



BLOOD BANK OF ALASKA POSITION DESCRIPTION

Position Title:	Director of Quality Assurance
Department:	Quality Assurance
Reports To:	Chief Executive Officer
FLSA:	Exempt
Position(s) Supervised:	Quality Assurance Staff

POSITION SUMMARY

The Director of Quality Assurance is responsible for ensuring all areas of the Blood Bank of Alaska are operating in compliance with applicable government regulations, accrediting agency standards or consignee requirements related to the collection, processing, testing and distribution of blood products, cellular therapy products and services. The QA Officer participates as a member of the BBA management team in planning, program formulation, and systems development. The QA Officer is responsible for designing, implementing, and monitoring the quality assurance program for all operating divisions of BBA.

The incumbent for this role must possess excellent conceptual, communication, and analytical skills. Must understand general work flow processes and equipment used in a medical facility. Must have excellent interactive skills necessary in communicating with co-workers and regulatory officials.

ESSENTIAL DUTIES AND RESPONSIBILITIES

Quality Assurance

- Establish and maintain aggressive compliance program that meets federal regulations, industry standards, and consignee or customer requirements. Oversee planning and implementation of quality assurance and operation projects.
- Review current and new regulations, standards or proposed changes with regard for potential impact on operations or SOP's. Review new and revised SOP's and validations for compliance with appropriate regulations and standards.
- Oversee and coordinate regulatory, accreditation and consignee inspections. Coordinate response with appropriate department managers.
- Oversee, prepare and review correspondence related to FDA licensure and licensure applications.
- Oversee internal audits. Audits may include BBA locations, processes, documentation, and supplier or service provider audits.
- Provide guidance for training programs to ensure compliance with regulations and standards. Actively educate staff on cGMPs, cGTPs, regulations, standards, procedures and processes.
- Establish and maintain oversight of system for prevention, detection, investigation, tracking, and corrective action of errors. Perform appropriate notification (e.g. FDA BPDRs or customer notifications) as appropriate.
- Oversee investigations including: ORs, BPDRs, Q&LB, PDIRs, etc.
- Oversee document control process and procedures. Work with the Document Control Specialists to ensure planning, implementation, tracking and review of all related documents follows appropriate policies and procedures.
- Maintain authority to approve or reject blood components, cellular therapy products, and supplies and review production records.



- Perform duties and promote 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.
- Work with all departments to ensure that SOPs are followed, ensuring the safety of blood and cellular therapy products and compliance with FDA and AABB requirements.
- Provide QA/compliance review of forms and documents as needed.
- Oversee Quality Committee and create management updates.

General Duties

- Maintain positive communication with all departments. Promote a positive work environment in which staff work cooperatively towards objectives.
- Assist management team in reviewing processes and recommending changes to improve quality.
- Attend all relevant meetings as scheduled and able to attend.
- Encourage employees to utilize appropriate support systems (SOPs, management, etc.) as necessary to resolve issues and answer questions.
- Build employee morale through recognition, strong leadership, constructive feedback and performance appraisal.
- Develop a team that embraces customer service. Focus on staff development in support of organizational objectives and standards. Identify professional development opportunities for applicable staff and self.
- Perform performance evaluation and disciplinary review of applicable staff.
- Make employee safety, timely reporting of safety issues and employee well-being a priority at all times.
- Maintain open and positive communication with management and staff.
- Exhibit support of BBA values, quality objectives, and customer service standards at all times. Promote the strategic direction of BBA to all employees.
- Help maintain positive image of BBA throughout the community while maintaining overall corporate image.
- 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, email or telephone contact. Must consistently deliver service in a timely, accurate, professional and friendly manner. Demonstrate a high level of problem-solving skills; identify and resolves problems in a timely manner, develops alternative solutions.

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.

SUPERVISORY KNOWLEDGE, SKILLS AND ABILITIES

1. Ability to identify needed changes in procedures, practices, goals, direction or structure of the department and organization. Ability to promote and implement these changes effectively in a timely manner.
2. Ability to work with others to achieve departmental and organization goals and objectives.
3. Ability to ensure that department budget is followed and objectives are met. Effectively monitor resources



and progress.

4. Ability to motivate and empower employees to utilize their abilities and talents effectively.
5. Ability to work effectively to improve the skills of employees by providing clear, specific and helpful feedback, and effective coaching and mentoring.
6. Demonstrate a positive attitude toward one's work and job.
7. Ability to act honestly and with integrity, showing respect for laws, the rights of others, and Blood Bank of Alaska mission.
8. Ability to adapt to various situations, to work effectively with a variety of individuals and groups, to understand and appreciate different and opposing perspectives of an issue, and to adapt approach as the requirements of the organization/department change.
9. Ability to change within the organization or to change job requirements as needed. Retain subject matter expertise in field or profession.
10. Demonstrate ability to work independently and in stressful situations.
11. Demonstrate personal attributes conducive to an auditor including: ethical, open-minded, diplomatic, observant, perceptive, versatile, tenacious, decisive, and self-reliant.

GENERAL KNOWLEDGE, SKILLS AND ABILITIES

1. Strong interpersonal and supervisory communication skills.
2. Ability to foster a working environment conducive to excellent customer service.
3. Ability to problem solve at an expert level through interpretation of regulatory guidelines, applicable laws and statutes, industry standards, and quality focused decision making.
4. Excellent writing ability for technical, professional and other related documents.
5. Demonstrate ability to network with internal and external resources, building relationships conducive to a quality environment and continued growth in knowledge areas related to industry.
6. Good organizational skills.
7. Knowledge of general safety and quality assurance procedures.
8. Ability to instruct and train on a continuous basis.
9. Ability to maintain confidentiality of donors, customers, employees and BBA business information.
10. Strong computer skills.
11. Ability to perform tasks of a detailed nature accurately within required timeframes and adapt to fluctuating workloads.
12. Effective written and verbal communication skills.

EDUCATION

Bachelor's Degree (BA) in relevant field and SBB (ASCP) preferred. American Society of Quality (ASQ) CQA preferred.

EXPERIENCE

Minimum five years in a highly regulated, compliance driven environment with responsibility and oversight for designing, implementing and monitoring the quality and compliance programs for all applicable divisions. Minimum 3 years' experience in donor testing laboratory or quality assurance support for donor testing laboratory preferred. Experience with cellular therapy programs preferred.

CERTIFICATES, LICENSES, ETC.

Minimum: Valid Driver's License. SBB (ASCP) and American Society of Quality (ASQ) CQA preferred.



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 Director of Quality Assurance and agree to perform the duties as stated.

Employee Print Name

Employee Signature Date

Supervisor Signature Date