



Appendix A. Job Descriptions: Examples

Production Positions

HS Diploma or Two-year Degree Positions

Process Technician. Responsible for the commercial-scale manufacture of the active pharmaceutical ingredient; sets controls, operates and maintains production and separation equipment; weighs, measures and checks raw materials; feeds raw materials into manufacturing equipment; monitors the production and separation equipment and process; ensures that manufactured batches contain the proper ingredients and quantities; maintains records and clean production areas to comply with regulatory requirements, good manufacturing practices, and standard operating procedures; and may also assist with in-process testing to make sure batches meet product specifications.

Manufacturing Prep Process Technician. Responsible for washing, drying and sterilizing glassware; maintains glass-washing facilities and performs routine maintenance on glass-washing equipment; weighs, measures and checks raw materials used in the manufacturing process; prepares media, reagents and buffers; maintains records and cleans the glass-washing and preparation areas to comply with regulatory requirements, good manufacturing practices, and standard operating procedures.

Formulation/Fill Technician. Responsible for preparing the finished product from the purified active pharmaceutical ingredient; operates and maintains equipment such as sterile filling machines; weighs, measures and checks to ensure the manufactured batches contain the proper ingredients and quantities; maintains records and cleans production areas to comply with regulatory requirements, good manufacturing practices, and standard operating procedures.

Packaging Technician. Uses manual and/or automated packaging systems to label, inspect and package the finished product; enters data and imprints computer-generated labels; maintains records and maintains the packaging area to comply with regulatory requirements, good manufacturing practices and standard operating procedures; and may perform initial checks of completed documents for completeness and accuracy.

BS Engineering Positions

Production or Process Engineer in Manufacturing. Designs, develops and implements manufacturing methods and equipment and maintains the day-to-day operation of a manufacturing process, including taking corrective action when required; works directly with operators to ensure that a particular product is manufactured, formulated and packaged according to specifications; works on implementing methods for manufacturing new products; reviews current methods for cost effectiveness and makes recommendations for process improvements for existing product lines; prepares reports, feasibility studies and cost analyses of processes; and maintains records and reporting systems for the coordination of manufacturing operations.

Process Engineer in Process Development. Responsible for the design, scale-up and validation of new processes from laboratory through pilot plant to large-scale manufacturing; participates in the design and start up of new manufacturing facilities, instruments and equipment; optimizes existing processes by developing and recommending new process formulas and technologies to achieve cost effectiveness and product quality.

QC/QA Positions

Two-year Degree Positions

Quality Control Assistant. Conducts routine and non-routine analysis of raw materials, in-process samples and finished formulations according to Standard Operating Procedures (SOPs); calibrates and maintains chemistry and microbiology lab equipment; compiles and analyzes data for documentation of test procedures and reports abnormalities.

Quality Assurance Assistant. Responsible for coordinating all activities related to providing the required documentation and implementing related documentation systems; coordinates the review and revision of procedures, specifications and forms; assists in compiling regulatory filing documents and maintaining computerized files to support all documentation systems.

BS Degree Positions

Quality Control Associate. Writes, revises and updates SOPs, quality control lab protocols and procedures; may perform special projects on analytical and instrument problem-solving; reviews data obtained by QC Assistant for compliance to specifications, GMP and regulatory requirements and reports abnormalities.

Process Quality Inspector. Performs a wide variety of inspections, checks, tests and sampling procedures for the manufacturing process; performs in-process inspection and documents results; monitors critical equipment and instrumentation; writes and updates inspection procedures and checklists as necessary

QA Auditor. Performs audits of production and quality control, ensuring compliance to in-house specification, standards, and regulatory requirements; ensures all documentation manuals are accurate, current and consistent with good manufacturing practices and regulatory requirements.

Quality Assurance Associate. Writes and edits Standard Operating Procedures, laboratory procedures, manuals and other documents; integrates various sources of information into a uniform style and language for regulatory compliance; assists in documentation for instructional, descriptive, reference and/or informational purposes.

Quality Control Engineer. Develops, revises and maintains standards for converting raw materials into products; designs and implements methods and procedures for inspecting, testing and evaluating the precision and accuracy of the manufacturing process; monitors the manufacture of a product to ensure that it conforms to in-house specifications, good manufacturing practices and regulatory requirements; prepares SOPs for testing procedures.

Validation Specialist. At the entry level, responsible for executing test validation procedures/protocols to demonstrate facility, equipment and process consistency and GMP compliance to ensure a product is manufactured in accordance with appropriate regulatory requirements and in-house standards; compiles and analyzes validation data; prepares reports and makes recommendations for changes and improvements; maintains appropriate validation documents.

Manufacturing Support

HS Diploma or Two-year Degree Positions

Instrumentation/Calibration Technician. Responsible for performing maintenance, testing, troubleshooting, calibration, and repair on a variety of circuits, components, analytical equipment, and instrumentation; calibrates instrumentation; performs validation studies; analyzes results and may develop test specification and electrical schematics; maintains logs, required documentation and spare parts inventories and may prepare technical reports with recommendations for solutions to technical problems.

Manufacturing Support Technician. Solves production problems caused by machinery in a specific process; determines why a particular machine is not performing as designed; maintains computer systems, electrical systems, heating and air conditioning systems, and other plant utilities.

Environmental Technician. Performs routine environmental monitoring tests; compiles and analyzes data; documents test procedures and results and reports abnormalities; carries out waste-treatment operations; assists in compiling regulatory filing documents.

BS Degree Positions

Maintenance Engineer. Manages the design, planning construction and maintenance of buildings and other facilities; plans, schedules and inspects all work on building, including preventive maintenance, repairs to air handlers, steam boilers, air conditioning, pumps and pipes, compressors and refrigeration.

Process Control Engineer. Designs and installs instrumentation and computer programs for automated monitoring and control of certain processes; establishes operating equipment specifications and improves manufacturing techniques; works closely with process-control technicians and equipment operators to get feedback on the operations of each process and determine how to avoid shut-downs.

Environmental Engineer. Develops techniques to reduce and recover usable materials from waste created during manufacture of a product; designs waste storage and treatment facilities, as well as pollution-control strategies for plant operations; may be responsible for monitoring all systems in a facility for compliance with government environmental regulations and preparing required documents.

Research and Development

Two-year or BS Degree Positions

Research Associate. Seeks out new and more efficient ways of using and producing existing products; explores new products or special variations of existing products and determines their usefulness and applicability; may work with marketing to ensure that a product will meet the needs of customers and with patent attorneys to determine if a new product or process is patentable.

Research Assistant. Performs laboratory experiments and tests according to GLP, under the direction of the Research Associate; makes detailed observations, analyzes data and interprets results; maintains laboratory equipment and keeps records according to regulatory requirements.

Other

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.

Customer Support Specialist. Responsible for ensuring delivery of the product in accordance with customer requirements and manufacturing capabilities; may serve as a contact for customers on technical issues; and responds to customer product inquiries.