



USAID
FROM THE AMERICAN PEOPLE

SKILLS AND KNOWLEDGE NEEDS ASSESSMENT FOR PHARMACEUTICAL INDUSTRY

**REPORT, VOLUME III
JOB DESCRIPTION TEMPLATES**

April 1, 2009

This publication was produced for review by the United States Agency for International Development



SKILLS AND KNOWLEDGE NEEDS ASSESSMENT FOR PHARMACEUTICAL INDUSTRY

REPORT, VOLUME III JOB DESCRIPTION TEMPLATES

DISCLAIMER: The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

CONTENTS

CONTENTS	3
1. QUALIFIED PERSON	5
1.1. Summary	5
1.2. Duties and Responsibilities	5
1.3. Job Requirements.....	5
1.4. Skills and Knowledge	5
2. HEAD OF PRODUCTION	6
2.1. Summary	6
2.2. Duties and Responsibilities	6
2.3. Job Requirements.....	7
2.4. Skills and Knowledge	7
3. HEAD OF QUALITY CONTROL.....	8
3.1. Summary	8
3.2. Duties and Responsibilities	8
3.3. Job Requirements.....	9
3.4. Skills and Knowledge	9
4. STORAGE/WAREHOUSE PERSON.....	9
4.1. Summary	9
4.2. Duties and Responsibilities	9
4.3. Job Requirements.....	10
4.4. Skills and Knowledge	10
5. LABORATORY SUPERVISOR.....	11
5.1. Summary	11
5.2. Duties and Responsibilities	11
5.3. Job Requirements.....	11
5.4. Skills and Knowledge	11
6. HEAD OF TECHNOLOGY/TECHNOLOGIST	12
6.1. Summary	12
6.2. Duties and Responsibilities	12
6.3. Job Requirements.....	12
6.4. Skills and Knowledge	12
7. R&D SPECIALIST	13
7.1. Summary	13
7.2. Duties and Responsibilities	13
7.3. Job Requirements.....	13
7.4. Skills and Knowledge	14
8. QUALITY CONTROL ANALYST, CHEMIST	14
8.1. Summary	14
8.2. Duties and Responsibilities	14
8.3. Job Requirements.....	15
8.4. Skills and Knowledge	15

9. MICROBIOLOGIST	15
9.1. Summary	15
9.2. Duties and Responsibilities	15
9.3. Job Requirements	16
9.4. Skills and Knowledge	16
10. LABORATORY TECHNICIAN	16
10.1. Summary	16
10.2. Duties and Responsibilities	16
10.3. Job Requirements	16
10.4. Skills and Knowledge	16
11. PRODUCTION OPERATOR	17
11.1. Summary	17
11.2. Duties and Responsibilities	17
11.3. Job Requirements:	17
11.4. Skills and Knowledge:	18
12. PACKAGING OPERATOR	18
12.1. Summary	18
12.2. Duties and Responsibilities	18
12.3. Job Requirements	19
12.4. Skills and Knowledge	19
13. COMPLAINT AND PHARMACOVIGILANCE OFFICER	19
13.1. Summary:	19
13.2. Duties and Responsibilities:	19
13.3. Job Requirements	20
13.4. Skills and Knowledge	20
14. REGISTRATION SPECIALIST	20
14.1. Summary	20
14.2. Duties and Responsibilities	20
14.3. Job Requirements	21
14.4. Skills and Knowledge	21
15. MARKETING SPECIALIST	21
15.1. Summary	21
15.2. Duties and Responsibilities:	21
15.3. Job Requirements	22
15.4. Skills and Knowledge	22

1. QUALIFIED PERSON

1.1. SUMMARY

Ensures that each batch has been produced and tested in accordance with directives and marketing authorization. Often the Qualified Person is the Head of Quality, but could also be the Head of Production. Key specialist for contacting internal and external audits, reports to the management and shareholders of the enterprise.

1.2. DUTIES AND RESPONSIBILITIES

1. Before batch release should ensure:
 - Manufacture has been carried out in accordance with Good Manufacturing Practice SOPs
 - The principal manufacturing and laboratory testing processes have been validated
 - Any deviations or planned changes in production or quality control have been authorized by the persons responsible
 - All the necessary checks and tests have been performed
 - All necessary production and quality control documentation has been completed and endorsed by the staff authorized to do so
 - The batch and its manufacture comply with the provisions of the marketing division.
2. Participate in establishing and maintaining a validation program for the entire company.
3. Handle complaints about potentially defective products and execute and coordinate product recalls.
4. Ensure that inspection issues raised by internal and external bodies are comprehensively resolved by the agreed deadlines.
5. Participate in development and review of different departmental SOPs.
6. Be a member of the company management team, including its strategic direction.
7. Manage the training process of employees.
8. Create methods and procedures for continuous improvement of production.
9. Prepare for and manage regulatory inspections.
10. Design criteria for an effective quality management system.
11. Monitor documentation and recordkeeping.
12. Conduct production planning, scheduling, and inventory control.

