

JOB DESCRIPTIONS

ANIMAL HANDLER – Usually, responsibilities are limited to receiving and caging animals and preparing groups of animals for studies. Utilized for restraining animals during various procedures and clean up of area of use.

ASSAY ANALYST – Responsible for doing cell cultures and performing assays and tests on tissue and cell cultures following SOP's. They may prepare glassware, reagents and media for cell culture use. They also perform, prepare and maintain tissues and cell cultures and maintain records required by GMP's. They also participate in the modification of assay procedures.

BIOCHEMICAL DEVELOPMENT ENGINEER – Responsible for the design and scale-up of processes, instruments and equipment from the laboratory through the pilot plant and manufacturing process. Assists manufacturing in problem solving with regards to equipment and systems. Develops and recommends new process technologies (see **PROCESS DEVELOPMENT ENGINEER**).

BIostatistician – Works with others to define and perform analyses of databases for publications, presentations at investigator meetings and meetings of professional societies. Usually requires a master's degree in biostatistics and 1-4 year's experience.

BUYER/PURCHASING AGENT – Responsible for obtaining materials, scientific equipment and services. Checks requisitions, obtains price quotes, examines bids and awards contracts. Develops new supply sources where vendors/suppliers are inadequate. Coordinates purchasing activities with other departments to maintain a planned inventory level. Monitors the cost, schedule and scope of assigned subcontractors to ensure the quality and value of contract(s).

CLINICAL COORDINATOR – Must be familiar with scientific/investigative process, however expertise may be limited to a specific functional area. Good oral and written communications skills a must. Project team experience and familiarity with standard computer programs essential. Coordinates the clinical development plan as outlined by company or Clinical Department, defines objectives, strategy and studies. Provides support for planning including detailed effort estimates, variances and conflicts and analyses and recommends solutions. Often responsible for project staffing requirements and tracking drug supply to outside vendors as well as providing ongoing, objective updates on progress/problems with projects.

CLINICAL DATA SPECIALIST – Responsible for collaborating with various departments on the design, documentation, testing and implementation of clinical data studies. Develops systems for organizing data to analyze, identify and report trends. Analyzes the interrelationships data and defines logical aspects of data trends.

CLINICAL PROGRAMER – Responsible for coordinating and monitoring the flow of clinical data into the computer database. Analyzes and evaluates clinical data, recognizes inconsistencies and initiates the resolution of data problems. Implements data management plans designed to meet project and protocol deadlines and consults in the design and development of clinical trials, protocols and report forms. May also act as a liaison between clinical management and subcommittees and project teams on an as-needed basis.

CLINICAL RESEARCH ADMINISTRATOR – Responsible for the clinical data entry and validation to ensure legibility, completeness and consistency of data. Assists users with requests for clinical documents and responsible for working with physicians and /or their staff to clarify any questionable information. May also be responsible for auditing internal patient files and studies and assisting with the development and evaluation of clinical record documents.

CLINICAL RESEARCH ASSOCIATE – Responsible for the design, planning, implementation and overall direction of clinical research projects. Evaluates and analyzes clinical data and coordinates activities of associates to ensure compliance with protocol and overall clinical objectives.

CRIMINAL IDENTIFICATION SPECIALIST – See Forensic Scientist

CRIMINAL INTELLIGENCE SPECIALIST – See Forensic Scientist

CRIMINALIST – See Forensic Scientist

DIRECTOR OF MANUFACTURING – Oversees all activities throughout the various areas of manufacturing usually from raw material procurement through filling and packaging. Responsible for overall financial, personnel, engineering, GMP/GLP issues and in process quality integrity within the manufacturing department. May include some responsibilities for patent applications.

DIRECTOR OF MARKETING – Responsible for overall management of the sales/marketing functions of a facility. Includes responsibility for sales forecast, budgeting for department and to an extent the company, technical assistance to customers and technical writing for sales brochures and labels/product inserts. Responsible for insuring registration of trade names and trademarks. Maintains a close relationship with Manufacturing to insure adequate product flow and with R&D in development of new products.

DIRECTOR OF R&D – Responsible for management of all R&D activities via interaction with the various Project Managers. Responsible for insuring timely patent applications. Insures assay development for products and the transfer of necessary technical information to Manufacturing and Regulatory Affairs.

DIRECTOR OF REGULATORY AFFAIRS – Responsible for the overall activities of the Quality Control and Quality Assurance Departments. Insures that all processes/equipment have been properly qualified and validated and that all plant activities are carried out in compliance with all pertinent GLP/GMP guidelines. Reviews all production batch records, outlines of production, SOP's, qualification protocols, and validation protocols to insure that they are valid and in compliance. Oversees QC's activities in release of final product for sale. Usually reviews all product labeling to insure that it complies with all outside agency specifications.

