software releases or rollouts.

Education/Experience

Requires BS/MS in Science and/or MSL (Masters in Library Science), and a minimum of 1-3 years' experience in a pharmaceutical or biomedical library. Knowledge of non-traditional information resources, such as CD-ROMs, online databases, and the Internet is essential. Other requirements (if applicable) include working knowledge of software version control, release and migration packages.

Approximate Salary Range

TBA

Patent/IP Attorney

Job Description

Works as an in-house counsel in the preparation and prosecution of patent applications, development and maintenance of the company's intellectual property (IP), and the development of intellectual property strategies and policies. Reviews, negotiates and drafts license, research, technology, material transfer agreements for IP consideration and protection. Reviews intellectual property provisions of various contractual arrangements and assists in rendering opinions on validity and infringement. In coordination with licensing counsel, drafts opinions and develops legal strategies for the company's business and research endeavors, and is involved in all copyright, trademark and litigation matters. Interacts extensively with scientists and counsels in-house clients on general contract, commercial and intellectual property issues. Depending on the size of the company may also be responsible for the supervision of patent support staff.

Education/Experience

Requires JD degree (Juris Doctorate) and BS in Science or related field, advanced degree preferred, and a minimum of 10 years experience in all aspects of US/Foreign intellectual property and patent laws relating to biotechnology. Must be admitted to practice before a state bar in the US patent Office. Experience with biotechnology and/or pharmaceutical patent prosecution, contract work and technology licensing as well as intellectual property strategy development and implementation is essential.

Approximate Salary Range

\$130,000 - \$140,000

Labor/Employment Law Attorney

Job Description

Provides legal representation, counseling and guidance in matters concerning labor relations, employment discrimination, occupational safety and health, affirmative action, unemployment compensation, wage and hour regulation,

wrongful discharge and other matters related to the employer-employee relationship. Represents company before state and federal courts, and/or administrative and arbitration tribunals, and during collective bargaining negotiations and labor arbitrations. Counsels company in all aspects of employee benefits law, including the design, implementation and operation of qualified retirement plans, welfare benefit plans and executive compensation programs; statutory and regulatory compliance; governmental filings and representation before regulatory agencies; issues relating to pension and welfare funds and employee benefits litigation.

Works with employer to insure compliance with new federal and state employment statutes and regulations, and advises management on employment issues such as hiring and firing, contract interpretation, non-compete, confidentiality and separation agreements, sexual harassment, Family and Medical Act (FMLA) and Fair Labor Standards Act (FLSA).

Education/Experience

Requires JD degree (Juris Doctorate) and BS in Business Administration or related field, and a minimum of 3-5 years labor and employment litigation experience in a large law firm or a combination of law firm and corporation. Strong practice experience in Title VII, ADA, FLSA, WARN, OSHA, FMLA, wrongful termination, discrimination claims and traditional labor law is essential. Knowledge of current legislative and regulatory changes in the employment area is preferred.

Approximate Salary Range

TBA

Contract Attorney

Job Description

Provides legal counsel and service on corporate, regulatory, judicial and legislative issues. Prepares contracts, amendments, subcontracts, subleases and non-standard agreements, as required. Analyses contracts, RFPs/RFQs, product acquisition agreements, and commercial leases from other firms for conformity and negotiates optimal terms. Identifies risk exposure; advises executive management on contractual obligations and issues; interfaces with corporate Contracts Department to escalate contract risks, and establishes and maintains document control management procedures. Keeps current on legislative issues, statutes, decisions, and ordinances of judicial bodies. Examines legal data to determine advisability of defending or prosecuting lawsuit. Provides legal guidance to staff and may act as agent of the corporation in various business transactions.

Education/Experience

Requires JD degree (Juris Doctorate) and BS in Business Administration or related field, and a minimum of 3-5 years experience in commercial litigation. Familiarity with all legal requirements involved in contractual dealings and a thorough knowledge of contract regulatory law is required.

Approximate Salary Range

TBA

Job Descriptions**Business Development:****Business Development and Marketing/Sales**

Note: The approximate salary ranges quoted here are estimates only. Salary structures within any company may vary based on company size, geographical location, labor market, level of experience, and/or educational qualifications.

Vice President of Business Development**Job Description**

Identifies, evaluates and pursues the strategic and financial prospects of new market opportunities. Directs the assessment of future markets and licensing potential and is responsible for coordinating commercial input to specific programs as necessary. Establishes new scientific and strategic partnerships, joint ventures and alliances. Follows-up on all partnership activity including the tracking, documentation and status reporting of all collaborations along the business development pipeline. Establishes and implements appropriate development strategies to support commercialization and licensing strategies. Interacts with existing corporate contacts, facilitates communication, keeps tracks of milestones and identifies scope for enhancing these relationships. Oversees the plan and execution of a comprehensive marketing strategy including responsibility for the preparation of presentation and marketing materials for professional meetings, seminars and conferences.