1.3. JOB REQUIREMENTS

1. Education to degree level in one of the following areas: pharmacy, medicine, chemistry, pharmaceutical chemistry and technology, biology.
2. Practical experience for at least two years in management in either production or quality control.

1.4. SKILLS AND KNOWLEDGE

1. Comprehensive knowledge of Armenian pharmaceutical legislation (as well as EU, WHO) on the manufacture, storage, and supply of medical products.
2. Knowledge of principles and practice of GMP and QA.
3. Interpersonal skills (leadership, delegation, communication, etc).

4. Knowledge of principles of design, selection, qualification and maintenance of premises, equipment, utilities, and services.
5. Knowledge of calibration, preventative maintenance and training processes.
6. Good statistical and math skills.
7. Knowledge of key therapeutic drug classifications.
8. Knowledge of disease states and their treatment with pharmaceuticals.
9. Knowledge of the major processing techniques, their limitations and control parameters.
10. Knowledge of the principles of process validation and control.
11. Knowledge of the principles of laboratory analysis.
12. Knowledge of pharmaceutical microbiology.
13. Knowledge of Good Laboratory Practices.
14. Ability to manage multiple tasks simultaneously,
15. Computer skills.
16. Good verbal and written communication skills.
17. Ability to work in a team environment.

2. HEAD OF PRODUCTION

2.1. SUMMARY

Organizes the manufacturing process and controls all stages of it, from the procurement of inputs to the release of final products. Together with the Head of Quality Control supervises the operations of the enterprise.

2.2. DUTIES AND RESPONSIBILITIES

1. Ensure that products are produced and stored according to the appropriate documentation.
2. Establish guidelines for continuous risk reduction.
3. Provide day-to-day management of the production floor.
4. Approve instructions relating to production operations.
5. Assure continuous improvement of production processes.
6. Ensure that production records are evaluated and signed by designated person before they are sent to the Quality Control Department.
7. Check the maintenance of the department, premises and equipment.
8. Ensure that the appropriate process validations and calibrations of control equipment are performed and recorded and the reports made available.
9. Ensure that the required initial and continuing training of production personnel is carried out and adapted according to need.
10. Responsible for safety, regulatory and/or environmental compliance.
11. Provides strong support linkage with the following departments:
 - Systems—maintain and upgrade manufacturing computer systems and network interfaces

- Plant Engineering—assist with the design and commissioning of new equipment or equipment modifications to provide for new product introductions and continuous improvement activities
- Validation/Tech Support—Facilitate plant trials, new product activities, and validation of existing and new procedures, equipment and computer systems
- Conduct training on new technologies, new products and new associated processes.
- Marketing department—review sales levels and plan new yearly production rate.

12. Responsible for yearly production planning

Functions jointly exercised with the Head of Quality Control; responsibilities relating to quality.

13. Authorize written procedures and other documents.

14. Monitor and controls the manufacturing environment.

15. Maintain and control plant hygiene.

16. Validate processes and calibrate analytical apparatus.

17. Oversee training, including the application and principles of quality assurance.

18. Approve and monitor suppliers of materials.

19. Approve and monitor contract manufacturers (outsourcing) (if any)

20. Designate and monitor storage conditions for materials and products.

21. Perform and evaluate in-process controls.

22. Oversee retention of records.

23. Monitor compliance with the requirements of GMP.

2.3. JOB REQUIREMENTS

1. Higher education in respective fields and 4+ years experience.
2. Bachelor degree in respective fields and 2+ years experience.
3. Experience in supervisory position.
4. Pharmaceutical industry background in operations.
5. Experience in good manufacturing practices (GMP).
6. Flexibility to work overtime and some weekends.

2.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of Armenian pharmaceutical legislation and regulation (medicines law, licensing law, etc.) GMP, environmental and other regulatory compliance requirements.
2. Thorough knowledge of work and safety procedures.
3. Good working knowledge of formulations and process technologies.
4. Thorough knowledge of all manufacturing operations, equipment, and SOPs.
5. Ability to devise solutions to problems that arise outside normal procedures and for systems-related issues.
6. Ability to adapt and manage different technologies.
7. Ability to provide effective leadership to employees in manufacturing, engineering and operations.