DOCUMENTATION SPECIALIST – This position is separate and different from that of Documentation Coordinator. This position generally requires a BS degree in an appropriate field as well as two years experience in documentation, QA, technical writing, etc. Responsible for coordinating all activities related to providing required documentation and implementing related documentation systems. Coordinates the review and revision of procedures, specifications and forms. Assists in compiling regulatory filing documents and in maintaining computerized files to support all documentation systems.

DRUG EXPERIENCE COORDINATOR – Responsible for handling the drug experience activities for marketed products. Provide drug information on the products. Oversee the day-to-day processing of adverse event information for marketed products and coordinate the receipt, classification, investigation and processing of adverse experience reports.

ENVIRONMENTAL HEALTH AND SAFETY SPECIALIST – Responsible for developing, implementing and monitoring industrial safety programs within a company. Inspects plant areas to ensure compliance with OSHA regulations. Evaluate new equipment and raw materials for safety and monitors employee exposure to chemicals and other toxic substances. They are responsible for monitoring all waste materials generated in a manufacturing environment and ensuring that wastes streams are being disposed of in a manner compliant with local, state and federal regulations. They conduct safety-training programs as required by federal and state OSHA guidelines. They may also be responsible for training employees in hazardous waste collection, disposal and radiation safety programs.

FACILITY/EQUIPMENT ENGINEER – Generally responsible for the purchasing, installation, monitoring and upkeep of distribution systems for incoming public utilities. In many companies, also responsible for compressed air, steam, vacuum , and WFI systems.

FERMENTATION ENGINEER – Responsible for the selection, purchase and installation of all plant fermentation systems. Ensures that air and steam supplies are of a quality required for the fermentation applications. Works with Qualification and Validation Engineers/Technicians to bring equipment on line. Provides problem solving in areas of contamination control, DO control, agitation/shear control, pH control, ORP control, etc.

FORENSIC SCIENTIST – It is very difficult to provide a collective title to many of the job duties in the area of Forensic Science. It appears to vary widely from state to state and country to country as to job titles for personnel performing seemingly identical duties. Following is a wild stab at attempting to provide titles matched to job duties for personnel in forensic science that may utilize a biotech/biological science degree. Criminalist; Laboratory Technician, Criminalist; Forensic Specialist; Forensic Serologist; Forensic Analyst; Crime Laboratory Analyst; - All of these job titles seem to have very similar or identical duties. Main duties are crime scene investigation, physiological fluid analysis, blood typing, DNA analysis, controlled substance analysis, blood alcohol analysis, spectroscopic analysis, HPLC, and GC analysis. Job positions without experience begin in the laboratory. As one advances in grade i.e. Senior Criminalist, Forensic Specialist 2 or 3 etc. duties may expand to testifying in court, directing the activities of other personnel etc.

Forensic Entomologist – Investigation of crimes/crime scenes based upon insects present.

FORENSIC TECHNOLOGIST – See Forensic Scientist.

GLASSWASHER – Responsible for washing and drying glassware and distributing it to the appropriate location(s). They may also be responsible for decontamination of the glassware prior to cleaning in some circumstances. Maintains the glass washing facility and picks up dirty glassware from appropriate areas. Performs routine maintenance of glass washing equipment. Prepares/wraps glassware/equipment for sterilization. In some cases, they may actually be responsible for the sterilization of glassware/equipment by autoclaving or in a dry air oven.

GLP/GMP AUDITOR – Observes actual laboratory procedures in process to insure that they are being performed in a manner compliant with GLP/GMP requirements. Prepares reports of actual observations and submits reports to the company's Compliance Officer.

GLP/GMP COMPLIANCE OFFICER – Reviews reports sent by GLP/GMP Auditor. Prepares reports of deviation from GLP/GMP to appropriate departments. Reviews batch records and in house SOP's to ensure that all comply with cGMP or GLP. Reviews manufacturing outlines prior to submission to appropriate agencies to ensure GMP/GLP compliance. Accompanies any inspectors from various regulatory agencies and assists in response to any citations from regulatory agencies.

GREENHOUSE ASSISTANT – Makes detailed observations detecting horticultural or pest problems and institutes corrective actions. Determines the optimal cultural conditions and performs tasks related to disease and pest prevention. May be required to collect, record and analyze data and interpret results. Troubleshoots and maintains greenhouse equipment.

HUMAN RESOURCES REPRESENTATIVE – Responsible for a variety of activities in personnel administration including employment, compensation and benefits, employee relations, EEOC and training programs. Conducts job interviews, counsels employees, maintains records and conducts research and analyzes data on assigned projects.

