Quality and Operational Improvement Engineer

Job Code: PAF2
Pay Level: 5A
Position #: 00012944
Org/Dept/Sub-dept #: 90 / 9170
Position Reports to: Sarah Dricken 00193102

Position Specific Summary:
The Quality Systems Manager will be located in Ankeny, IA and will be responsible for achieving accreditation and maintaining compliance with regulatory and accrediting agencies (CLIA, TNI, AIHA, ISO, EPA, etc). In collaboration with operational leadership, implements and maintains the Quality Management Program based on the Quality System Essentials (QSEs) for the organization.

Key Areas of Responsibilities and Specific Job Tasks

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<th>Classification</th>
<th>Key Areas of Responsibilities</th>
<th>Specific Job Duties and Tasks</th>
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| Apply Process Improvement, Quality Engineering, and Management Engineering Concepts and Methodologies | • Oversees test method verification and validation processes to ensure adherence to regulatory requirements and best practice.  
• Reviews and evaluates regulatory compliance gaps and assists in process improvements to address gaps.  
• Assists with and ensures compliance with employee competency assessment and documentation. |
| Collect and Analyze Data | • Collects, reviews, and summarizes performance of quality metrics to ensure operational standardization and regulatory compliance. Makes recommendations for quality measures.  
• Assists with documentation, tracking, and resolution of non-conforming events.  
• Follows data collection processes, analyzes data, and prepares reports. |
| Project Management | • In collaboration with operational leadership, plans and implements quality improvement projects based on results of internal and external audits, changes in accreditation requirements, or review of data from quality indicators. |
| Quality Assurance and Compliance | • Responsible for achieving accreditation and maintaining compliance with regulatory and accrediting agencies (CLIA, TNI, AIHA, ISO, EPA, etc).  
• In collaboration with operational leadership, implements and maintains the Quality Management Program based on the Quality System Essentials (QSEs) for the organization.  
• Monitors, tracks, and coordinates proficiency testing program and ensures compliance.  
• Organizes and conducts internal audits.  
• Coordinates external audits.  
• Develops, implements, and maintains the Quality Management Plan, Quality policies and procedures, and document control system.  
• Assists in identifying and developing appropriate quality indicators. |
| Training/Education | • Serve as a site resource for laboratory safety activities.  
• Acts as a quality and compliance educator and consultant to laboratory staff.  
• Actively participate in Quality Management Committee and Internal Audit Task Force. |
### Laboratory Policies and Standards

- Ensures compliance with standards for different types of laboratory environments.
- Describes existing and evolving standards and procedures and their impact on organization.
- Exercises independent judgment and takes action with exceptions and special issues.
- Collaborates with other functions in establishing and documenting joint standards.
- Participates in the development of laboratory policies and practices.
- Describes impact of standards and policies across laboratory specialties.

Other duties as assigned.

### Universal Competencies

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<tr>
<th>Collaboration/Positive Impact</th>
<th>Ability to work with a variety of individuals and groups in a constructive and civil manner and utilize existing resources and learning to achieve or exceed desired outcomes of current and future organizational goals/needs.</th>
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<td>Diversity, Equity and Inclusion</td>
<td>Ability to work with a variety of individuals and groups in a constructive and respectful manner while appreciating the unique contribution of an inclusive workforce that brings together the talents of people across multiple identities, including: race, creed, color, religion, national origins, age, sex, pregnancy, disability, veteran or military status, sexual orientation, gender identity, or associational preferences.</td>
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<tr>
<td>Service Excellence/Customer Focus</td>
<td>Ability to meet or exceed customer service needs and expectations and provide excellent service in a direct or indirect manner. Ability to effectively transmit and interpret information through appropriate communication with internal and external customers.</td>
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### Technical Competencies