8. Ability to interact with senior executives, senior technical managers, business heads, customers, and suppliers within and outside the company.
9. Ability to pursue and manage process optimization.
10. Ability to coach, counsel, manage, and direct personnel in appropriate division/business unit assignments.
11. Ability to interact and negotiate with regulatory agencies on routine compliance issues.
12. Ability to manage multiple tasks simultaneously.
13. Computer skills.
14. Good verbal and written communication skills.
15. Ability to work in a team environment.

3. HEAD OF QUALITY CONTROL

3.1. SUMMARY

Controls quality issues (maintains production and product quality); manages the work of the QC Laboratory and its staff. Together with the Head of Production supervises the operation of the enterprise.

3.2. DUTIES AND RESPONSIBILITIES

1. Approve or reject starting materials, packaging materials, and intermediate, bulk and finished products in relation to their specifications.
2. Evaluate batch records.
3. Ensure that all necessary laboratory testing is carried out.
4. Approve specifications, sampling instructions, test methods and other quality control procedures.
5. Approve and monitor any contract analysts (if there are).
6. Check the maintenance of the department (lab), premises and equipment.
7. Ensure that the appropriate validations, including those of analytical procedures and calibrations of control equipment are carried out.
8. Ensure that the required initial and continuing training of department personnel is carried out and adapted to needs.
9. Manage activities of Quality Testing Laboratories.
10. Review of documentation for new product introduction, method validation, instrument validation and updating of testing standards, test methods, stability analytical reports and SOPs.
11. Liaise with QC, Technology, Production and Registration.

Functions jointly exercised with the Head of Production; responsibilities relating to quality.

12. Authorization of written standard operational procedures and other documents.
13. Monitoring and control of the manufacturing environment.
14. Maintenance and control of plant hygiene.
15. Process validation and calibration of analytical apparatus.
16. Training, including the application and principles of quality assurance.
17. Approval and monitoring of suppliers of materials.

18. Approval and monitoring of contract manufacturers (outsourcing) (if any).
19. Designation and monitoring of storage conditions for materials and products.
20. Performance and evaluation of in-process controls.
21. Retention of records.
22. Monitoring of compliance with the requirements of GMP.
23. Inspection, investigation, and taking of samples, to monitor factors that may affect product quality.

3.3. JOB REQUIREMENTS

1. University or college degree or diploma from a recognized institution in a science-related subject.
2. University degree in chemistry with 4+ years in analytical and microbiological pharmaceutical experience.
3. Ph.D. in chemistry with 4+ years of analytical and microbiological pharmaceutical experience desirable.
4. Experience in a pharma lab with experience in analytical methods and instrumentation.

3.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of Armenian and international pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.) GMP, Environmental and other regulatory compliance requirements.
2. Knowledge of GLP, GMP and Safety procedures, including those pertinent to them.
3. Knowledge of work and safety procedures.
4. Knowledge of instrument and method validation.
5. Ability or aptitude for continuous learning and analytical problem solving.
6. Ability to manage multiple tasks simultaneously,
7. Computer skills.
8. Good verbal and written communication skills.
9. Ability to work in a team environment.

4. STORAGE/WAREHOUSE PERSON

4.1. SUMMARY

Organizes proper stocking of inputs, intermediate products, final pharmaceuticals and their release. Special emphasis is made on safety and hazard issues.

4.2. DUTIES AND RESPONSIBILITIES

1. Implement and maintain procedures designed to maintain accurate inventories, proper input and storage of the various categories products: starting and packaging materials, finished products, products in quarantine, and released, expired, rejected, returned or recalled products.
2. Implement and maintain procedures designed to maintain accurate inventories, proper storage of radioactive materials, narcotics and other hazardous, sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion, (e.g.

combustible liquids and solids and pressurized gases) should be stored in a dedicated area that is subject to appropriate additional safety and security measures.

3. Responsibility for monitoring and enforcing quality and productivity standards.
4. Coordination and management of the flow of materials, ensuring proper receipt, storage, packing, shipping and documentation of these processes.
5. Adhering to and improving the standard operating policies and promoting regulatory and safety compliance.
6. Supply of components and raw materials to the respective departments.
7. Load and unload all domestic and export production.
8. Maintain forklift trucks according to established procedures.
9. Coordinate and record housekeeping tasks (e.g. sweeping, product consolidation) to maintain neat, clean, dry and maintain acceptable temperature limits.
10. Utilization of computerized material tracking system to locate components and maximize warehouse space.
11. Input data into receiving system and shipping system.
12. Provide daily direct supervision to warehouse and distribution activities.
13. Provide strong leadership, coaching and training of warehouse colleagues.
14. Oversee the operations of designated warehousing and distribution functions to ensure that they comply with government and corporate requirements while striving to continually improve.
15. Assist with ensuring proper building and equipment maintenance.
16. Provide a strong emphasis on safety for the warehouse and facility environment.