LIBRARY ASSISTANT – Maintains serial control and locates and orders journal articles and/or books that are unavailable locally. Performs special data gathering projects as requested and is responsible for on-line computer searching of scientific databases.

MANUFACTURING ASSOCIATE – See Manufacturing Technician in current book.
MANUFACTURING ENGINEER – Responsible for developing, implementing and maintaining methods, operation sequences and processes in manufacturing. Works with the engineering department to coordinate the release of new products. Estimates manufacturing costs, determines time standards and makes recommendations for process requirements of new or existing product lines. Maintains records and reporting systems for the coordination of manufacturing operations as required.

MANUFACTURING MANAGER – Oversees the overall operation of a specific manufacturing area. Responsible for preparation of initial record packets for submission to regulatory agencies. Responsible for supervising capital improvements within designated area and adherence to areas expense budget. Interviews potential new hires/transfers into area. Insures that all batch records and SOP's are kept up to date and that they are compliant with all regulatory statutes.

MEDIA PREPARATION TECHNICIAN – Responsible for production of all necessary media for all or specific areas within a company. Weighs, formulates, sterilizes and dispenses all necessary media. May perform growth parameter studies and sterility tests on each media batch. Responsible for equipment cleaning and maintenance and raw material inventory.

PACKAGING OPERATOR – Responsible for final packaging of filled product. Ensures that product is properly labeled and packaged in correct configuration. May be responsible for maintaining two discrete areas; one for unreleased product and one for released product. Ensures that proper up to date labels, inserts and outer packaging materials have been used. Responsible for maintaining all packaging equipment. Maintains inventory control of all labeling materials.

PATENT ADMINISTRATOR – Responsible for preparing and coordinating all procedural documentation for patent filings and applications. Tracks in house research studies and recommends the need for and timing of patent filings. Assists attorneys with the drafting and editing of patent applications and collects and evaluates supporting data. Maintains a tracking system to comply with trademark regulations. May assist with the determination of the necessity and approach to contracts to ensure protection of proprietary technology. Usually responsible for tracking and submission of payment for legal fees.

PATENT AGENT – Responsible for the preparation, filing and processing patent applications. Negotiates and drafts patent licenses and other agreements. Conducts state of the art searches and may assist with appeal and interference proceedings.

PLANT BREEDER – Responsible for the design, development, execution and implementation of plant breeding research projects in collaboration with a larger research team. May be responsible for project planning and personnel management within the project. Uses exotic germplasm and works with various mating systems and integrates them with biotechnology as needed to enhance selection methods and accelerate product development.

PLANT MANAGER – Responsible for overall operations of a specific plant/operation. Responsible for development and monitoring of all budgetary processes. Ordinarily, all departments' managers report to the plant manager. The plant manager must have a broad range of skills including knowledge of basic engineering, manufacturing, purchasing, quality control, filling, packaging, etc.

POSTDOCTORAL FELLOW – A PhD that usually has little to no experience that joins the staff for two to three years to gain necessary experience.

PROCESS DEVELOPMENT ASSOCIATE – Responsible for implementation of production procedures to optimize manufacturing processes and regulatory requirements. Assist in creating scalable processes with improved product yield and reduced manufacturing costs. Researches and implements new methods and technologies to enhance operations. May be involved in packaging and distribution processes and in the maintenance of production equipment. Works closely with R&D and usually responsible for the transfer of new products from R&D into Manufacturing.

PROCESS DEVELOPMENT ENGINEER – Works with the Process Development Associate to research, recommend and install necessary production equipment to implement new product production. Assists in modification of existing equipment to efficiently produce new or reworked product lines.

PRODUCTION PLANNER/SCHEDULER – There is both a Marketing and a Manufacturing function to this job. Those functions in marketing involve converting figures from Sales Representatives and/or Market Research Analyst into requirements of certain configurations of salable product over some period of time (i.e. a market or sales forecast). The function in Manufacturing involves in converting those configurations into numbers of batches of product required to ensure salable products available at the required time. The Manufacturing function requires a very good understanding of the production processes, QA requirements, and regulatory time factors.

PROFESSIONAL CONSULTANT – Usually a person in business for themselves. Usually has a broad knowledge of most aspects of a various field(s). They may consult for a company in any of the listed job functions.

QUALIFICATION ENGINEER – Under cGMP's, all pieces of equipment must be proven capable of adequately and consistently performing the function for which they are intended. This job function involves in determining what parameters are necessary to prove and preparing a "Qualification Protocol". The Engineer then works closely with

the Qualification Technician to insure that the protocol covers all necessary aspects and that the technician carries out the protocol as designed. This step and job function is sometimes combined with that of Validation Engineer.