Education/Experience

Requires MBA and science degree with a minimum of 8 years business development experience in a biotech/pharmaceutical environment. Prior experience in dealing with corporate partners and in negotiating and completing agreements is required. A thorough understanding of the processes of due diligence, asset valuation, alliance integration and portfolio management combined with a scientific and business acumen is also desirable.

Other requirements may include extensive contacts in the pharmaceutical/biotechnology industrial community relevant to the licensing of targets, leads and drugs.

Approximate Salary Range

TBA Other requirements may include extensive contacts in the pharmaceutical/biotechnology industrial community relevant to the licensing of targets, leads and drugs.

Director of Business Development**Job Description**

Manages the identification, evaluation, and development of pharmaceutical and

biotechnology prospects for new business opportunities. Develops proposals and term sheets for prospects and manages the day-to-day aspects of closing, including the utilization of legal counsel, and coordination with accounting, finance, human resources and other functional areas. Performs market research, analyzes new market opportunities and pursues new business opportunities. Organizes, tracks, documents and reports on the status of all prospects in the business development pipeline. Participates in the development and execution of a comprehensive marketing strategy, including sales and presentation materials, marketing communications, and industry trade shows and conferences. Also participates in the development of strategic partnerships, joint ventures and alliances, as well as technology and intellectual licensing opportunities, with industry, academia and government agencies.

Education/Experience

Requires BS, MBA is strongly preferred, with a minimum of 8 years experience in selling, networking, and negotiating contracts with pharmaceutical and biotechnology companies at the executive level, specifically within the drug discovery and development areas. Strong business acumen, organizational and analytical skills are required.

Approximate Salary Range

TBA

Manager of Corporate Planning

Job Description

Responsible for managing the financial planning processes including long-range/strategic planning and short-range/tactical planning for the company. Designs and refines financial planning processes and coordinates the execution of those processes across various operating groups. Participates in setting targets and planning guidelines. Assists the CFO in crafting and presenting key messages regarding the corporation's financial plans and outlook to internal audiences (including executive management team and Board of Directors) and external audiences (including securities analysts and key investors). May perform and coordinate special analysis projects for the CFO as required. Conducts competitive analysis by monitoring the competitive environment and reports on developments with significant potential to impact future business prospects. Provides finance support for key functions including IT, HR, Legal, Business Development and Finance.

Education/Experience

Requires BS/BA with a minimum of 8 years financial planning and analysis experience. MBA is preferred.

Approximate Salary Range

TBA

Business Development Research Analyst

Job Description

Provides detailed market analysis and competitive intelligence on a periodic or

project basis. Assists Director in the formulation and execution of strategies and tactics required to achieve business development goals and advises executive management in the definition and development of investment growth strategies for the company. This includes assessing and pursuing expansion, acquisition and partnering opportunities as well as managing the activities and processes for diversification and business growth in line with the corporate strategic plan. Works with internal and external counsel to evaluate intellectual property of licensing and acquisition candidates. Provides recommendations to facilitate partnering decisions, including design of deal structures and alternatives. Negotiates and maintains research agreements with investigators and their institutions. Secures licenses required for ongoing discovery and development operations and maintaining long-term partner relationships.

Education/Experience

Requires a BS in scientific field, MS or PhD is preferred and a minimum of 3-5 years experience in biotechnology/pharmaceutical business development or licensing environment. Experience in strategy consulting, investment banking or corporate partnering/deal making processes is highly desirable.

Approximate Salary Range

TBA

Vice President of Marketing

Job Description

Develops and implements strategic and tactical marketing programs to drive revenue growth and product contributions. Accountable for all aspects of brand performance including identifying business issues and creating solutions to drive brand performance. Develop brand strategies and manage implementation of brand campaigns and programs. Monitors brand revenue and expense forecasts to achieve revenue and earnings targets. Manages all vendor and agency relationships to achieve maximum Return on Investment (ROI) on all marketing programs. Maintains and develops marketing staff. Provides appropriate direction to field sales team to assure optimal execution of all programs. Works with Corporate Development, Project Management and senior management regarding strategic planning and product development. Works with research professionals to provide commercial input to the development of new products.

Education/Experience

Requires a BS in scientific field, MBA is highly desirable and a minimum of 2 years strategic marketing experience and 4 years marketing experience in biotechnology/pharmaceutical business development environment. Prior experience in successful product launches is desirable.