4.3. JOB REQUIREMENTS

1. At least vocational education in relevant areas.
2. Warehouse-related experience.
3. Knowledge of safety requirements and transportation rules.
4. Experience in Warehouse Management Automated Systems
5. Flexibility to work 12-hour days (including weekends), overtime and all shifts

4.4. SKILLS AND KNOWLEDGE

1. Knowledge of Armenian and international regulations on narcotics and psychoactive drugs.
2. Knowledge of GMP, Good Storage Practices and Good Distribution Practices.
3. Knowledge of work and safety procedures.
4. Willingness and ability to operate a forklift truck.
5. Ability to wear respiratory protection to perform specific tasks.
6. Ability and willingness to manage and train others.
7. Ability to lift and bend, and move heavy objects.
8. Ability to manage multiple tasks simultaneously,
9. Computer skills.
10. Good verbal and written communication skills.
11. Ability to work in a team environment.

5. LABORATORY SUPERVISOR

5.1. SUMMARY

Conducts direct supervision of the QC Laboratory. Ensures the proper retention of documents and effective operation of equipment and instruments.

5.2. DUTIES AND RESPONSIBILITIES

1. Organize activities involved in conducting tests and/or assaying of raw material, intermediates or finished products.
2. Organize analysis of finished product, in-process, stability and (where necessary) validation samples.
3. Organize production process validation.
4. Supervise employees performing testing and support activities.
5. Critically evaluate data generated and recommend acceptance or rejection of samples, and perform lab work accurately and timely.
6. Maintain records, develop productivity improvement plans, maintain adequate inventory of supplies, training records.
7. Ensure that laboratories are in compliance with GMP and GLP regulations as well as company procedures; that the products and materials are tested as specified in the specifications and methodologies.
8. Maintain adequate instrumentation and laboratory facilities.
9. Maintain a safe working environment.
10. Maintain an awareness of technical developments in instrumentation analysis.
11. Ensure that equipment and services are kept in a safe and validated condition.
12. Approve all work generated by analysts. Approve laboratory validation and calibration reports.
13. Update SOPs, Process Specific Training Modules, Control procedures, etc.
14. Train personnel to ensure employees are competent and qualified.
15. Control laboratory investigation in the laboratory.
16. Control purchasing of laboratory equipment and chemicals.
17. Assist in internal and external audits.

5.3. JOB REQUIREMENTS

1. University degree in chemistry with 4+ years in analytical and microbiological pharmaceutical experience.
2. Ph.D. in chemistry with 4+ years of analytical and microbiological pharmaceutical experience is desirable.
3. Experience in a pharma lab with experience in analytical methods& instrumentation.

5.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of Armenian pharmaceutical legislation and regulation (medicines law, licensing law, etc.) GMP, environmental and other regulatory compliance requirements.
2. Knowledge of GLP, GMP and safety procedures.
3. Knowledge of instrument and method validation.

4. Good interpersonal and supervisory skills.
5. Ability or aptitude for continuous learning and analytical problem solving.
6. Ability to manage multiple tasks simultaneously,
7. Computer skills.
8. Good verbal and written communication skills.
9. Ability to work in a team environment.

6. HEAD OF TECHNOLOGY/TECHNOLOGIST

6.1. SUMMARY

Deals with technological aspects of the manufacturing of pharmaceuticals. Engaged in engineering design, selection and maintenance of the technological equipment and process improvement.

6.2. DUTIES AND RESPONSIBILITIES

1. Develop and perform work in accordance with SOPs, GMPs and established safety procedures.
2. Develop strategy, evaluation and selection of production process technology, taking into consideration current and future needs.
3. Responsible for evaluation, pilot and vendor testing, and selection of process equipment, as well as associated clean utilities.
4. Responsible for process validation
5. Responsible for complete process engineering design.
6. Responsible for set process engineering technical standards and standard practices.
7. Develop and maintain process descriptions, process block flow diagrams, specifications, and other process/equipment documents for engineering, design, operations and regulatory filings.
8. Primary contact for process engineering and technology issues/questions of regulatory agencies.
9. Responsible for continuous production process improvement for highest efficiency.
10. Responsible for production process modification and upgrades.
11. Integrate and contribute to cross-functional design, product and project teams.
12. Responsible for establishment and maintenance of disposal processes

6.3. JOB REQUIREMENTS

1. B.S or M.S. in chemical engineering
2. Technology leadership in the pharmaceutical Industry.
3. Experience in discussion and inspections with regulatory agencies.

