**Classification Specification for Unclassified Service**

**Title:** Director, Quality Assurance & Regulatory Affairs - Hoxworth  
**Pay Scale Group:** 17

**Essential Function**

Under general supervision from a designated administrator, oversee and direct the coordination of regulatory compliance throughout the blood center (e.g., submission of license applications to the FDA, review and investigate error reports and submit findings to the FDA, coordinate recall notifications and supervise Internal Audit and Metrology Programs).

**Characteristic Duties**

- Direct the coordination of regulatory compliance with the Food & Drug Administration (FDA).
- Monitor activity and manage investigation of process and procedures errors to be provided to the appropriate personnel/agency.
- Supervise programs and projects necessary for maintaining quality, licensure, and accreditation.
- Supervise internal audits and follow-up; review results and provide feedback as needed.
- Provide oversight in Standard Operation Procedures (SOPs) management through the blood center to include, but not limited to, SOP distribution and archival.
- Develop departmental SOPs for new processes and update existing SOPs.
- Keep abreast of state and federal regulations governing compliance.
- Prepare and monitor budget, term contracts, purchase requests, etc.
- Prepare biological product deviation reports for FDA and other statistics.
- Participate in and coordinate educational programs concerning quality assurance/compliance for staff and students.
- Maintain professional growth, represent the University at meetings/seminars and serve on various committees.
- May provide direct supervision to exempt and non-exempt staff (i.e., hiring/firing, performance evaluations, disciplinary action, approve time off, etc.).

*An affirmative action/equal opportunity institution*
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- Perform related duties based on departmental need.

Minimum Qualifications

- Bachelor’s degree with three (3) years experience; -OR- Associate’s degree with five (5) years experience; -OR- seven (7) years experience. Degree must be in Medical Technology, Biology, Chemistry, or a related field. Experience must be in clinical laboratory/blood center (e.g., hematology, immunohematology, etc). Experience may also require at least one (1) year supervision.