Approximate Salary Range

TBA

Marketing Research Analyst

Job Description

Provides information on marketed and pipeline products, including assessment of

strategic direction and marketplace analysis. Uses primary and secondary qualitative and quantitative market research data to create financial models and provide analytical support to existing and new marketing and sales strategies. Researches market trends, awareness, adoption and attitudes of newly launched products. Analyzes provider, patient and other relevant data sets to support targeting strategies for sales and marketing promotions. Advises management on competitive activities and strategies and performs market research to support business development, including market assessment, feasibility, profitability and strategic fit. May interface with external partners, vendors or clients, to support both direct and indirect market research efforts. May be expected to deliver regular communications and/or briefings in support of strategic efforts, global market awareness and product development activities.

Education/Experience

Requires BS in Economics, Econometrics, Statistics or financial analysis combined with 1-3 year's experience in data analysis and marketing research in a healthcare/pharmaceutical environment. Exceptional verbal and written skills are required to effectively synthesize information and communicate direction to management.

Approximate Salary Range

TBA

Product Marketing Manager

Job Description

Responsible for managing all aspects of product marketing, product strategy and development, strategic planning and creation and implementation of marketing strategies. Specific responsibilities include business case development for new/existing product initiatives, launch plan creation, management of product life cycle, and high level technical and sales support to internal and external groups. Provides direction to sales training to identify training needs and interfaces with Sales Managers and Sales Consultants to identify and address product issues/opportunities. Works with Market Research to develop sales forecasts and identify primary and secondary market research needs. Manages marketing resources and builds and sustains relationships with internal and external customers. Also involved in product definition, product feature positioning, forecasting, competitive analysis, solution pricing, and development of marketing materials.

Education/Experience

Requires a BS or MS in life sciences or a related discipline; MBA is desirable, plus 3-5 years experience in marketing with emphasis on market strategy, product development and business case analysis in a life science research environment.

Approximate Salary Range

TBA

Job Descriptions

Project Management:

Project Management for all departments in the company

Note: The approximate salary ranges quoted here are estimates only. Salary structures within any company may vary based on company size, geographical location, labor market, level of experience, and/or educational qualifications.

Director of Project Management

Job Description

Oversees project development efforts for strategic programs and projects. Coordinates and develops yearly programs, strategic plans and annual project budgets. Provides direct input into corporate strategic planning, development management processes, critical path issues/solutions, resource management, and project management from conception through development cycle. Responsible for managing multiple global cross-functional project teams simultaneously and reporting project status to executive management. Collaborates with senior project managers, functional directors and managers to assure integration of project, company, and functional goals towards achieving project milestones and timetables. Identifies issues that may delay product or project and recommends appropriate action to be taken. Supports overall team function and project managers in their strategic function.

Education/Experience

Requires BS/MS, PhD preferred in life sciences, MBA degree is preferred and a minimum of 8 years experience in a pharmaceutical or biotechnology environment. A background in Chemistry, Biochemistry, Medical or Pharmaceutical Regulatory Affairs is important and demonstrated experience managing interdisciplinary development teams is required.

Approximate Salary Range

\$110,00 - \$145,000

Associate Director of Project Management

Job Description

Ensures scientific research, clinical studies, or biomanufacturing projects are completed on time, on-schedule and within budget. Establishes project milestones, manages program budgets/work plans, and ensures that the resources assigned to projects are adequate to meet program objectives. Monitors project expenses against budget and works with project managers and project teams to identify risks, contingencies and alternatives. May assist in the facilitation, motivation and evaluation of project team members. Manages all project and client communications including team meetings, client meetings, budget reports and progress reports.

Education/Experience

Requires BS/MS in life sciences, MBA or Post-Graduate Level science degree is

preferred, and a minimum of 5 years project management experience in a pharmaceutical or biotechnology environment. A fundamental understanding of drug development processes and strategies are also helpful.

Approximate Salary Range

TBA

Project Manager

Job Description

Manages all daily project management activities, including project schedule development, project budget, team leadership, intra-division liaison, project communication, staffing activities, status reporting, and resource plan development. Identifies and tracks critical path/activities, risks, contingencies and alternatives. Supervises and mentors team members and ensures team members understand project objectives, specifications, deliverables, timelines and tasks. Other responsibilities include recording meeting minutes, tracking action items, preparing meeting agendas, coordinating global and sub-team activities and disseminating project information.

Education/Experience

Requires BS in scientific discipline, MBA a plus and a minimum of 3-5 years staff management or supervisory experience in a pharmaceutical or related industry.

Approximate Salary Range

\$70,000 - \$90,000

Project Assistant

Job Description

Responsible for performing departmental project management activities as assigned by a supervisor or project manager. Duties typically include the collection of project plan updates, maintenance or modification of project plan documentation and the preparation/distribution of project status reports. Other responsibilities may include assisting the project manager in the identification and scheduling of project deliverables, milestones, and required tasks, and/or establishing standards for project reporting and documentation.

Education/Experience

Requires BS in scientific discipline and a minimum of 3 years related experience in a pharmaceutical or related industry.

Approximate Salary Range

TBA