6.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of GMP regulatory requirements, including pertinent specifications.
2. Thorough knowledge, experience in novel, emerging and disposable process technology.
3. Knowledge of work and safety procedures.
4. Ability to manage multiple tasks simultaneously.

5. Computer skills.
6. Good verbal and written communication skills.
7. Ability to work in a team environment.

7. R&D SPECIALIST

7.1. SUMMARY

Conducts intensive R&D with the purpose of improving characteristics (especially the shelf life and stability) of existing range of pharmaceuticals, and synthesize new varieties. Also conduct analytical assessments and assist other employees in preparation and retention of various documents.

7.2. DUTIES AND RESPONSIBILITIES

1. Participate in development of current pharmaceuticals and contribute to development of future products.
2. Design and conduct R&D experiments for new product development.
3. Write and or review R&D and product evaluation protocols.
4. Review current stability practices, evaluate stability data, and make recommendations for improvements and extending shelf life of the current products.
5. Optimize the composition of the current products and new product developments.
6. Trouble shoot existing products to find areas for performance improvements and product cost reductions.
7. Provide scientific and technical support to senior staff members, as required, in the identification and development of new opportunities, leading to commercially viable proprietary formulation and process technologies.
8. Identify and implement new (and/or streamline current) equipment, process and documentation systems and procedures or improve the existing ones.
9. Assist in the preparation of GLP documentation.
10. Provide analytical testing support for raw material release, in-process, experimental studies and clinical batch release, and stability testing programs.
11. Take the primary/supporting analytical role in R&D development programs, from early formulation/process development experimental studies to clinical batch release, registration, scale-up and tech transfer, to the validation stages for new pharmaceutical products using the company's technology platforms.
12. Preparation and/or review of documentation including but not limited to SOPs, SAMs (standard analytical methods, both development and validation documents), master batch records and protocols for stability, sampling and equipment validation.

7.3. JOB REQUIREMENTS

1. B.S. in chemistry, pharmacy, biochemistry or life science with 6+ years' proven experience in product development.
2. M.S. in chemistry, pharmacy, biochemistry or life science with 4+ years' proven experience in product development is desirable.
3. Ph.D. in chemistry, pharmacy, biochemistry or life science with 2+ years experience in product development is desirable.

7.4. SKILLS AND KNOWLEDGE

1. Ability to troubleshoot and solve scientific and technical challenges either alone or in a team environment.
2. Thorough understanding of current product attributes and manufacturing processes.
3. Knowledge of work and safety procedures.
4. Working knowledge of mathematical / statistical design and modelling.
5. Strong leadership.
6. Ability to think critically and creatively.
7. Ability to influence and motivate others.
8. Ability to manage multiple tasks simultaneously.
9. Computer skills.
10. Good verbal and written communication skills.
11. Ability to work in a team environment.

8. QUALITY CONTROL ANALYST, CHEMIST

8.1. SUMMARY

Conducts laboratory analysis and testing at all stages of the manufacture of pharmaceuticals. Ensures the proper functioning of laboratory equipment and instruments. Prepares various documents and protocols and ensures their proper retention.

8.2. DUTIES AND RESPONSIBILITIES

1. Test all laboratory samples including raw materials, in-process, finished products, validation, stability, environmental (as per written procedure or as per pharmacopeia).
2. Observe GLP/GMP at all times.
3. Record analytical results accurately.
4. Operate, maintain, and calibrate laboratory instruments.
5. Maintain usage of laboratory chemicals and keep records.
6. Prepare and execute instrument qualification and method validation protocols.
7. Ensure that the laboratory is kept clean, tidy and safe at all times.
8. Report any nonconformance, instrument malfunction, accident or other abnormal occurrence to immediate superior.
9. Verify analytical data of other analysts in the lab as requested.
10. Review and interpret data for conformance to procedures, standards and protocols and/or real-time recognition of aberrant data and results.
11. Troubleshoot equipment and methods as required.
12. Assist in improvement of quality systems by creating or revising worksheets and other lab documentation systems.
13. Comply with and implement safety standards.
14. Execute notification to management when required by procedures or standards.
15. Participate fully in cross-functional training.

