



BLOOD BANK OF ALASKA POSITION DESCRIPTION

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| Position Title: | Quality Systems Specialist |
| Department: | Quality Assurance |
| Reports To: | Director of Quality Assurance |
| FLSA: | Non-Exempt |
| Position(s) Supervised: | None |

POSITION SUMMARY

This position will work under the direction of the Director of Quality Assurance. This position will assist in facilitating changes to existing policies and procedures, assist in the promotion of organizational compliance with applicable accrediting, state and federal regulations, manage BBA's occurrence program and BPDR reporting to the FDA, perform audits, and perform investigations such as Q&LB and Bacterial Detection.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Facilitate changes to existing policies and procedures. This may include writing/updating policies, processes, and procedures and writing validation protocols for new equipment, processes and/or products or update existing protocols.
- Perform QA investigations including: Occurrence Reports, Post Donation Information, Biological Product Deviations, Quarantine and Lookback for positive test results, etc. Participate in the maintenance and improvement of the investigations to include incident and complaint reporting and analysis.
- Provide QA/compliance review of forms and documents, including review of QC Lab forms, nursing/donor counseling documentation (e.g. positive bacterial detection or test results, donor reaction records, etc.) and post donation information (PDIR and FLUPs).
- Assist with the review, compilation and submission of FDA reports, correspondence, product licensing, etc.
- Perform duties in compliance with all applicable regulatory and accrediting agencies. Ensure OSHA regulations, cGMPs and cGTPs are adhered to.
- Follow all pertinent SOP's that relate to this position. Document required information on appropriate records as needed.
- Attend all relevant meetings as scheduled and able to attend.
- Serve on the Quality Committee as requested.
- Assist in the development of operational audit plans, performance of audits, writing audit reports and issuing audit findings to the appropriate department management. Audits will include: blood center and cellular therapy departments and processes, supplier and service provider audits, and additional audits as requested by Director of Quality Assurance(e.g. document storage areas, etc.).
- Provide support during external audits (FDA, AABB, plasma consignee).
- Maintain positive communication with all departments. Promote a positive work environment in which staff work cooperatively towards objectives.
- Encourage employees to utilize appropriate support systems (SOPs, management, etc.) as necessary to resolve issues and answer questions.
- Exhibit support of BBA values, quality objectives, and customer service standards at all times.
- Perform duties as Document Control Specialist, copyholder, owner, author, etc.
- Help maintain positive image of BBA throughout the community while maintaining overall corporate image.
- Oversee organization and maintenance of document storage areas at main center and warehouse. Manage document retention process.



- Perform other duties as assigned and qualified to do.

CUSTOMER INTERACTION/PROBLEM SOLVING

- Must maintain a high standard for conscientious, courteous, and enthusiastic service to internal and external customers, and the public in general.
- Must make customer's needs a high priority in face-to-face or telephone contact.
- Must consistently deliver service in a timely, accurate, professional and friendly manner.
- Must demonstrate a high level of problem-solving skills.

QUALIFICATION REQUIREMENTS

To perform this job successfully, each essential duty (as listed above) must be performed satisfactorily. The requirements listed below are representative of the knowledge, skill and/or ability required.

GENERAL KNOWLEDGE, SKILLS AND ABILITIES

- Strong interpersonal and communication skills.
- Strong computer skills. Ability to type and operate a personal computer. Proficient in Microsoft Office applications (Word, Excel, PowerPoint) or willing to learn.
- Ability to work independently, perform tasks of a detailed nature accurately within required timeframes, and adapt to fluctuating workloads.
- Exceptional organizational skills and ability to prioritize work.
- Thorough knowledge of business English, spelling, and punctuation. Effective written and verbal communication skills. Excellent writing ability for technical, professional and other related documents.
- Ability to problem solve at a high level through interpretation of regulatory guidelines, applicable laws and statutes, industry standards, and quality focused decision making.
- Demonstrate ability to network with internal and external resources, build relationships conducive to a quality environment and continue growth in knowledge areas related to industry.
- Ability to organize and maintain company records.
- Ability to interface effectively and harmoniously with employees, public and regulatory inspectors.
- Knowledge of general safety and quality assurance procedures.
- Ability to maintain confidentiality of donors, customers, employees and BBA business information.

EDUCATION

Associates or Bachelor's Degree in relevant field strongly preferred. Experience may be substituted on a year for year basis with a demonstrated ability to perform advanced technical writing and regulatory interpretation.

EXPERIENCE

Minimum three years in a highly regulated environment preferred with responsibility for compliance, policy and procedure development and implementation while working with a diverse employee population geographically dispersed.

CERTIFICATES, LICENSES, ETC.

Minimum: Valid Driver's License
Preferred: MLT, MT or SBB (ASCP) and/or American Society of Quality (ASQ) CQA.



Blood Bank of Alaska
Helping Alaska patients in need

WORK ENVIRONMENT

Majority of time is spent sitting; extensive use of computer/computer terminal. Work Conditions: Potential hazard due to exposure to blood or other potentially infectious materials. The Blood Bank of Alaska follows OSHA Bloodborne Pathogens Standards in the workplace.

It's expected that the employee will perform the job duties described above and can stand and/or sit for prolonged periods of time. Furthermore it is expected that the employee is able to walk moderate distances, climb stairs, reach/push/pull, and bend in order to perform his/her job duties. Employee is expected to lift up to 30 pounds in performing his/her job duties.

The above is intended to describe the job functions, the general supplemental functions, and the essential requirements for the performance of this job. It is not to be construed as an exhaustive statement of all of the supplemental duties, responsibilities, or non-essential requirements.

My signature below indicates that I have read and understood the position description for Quality Systems Specialist and agree to perform the duties as stated.

Employee Print Name

Employee Signature Date

Supervisor Signature Date