QUALIFICATION TECHNICIAN – Responsible for testing equipment to ensure that it consistently performs in a given manner by utilizing the “Qualification Protocol” developed by the Qualification Engineer. Prepares a written report for the Qualification Engineer relating performance vs. protocol.

QUALITY ASSURANCE AUDITOR – Responsible for performing audits in manufacturing and quality control to ensure compliance to in house specifications, standards and GMP’s.

QUALITY CONTROL ANALYST – Responsible for conducting routine and nonroutine analysis of raw materials. Compiles data for documentation of test procedures and reports abnormalities. Reviews data obtained for compliance with specifications and reports abnormalities. Revises and updates SOP’s and may perform special projects on analytical and instrument problem solving.

QUALITY CONTROL ENGINEER – Responsible for developing, applying, revising and maintaining quality standards for processing materials into partially finished or finished products. Designs and implements methods and procedures for inspecting, testing and evaluating the precision and accuracy of products and prepares documentation for inspecting testing procedures. May also be responsible for ensuring conformance to in house specifications and GMP’s and may conduct training programs.

R&D PROJECT MANAGER – Responsible for the overall direction of a specific project(s) within the R&D department. Usually has a group of Research Assistants and Technicians that work on that/those specific project(s). Prepares Gant charts and insures that the project stays on schedule and on budget. Usually also responsible for overseeing the development of necessary QC tests to determine safety, purity an efficacy.

REGULATORY AFFAIRS SPECIALIST – Coordinates and prepares document packages for submission to regulatory agencies, internal audits and inspections. Compiles all materials required for submissions, license renewals and annual registrations. Monitors and improves tracking and control systems and keeps abreast of regulatory procedures and changes. They may work with regulatory agencies and recommend strategies for earliest possible approvals of clinical trial applications.

RESEARCH ASSISTANT – See job description of Research Associate already in book.

SCIENTIFIC PROGRAMMER ANALYST – Designs, develops evaluates and modifies computer programs for the solution of scientific or engineering problems and for the support of research and development efforts. Analyzes existing systems and formulates logic for new systems. Devises logical procedures, prepares flow charts, performs coding tests and debugs programs. Provides input for the documentation of new or existing

programs, and determines system specifications, input/output processes and working parameters for hardware/software compatibility.

STERILE FILLING OPERATOR – Responsible for the aseptic filling of final product into final containers. This may involve the filling of liquids, powders, pastes, devices etc. Ensures that integrity of filling area is not compromised and that all gowning and filling procedures comply with GMP's. Prepares and may sterilize the containers for final filling. Maintains all filling equipment.

STERILE FILLING/PACKAGING SUPERVISOR – Responsible for the overall operation of the aseptic filling area and personnel. Provides training for operators to insure that GMP guidelines for gowning, staging, filling, stoppering/capping, labeling, fill volume checks etc. Ensures that bottles/vials have been properly sterilized and that all validated loading protocols are followed. May also be responsible for interpreting dosimeter readings for gamma sterilization meet the necessary parameters. Ensures batch integrity until product is transferred to labeling and packaging. May also be responsible for integrity testing of any filters utilized to sterilize liquid or gas products.

STERILIZATION TECHNICIAN – Ensures that all materials are properly wrapped/prepared prior to sterilization. Ensures that proper method of sterilization of is used for the materials. Loads sterilizers according to predetermined, validated loading pattern and documents loading, sterilization method, temperatures, humidity, times, cool down etc. Files and maintains all sterilization records. Prepares materials and assists in validation of sterilization procedures.

TECHNICAL RECRUITER – Responsible for recruiting, interviewing and screening applicants for technical exempt and nonexempt positions. Coordinates preemployment physicals, travel, reporting dates, security clearances and employment processing for technical personnel. Conducts advertising and reviews employment agency placements. Maintains college recruiting, affirmative action and career development programs.

TECHNICAL WRITER – Responsible for writing and editing SOP's, clinical study protocols, laboratory procedure manuals and other related documents. Edits and /or rewrites various sources of information into a uniform style and language for regulatory compliance and assists in developing documentation for instructional, descriptive, reference and/or informational purposes.

VALIDATION ENGINEER – Prepares protocols for equipment and/or processes that will demonstrate that the equipment or process will consistently produce a product that meets the in house as well as regulatory agencies requirements for purity, safety and efficacy. Ensures that subsequent SOP's reflect all necessary steps incorporated into the validation protocol. Review reports from the Validation Technicians to ensure that the protocol was followed without exception and that the outcome was satisfactory. Work with various company departments to revalidate equipment/processes if any substantial change is made.

VALIDATION TECHNICIAN – Perform all validation tests on equipment/processes as outlined in the validation protocol. Prepare a report for the Validation Engineer summarizing the tests and results.