16. Develop training materials, train and mentor others.

8.3. JOB REQUIREMENTS

1. At least B.S. in chemistry, analytical chemistry or a related subject.
2. Relevant laboratory experience.
3. Experience in pharmaceutical testing, along with method development, validation experience and working knowledge of GMP.

8.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge GLP/GMP requirements, including specifications pertinent to them.
2. Ability to read, analyze, interpret and communicate technical data, technical procedures or regulations.
3. Knowledge of work and safety procedures.
4. Knowledge of laboratory instrumentation
5. Strong technical ability and ability to troubleshoot GC, HPLC and dissolution testing methods.
6. Ability to work in a lab environment, including wearing appropriate PPE and other safety equipment (such as respirator).
7. Excellent organizational, planning and judgment skills.
8. Ability to manage multiple tasks simultaneously,
9. Computer skills.
10. Good verbal and written communication skills.
11. Ability to work in a team environment.

9. MICROBIOLOGIST

9.1. SUMMARY

Conducts various microbiological analyses at the QC Laboratory, implements validation, develops qc systems. Primary contact for microbiology-related issues and inspections of regulatory authorities.

9.2. DUTIES AND RESPONSIBILITIES

1. Work in accordance with SOPs, GMPs and GLPs.
2. Carry out sampling and microbiological analysis of samples and environmental monitoring functions.
3. Validate testing methods.
4. Document results or enter data into Laboratory Information Management System.
5. Isolate and identify micro-organisms.
6. Review trending and results.
7. Report out-of-trend or out-of-specification results.
8. Complete laboratory investigation and prepare associated reports.
9. Responsible for development, execution and maintenance of Quality Control systems, standards, practices and procedures for raw materials, utilities, environmental, in-process and final product testing.

10. Support continuous process performance evaluation and continuous process improvement for highest efficiency.
11. Integrate, contribute, and/or lead cross-functional project teams as required.
12. Primary contact for all QC microbiology-related filings and inspections of regulatory agencies.

9.3. JOB REQUIREMENTS

1. University or advanced degree in microbiology or related sciences.
2. Minimum of 2+ years GMP quality control and/or QC-related experience, at least 1 year of which is direct microbiology laboratory experience.

9.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of GMP, GLP and safety requirements.
2. Thorough knowledge of microbiology and GMP as applied to microbiological control of production.
3. Current knowledge or proven interest in starting up and qualifying new facilities, tech transfers and manufacturing operations.
4. Knowledge of laboratory instrumentation and methods.
5. Ability to manage multiple tasks simultaneously.
6. Computer skills.
7. Good verbal and written communication skills.
8. Ability to work in a team environment.

10. LABORATORY TECHNICIAN

10.1. SUMMARY

Conducts various types of testing, maintains QC laboratory equipment, instruments and glassware.

10.2. DUTIES AND RESPONSIBILITIES

1. Responsible for performing full QCS testing on starting and packaging materials, in-process batches and finished product.
2. Maintain and utilize instrumentation for analytical purposes.
3. Support manufacturing in a timely manner by analyzing all intermediates and finished product that enters the laboratory.
4. Prepare and keep records on analysis of intermediates, finished batches, and packaged products.
5. Assist the chemist(s) in special projects, including plant trial and process validation testing.
6. Conduct cleaning responsibilities of workplace.
7. Daily instrument calibration.

10.3. JOB REQUIREMENTS

1. Vocational education in general chemistry or related subject
2. Experience in pharmaceutical laboratories.

10.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of GMP and GLP.

2. Knowledge of work and safety procedures.
3. Detail-oriented recordkeeping skills.
4. Ability to manage multiple tasks simultaneously.
5. Computer skills.
6. Good verbal and written communication skills.
7. Ability to work in a team environment.

11. PRODUCTION OPERATOR

11.1. SUMMARY

Engages in pharmaceutical manufacturing, and maintenance of manufacturing equipment, supervises the operation of equipment and instruments.

11.2. DUTIES AND RESPONSIBILITIES

1. Work as part of a team performing the various stages of pharmaceutical production as defined by GMP, SOPs, established safety procedures and company policies and procedures relative to production, testing/inspection, and documentation of quality products.
2. Operate assigned machinery—service machines with materials, remove finished materials from machine, and ensure smooth flow of product.
3. Report any deviations from standards to team leader promptly.
4. Complete and review on-line batch records. In case of problem, immediately report to area management.
5. Keep to the manufacturing schedule and ensure all documentation is completed accurately, legibly and on time and maintain records as required.
6. Sterile core operators also must have an understanding of aseptic behaviors; media fills including line interventions, and a basic knowledge of viable and nonviable monitoring equipment, including performing sampling both inside and outside the sterile core.
7. Perform visual and physical checks of in-process and finished materials.
8. Follow batch and SOP instructions to perform in-process and finished product sampling. Label and deliver samples to appropriate locations (laboratory, etc.).
9. Perform end-of-day cleaning of equipment and manufacturing facility, especially the aseptic areas.
10. Take responsibility for assembling, testing, disassembling, and sanitizing filling and packaging equipment.
11. Be familiar with job-related hazards. Report all discrepancies to process facilitator.
12. Contribute to the continuous improvement of processes, procedures and quality.
13. Perform inventory control and reconciliation activities.
14. Maintain flexibility in conducting filling, inspection, and packaging functions.
15. Assist technical staff with preventive maintenance procedures.

