Job Description *Title* **Head of Quality Franklin, TN**		
Department Department: Quality	***Reports to: President and Chief Executive Officer*** ***Supervises: Yes***	
Effective Date: ***July 21, 2016***	*Page: 1 of 4*	***FLSA: Exempt***

Position Overview

The Head of Quality has primary accountability for the development and continuous improvement of Pierian's global Quality System to ensure that these procedures, policies, processes, and systems meet the needs of the company's global business. These needs include regulatory compliance, effective quality management, operational scalability, and the flexibility required by our rapidly growing business. The VP is responsible for the promotion of quality awareness and continuous improvement throughout the organization while developing, implementing, maintaining and improving the quality system and ensuring compliance with all applicable regulatory requirements. The QA leader must be results-driven and team-oriented with an enthusiastic attitude, strong leadership, broad perspective, deep expertise in quality systems, excellent interpersonal skills, and the ability to influence outcomes in a changing regulatory environment. The Head of Quality maximizes the effectiveness of our Quality System through direct management of Pierian's QA resources and through effective collaboration and influence with company executives, functional area leaders, and key subject matter experts throughout the organization, including Operations, R&D, IT, Commercial, and other areas.
The ideal candidate will have experience including medical devices, in vitro diagnostics, and clinical laboratory regulations, quality systems, and best practices; extensive management experience and a successful track record in development and ongoing improvement of Quality Systems in a highly dynamic laboratory testing environment.

Essential Job Functions

- Lead the strategic development, implementation, application, and continuous improvement of Pierian's global Quality System meeting both operational quality and regulatory requirements for our global business, with an initial focus on the US, EU, and UK.
- Lead Pierian's Corporate Quality Assurance function, with direct management responsibility for the staff and accountability for ensuring that this team has the technical and professional skills, organizational structure, capacity, and business processes in place to maximize the value of Pierian's Quality System.
- Facilitate effective cross-functional communication, alignment, collaboration, leadership and execution on quality-related objectives, plans, and priorities.
- Keep abreast of the evolving regulatory policy and industry best practices related to Laboratory Developed Tests and In Vitro Diagnostics in the US and internationally, leading the evolution of our Quality System as appropriate to adapt to these requirements.
- Develop business cases for proposed investments and changes in systems, processes, staffing, and organizational development for Quality Assurance, providing clarity on costs, benefits, alternatives, resource requirements, and other relevant information to enable timely, effective decision making.
- Provide expert advice to executives and functional area managers on QA related issues, including those with company-wide or external impact.
- Collaborate with functional areas to establish and update metrics that are reported to the Board and upper management that highlights risks and key opportunities for continuous quality improvement.
- Provide QA input to manufacturing, Quality Control, and product development processes to maintain compliance with the relevant quality regulations and international standards.

- Provide QA input and resources to author, review and finalize quality-related documents for regulatory submissions globally, including PMA, 510(k), and CE-IVD.
- Provide QA input and resources to software development and IT organizations to develop, implement and maintain software and computer systems and software development lifecycles, including software QA and validation.
- Host FDA/third party regulatory audits (including pre-approval inspections for PMAs), and ensure follow up on findings/observations issued including issuing CAPAs as needed.
- Serve as Pierian's Quality Management Representative to FDA, other regulatory bodies, and ISO auditors.
- Lead Quality System Management Review meetings, in accordance with regulations and internal procedures.
- Identify and suggest functional improvements to the Document Control and Quality Assurance organizations to further ensure regulatory compliance and constant inspection readiness.
- Ensure Quality representation on Product Development Design teams.
- Ensure that budgets, schedules, and department performance requirements are met.
- Lead the Quality team, ensure appropriate resourcing and qualification of personnel through mentoring, training and development activities.
- Identify and implement best practices to improve efficiency and maintain compliance and lead the function in continuous process improvement.
- Work with project and business managers to define specific customer requirements and application of the quality systems for each project.
- As the Quality System Management Representative, ensure that quality systems functions such as document and change control, design control, risk management process, production and process controls, supplier evaluation and control, control of nonconforming materials, complaint handling, corrective and preventive action, and the internal audit program are effective and compliant.
- Implement appropriate activities to ensure regulatory compliance and adherence to the quality system.
- Monitor external changes to the regulatory environment to ensure the continued compliance of the quality system.
- Represent the business during any audit processes, internal or external.
- Take action on any audit findings, to reinforce compliance or remedial action on any unsatisfactory findings.
- Other duties as assigned.

Education/Experience Requirements

REQUIRED

- B.S. Degree or Master's Degree, higher preferred, in a related scientific or engineering discipline
- Minimum 8 years of experience in a QA leadership and management role (e.g. Director, Senior Director) in medical device / IVD field, with direct management responsibility for QA personnel and responsibility for a broad spectrum of Quality System elements

- Demonstrated success leading cross-functional development, implementation, application, and maintenance of Quality Systems which comply with FDA QSR, GCP, GLP, CLIA, and related US and international regulations and ISO standards pertaining to IVD development and ongoing commercial manufacturing and delivery. Successful track record of selecting, implementing, and optimizing electronic quality management system software including modules for document control, complaints, non-conformances, CAPA, and other Quality System functions
- Successful track record leading FDA and ISO inspections and internal quality audits.
- Experience in authoring both internal and externally facing quality related documents

PREFERRED

- ASQ certification (CMQ/OE, CQA, etc.) and/or RAC certification.
- Experience with molecular diagnostic assays is strongly preferred.
- Working knowledge and experience with Clinical Laboratories, Laboratory Developed Tests, and the relevant regulatory requirements and quality standards (e.g. CLIA, CAP, NY, EU IVDD, and ISO 15189) is highly desirable.
- Previous experience in other functional areas (R&D, Quality Control, Operations), in addition to QA experience is a plus.

Knowledge, Skills, and Abilities (KSAs)

- Extremely detail-oriented with strong organizational skills and high quality standards.
- Highly skilled in technical writing, document editing and management, and computerized systems.
- Effective analytical, technical and problem solving skills.
- Demonstrated ability to make sound, compliant judgments and decisions.
- Superb interpersonal and verbal communication skills, with the ability to effectively communicate with employees, functional area and executive management, customers, and business partners.
- Self-motivated, hands-on critical thinker and problem solver, with the ability to lead by example, an enthusiastic, optimistic outlook, and a collaborative style.
- Ability to integrate and apply feedback in a professional manner.
- Thorough knowledge of current quality management practices, including US FDA Laws and International regulations, design controls, manufacturing and servicing.
- Strong knowledge of US FDA and worldwide medical device regulations, including FDA Class III and Class II medical devices.
- Exceptionally strong team leader and team player with excellent interpersonal and communication skills, and experience working with end-users in a coaching capacity.
- Demonstrated ability to motivate and manage multiple levels of personnel. Skilled at identifying and developing personnel.
- Effective interpersonal and collaborative skills. Creating and supporting compliant win-win situations.

Effective utilization of negotiation and influencing skills.

- Sets high standards of performance for self and others; assumes responsibility and accountability for successfully completing assignments or tasks; self-imposing standards of excellence versus having standards imposed.
- Seeks appropriate input to decisions and recognizes impact and implications for other areas. Decision making is timely, practical, clear and open.

Travel, Physical Demands, and Work Environment

- Some travel required
- Standing or sitting for long periods of time may be necessary

NOTE: This job description is not intended to be all-inclusive. Employee may perform other related duties as negotiated to meet the ongoing needs of the organization. Pierian is an Equal Opportunity Employer with a strong commitment to the achievement of excellence and diversity.

PHYSICAL REQUIREMENTS CHECK-OFF FORM

Check off only the physical abilities that can be directly related to the essential functions of the job. (***Caution:*** Make sure you are not setting stricter requirements than for similar workers already employed.)

Job Title:				
Physical Activity Required	**Amount of time**			
	None	**Less than 1/3 (Occasionally)**	**1/3 to 2/3 (Frequently)**	**More than 2/3 (Regularly)**
Standing			X	
Walking			X	
Sitting			X	
Fingering or manual dexterity		X		
Repetitive finger motion		X		
Lifting or exerting force				
Up to 10 pounds		X		
Up to 25 pounds	X			
Up to 50 pounds	X			
Up to 100 pounds	X			
Over 100 pounds	X			
Reaching or stretching		X		
Climbing or balancing	X			
Crouching or stooping		X		
Speaking				X
Hearing				X
Seeing (with correction)				X

Completed by: Robert Henry Date: 7/21/2016