11.3. JOB REQUIREMENTS:

1. Vocational education at least.
2. 2+ years experience in the pharmaceutical industry.

3. Experience with machine changeovers and use of hand tools strongly preferred.
4. Ability for visual test verification.

11.4. SKILLS AND KNOWLEDGE:

1. Complete understanding of GMP requirements, including relevant specifications.
2. Thorough knowledge of sterile room techniques, where appropriate, and chemical handling and storage.
3. Mechanical/technical aptitude.
4. Thorough knowledge of work and personal safety requirements.
5. Working knowledge of automated and semi-automated inspection equipment.
6. Ability to independently read and comprehend documents such as safety rules, operating and maintenance instructions, and procedure manuals.
7. Ability to select the correct actions when operational conditions change.
8. Knowledge of product security controls, including controlled-substance handling.
9. Ability of visual control of testing process.
10. Good attention to detail. Ability to keep accurate records and perform mathematical calculations.
11. Ability to manage multiple tasks simultaneously.
12. Computer skills.
13. Good verbal and written communication skills.
14. Ability to work in a team environment.

12. PACKAGING OPERATOR

12.1. SUMMARY

Conducts packaging processes of pharmaceuticals, checks the exactness of the technological packaging equipment, makes inspections of packaging materials.

12.2. DUTIES AND RESPONSIBILITIES

1. Handle all packaging process stages (packaging and labeling).
2. Follow necessary SOPs, GMP regulations and safety guidelines and company policies and procedures relative to production, testing/inspection, and documentation of quality products.
3. Read and follow packaging instructions.
4. Perform in-process testing and finished goods inspection as required in SOPs and batch documentation.
5. Complete all necessary production and maintenance paperwork.
6. Set up, operate and adjust packaging equipment to maximize quality and output.
7. Perform minor troubleshooting and corrections.
8. Perform tasks to support room cleaning, inspection, assembly, case packing, material handling and facility cleaning.
9. Generate and/or support new ways to increase productivity and efficiencies.
10. Perform other duties as requested.

12.3. JOB REQUIREMENTS

1. Vocational education at least.
2. 1 year (recent/contiguous) experience operating filling/packaging equipment.
3. Experience with machine changeovers and use of hand tools preferred.
4. Flexibility to work weekends, overtime and all shifts.

12.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of GMP procedures, including the specifications pertinent to them.
2. Knowledge of work and safety procedures.
3. Good math skills.
4. Ability and willingness to learn new things (i.e., hand tool use, use of manuals).
5. Ability to adjust quickly to new responsibilities and tasks.
6. Ability to lift, push and pull up to 15-25 kg.
7. Ability to stand, bend and walk for 8-10 hours daily.
8. Mechanical aptitude.
9. Excellent eye-hand coordination. Good eyesight for inspection of finished product.
10. Ability to manage multiple tasks simultaneously,
11. Computer skills.
12. Good verbal and written communication skills.
13. Ability to work in a team environment.

13. COMPLAINT AND PHARMACOVIGILANCE OFFICER

13.1. SUMMARY:

Keeps records on complaints and conducts investigations. Cooperates closely with regulatory Authorities on safety issues. Follows the changes and modifications in local and international markets, reviews analytical materials.

13.2. DUTIES AND RESPONSIBILITIES:

1. Follow all SOPs, appropriate regulations and company policies and procedures, relative complaints including the need to consider a recall and adverse reactions monitoring of products.
2. Record any complaint concerning a product defect with all the original details and report to designated person for appropriate action.
3. Investigate whether a complaint was caused because of counterfeiting.
4. Serve as contact person for communication with regulatory authorities on drug safety issues.
5. Review and report on spontaneous adverse events internally to assigned person and externally to regulatory authority.
6. Investigate and follow up international and Armenian adverse event reports.
7. Review and submit periodic safety update reports (PSURs) and annual safety reports (ASRs) to regulatory authorities.

8. Define evaluation plan with partners (physicians, team members, business partners) to assess and complete responses for inquiries from regulatory authorities and internal and other external sources about product safety.
9. Oversee training of affiliate personnel on relevant drug safety responsibilities.
10. Responsibility for preparation and maintenance of pharmacovigilance plans.
11. Identify and propose process improvements.
12. Receive and clarify drugs' safety instructions and communicate relevant safety information to the appropriate persons.

13.3. JOB REQUIREMENTS

1. B.S. or M.S. degree in pharmacy or clinical education.
2. 2+ years of relevant experience.

13.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of Armenian and international pharmaceutical legislation and regulation.
2. Thorough knowledge of GMPs.
3. Thorough knowledge of product safety within pharmaceuticals and other safety procedures.
4. Thorough knowledge and experience of adverse event reporting.
5. Project management skills.
6. Ability to manage multiple tasks simultaneously,
7. Computer skills.
8. Good verbal and written communication skills.
9. Ability to work in a team environment.

14. REGISTRATION SPECIALIST

14.1. SUMMARY

Primary contact for regulatory authorities. Preparation, submission, analysis and retention of various documents. Contribution to development of new product descriptions, guidance and instructions.

14.2. DUTIES AND RESPONSIBILITIES

1. Facilitate the regulatory aspects of projects/products, including documentation submitted to regulatory agencies and regulatory agency interactions.
2. Ensure that documentation is complete and complies with applicable regulatory requirements.
3. Assess documents from regulatory agencies.
4. Review documentation from other internal departments.
5. Provide consultations on regulatory documents to other internal departments.
6. Contribute to analyses of regulatory guidance documents, regulations that affect company products and operations.
7. Monitor, analyze and advise on existing and new regulatory requirements that may affect the development process and emerging trends. Balance ideas and practices against regulatory risks.

8. Coordinate regulatory inspections and audits.

14.3. JOB REQUIREMENTS

1. Master's degree in pharmacy, chemistry, pharmacology or related subject.
2. Ph.D. in pharmacy, chemistry, pharmacology or related subject.
3. 3+ years experience in the registration and re-registration of pharmaceutical products with good track records and references.

14.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of regulatory requirements for Armenia and other countries (where company plans to export), including registration procedures.
2. Thorough knowledge of international guidelines.
3. Knowledge of work and safety procedures.
4. Ability to coordinate company's operations with requirements of regulatory agencies.
5. Ability to manage multiple tasks simultaneously,
6. Computer skills.
7. Good verbal and written communication skills.
8. Ability to work in a team environment.

15. MARKETING SPECIALIST

15.1. SUMMARY

Development of marketing strategy and policies, implementation of marketing research, application of promotional tools, analysis of market share and position, initiation of events.

15.2. DUTIES AND RESPONSIBILITIES:

1. Operate in accordance with pharmaceutical legislation and regulations of Armenia and countries where exports are sent, as well as company policies and procedures.
2. Operate in accordance with internal marketing operating practices and procedures.
3. Develop marketing strategy through market research.
4. Annual marketing planning.
5. Develop product marketing plan and proactively align the product's promotional requirements.
6. Develop and manage advertising, educational and other material.
7. Work across functions to coordinate development of marketing materials and ensure consistent delivery of brand message to consumers.
8. Regularly perform professional analysis and qualitative/quantitative research of the market. Conduct research on competitors.
9. Conduct market segmentation and consumer targeting.
10. Provide product briefings and training to sales specialists.
11. Perform field visits to monitor implementation of marketing strategy by sales specialists.
12. Participate in the preparation of sales, market share, patient, promotional – and promotional budget – objectives.

15.3. JOB REQUIREMENTS

1. Bachelor's degree in marketing or related field.
2. 3+ years experience in marketing or promotional fields.
3. Experience in advertising fields and working with mass media.
4. MBA preferred.

15.4. SKILLS AND KNOWLEDGE

1. Thorough knowledge of Armenian drug regulations on promoting medication (medicines law, advertisement law).
2. Thorough knowledge of international guidelines on promoting medication (WHO, EU, etc).
3. Strategic thinking and analytical skills.
4. Be self-directed and inquisitive.
5. Ability to motivate others.
6. Ability to work effectively in changing environment.
7. Strong project management, budget management, and prioritization skills.
8. Strong decision-making skills and experience.
9. Knowledge of marketing and promotion techniques.
10. Ability to manage multiple tasks simultaneously.
11. Computer skills.
12. Excellent verbal and written communication skills.
13. Ability to work in a team environment.