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<th>Business Process Design (Extensive)</th>
<th>Has led multiple business process design or re-engineering initiatives.</th>
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<td>Trains others to identify and implement required infrastructure to support specific processes.</td>
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<td>Assesses potential implications of re-engineering for multiple functions or departments.</td>
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<td>Demonstrates mastery of re-engineering concepts, methods, and tools.</td>
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<td>Redesigns or enhances business processes to meet regulatory requirements.</td>
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<td>Participates in design and implementation of a supporting organizational structure.</td>
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<td>Data Gathering and Reporting (Extensive)</td>
<td>Oversees multiple data-gathering and analysis initiatives.</td>
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<td>Analyzes complex reports as revealed by the data.</td>
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<td>Teaches others the calculations necessary to capture data and develop more complex reports.</td>
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<td>Prepares cost-benefit analyses of alternative approaches.</td>
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<td>Develops criteria for selecting data gathering and reporting tools and techniques for various projects.</td>
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<td>Reviews and verifies data and reports for accuracy.</td>
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<td>Managing Organizational Change (Extensive)</td>
<td>Plans, implements, and manages change in a variety of significant settings.</td>
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<td>Translates the desired organizational traits to tactical steps and procedures.</td>
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<td>Accurately anticipates impact of change, both positive and negative.</td>
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<td>Works with team to identify and remove obstacles to change.</td>
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<td>Monitors effectiveness of the change effort with particular attention to extent of acceptance.</td>
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<td>Makes sure to consider impact of changes outside own unit or organization.</td>
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| **Planning: Tactical, Strategic (Extensive)** | • Develops, refines, and communicates tactical plans for own responsibilities.  
• Plans for allocation of resources in line with unit goals, technical and business objectives.  
• Provides the right level of detail as input for strategic plan development.  
• Demonstrates the value and necessity of linking tactical plans to overall strategic plan.  
• Ensures the planning process is integrated with the overall business plan.  
• Ensures attention to the detail and dependencies of existing departmental-level plans. |
| **Training Delivery (Extensive)** | • Delivers training modules from existing lesson plans.  
• Designs methods for assessing the effective delivery against stated objectives.  
• Advises on adult learning principles and delivers relevant examples for learning and development.  
• Evaluates the effectiveness of modules, while supporting training materials.  
• Analyzes feedback and suggestions to course developers on potential improvements.  
• Reviews proficiency and creativity in handling multiple skill levels in the same class. |
| **Decision Making and Critical Thinking (Working)** | • Assists in assessing risks, benefits and consideration of alternatives.  
• Participates in documenting data, ideas, players, stakeholders, and processes.  
• Applies an assigned technique for critical thinking in a decision-making process.  
• Recognizes, clarifies, and prioritizes concerns.  
• Identifies, obtains, and organizes relevant data and ideas. |
| **Effective Communications (Extensive)** | • Communicates well downward, upward, and outward.  
• Employs appropriate methods of persuasion when soliciting agreement.  
• Maintains focus on the topic at hand.  
• Adapts documents and presentations for the intended audience.  
• Reviews others' writing or presentations and provides feedback and coaching.  
• Demonstrates both empathy and assertiveness when communicating a need or defending a position. |
| **Laboratory Practice Quality Assurance (LPQA) (Extensive)** | • Oversees and prepares contingency plans for potential problems in standard LPQA procedures.  
• Designs data auditing criteria to evaluate the validity of collected data.  
• Directs the selection of LPQA techniques in complex laboratory environments.  
• Optimizes key stages (e.g. analytical stage) in the LPQA process to improve efficiency.  
• Evaluates LPQA precautionary measures; prevents the practice of faulty laboratory processes.  
• Coordinates interdepartmental and external LPQA procedures. |
| **Quality Management (Extensive)** | • Communicates key benefits of a quality management process.  
• Develops quality assurance processes based on Six Sigma, ISO 9000 or Baldrige principles.  
• Develops expertise in quality assurance tools, techniques, and standards.  
• Interprets results of quantitative and statistical tools and explains results to others.  
• Conducts and directs quality reviews.  
• Develops programs for motivating personnel to meet or exceed quality goals. |

As part of performing the key areas of responsibility and competencies described above, staff members are expected to meet reasonable standards of work quality and quantity, as well as expectations for attendance established by their supervisor. Staff members are also expected to comply with policies governing employee responsibilities and conduct, including those contained in the University Operations Manual.
Proficiency levels are defined as:

**Basic Application** - Uses basic understanding of the field to perform job duties; may need some guidance on job duties; applies learning to recommend options to address unusual situations.

**Working Experience** - Successfully completes diverse tasks of the job; applies and enhances knowledge and skill in both usual and unusual issues; needs minimal guidance in addressing unusual situations.

**Extensive Experience** - Performs without assistance; recognized as a resource to others; able to translate complex nuances to others; able to improve processes; focus on broad issues.

**Expert/Leader** - Seen as an expert and/or leader; guides, troubleshoots; has strategic focus; applies knowledge and skill across or in leading multiple projects/orgs; demonstrates knowledge of trends in field; leads in developing new processes.

**Position Qualifications**

**NOTE:** Education OR experience may be increased or decreased by one level for most positions.

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<th>Education or Equivalency Required</th>
<th>A Bachelor’s degree in biology, chemistry, laboratory science, or related field or an equivalent combination of education and experience is required.</th>
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| Required Qualification | • Demonstrate 3 years or more of recent (within the last 10 years) experience in certified (for example, CLIA, TNI, AIHA, ISO or equivalents) medical, environmental, or public health laboratory.  
  • 1 year experience conducting internal or external audits.  
  • Extensive knowledge of quality control, quality management systems, method validation and verification, accreditation, proficiency testing, and quality improvement.  
  • Previous policy and procedure development experience.  
  • Previous experience with document control systems.  
  • Excellent organizational and work plan development skills.  
  • Strong computer skills, including Microsoft Office products.  
  • Ability to lead multidisciplinary teams.  
  • Outstanding attention to detail and deadlines.  
  • Outstanding written and verbal communication skills.  
  • Ability to read, interpret, and explain regulations, guidance documents, and technical procedures.  
  • Prior completion of a college-level statistics course. If not completed prior to hire, this will be required within 12 months of start date. |
| Preferred Education or Equivalency Required | • A Master’s degree in biology, chemistry, laboratory science or related field or an equivalent combination of education and experience is required. |
| Preferred Certification | • Certified Quality Auditor CQA(ASQ), Quality Improvement Associate CQIA(ASQ), Manager of Quality/Organizational Excellence CMQ/OE (ASQ) or similar quality certification. |
| Desirable Qualification | • Previous lab supervisory or quality management experience.  
  • Previous experience with process improvement tools such as Lean, Six Sigma, etc.  
  • Familiarity with CLIA, TNI, AIHA, and ISO standards. |

See requisition # 19003598 at [https://jobs.uiowa.edu](https://jobs.uiowa.edu) within Admin / Scientific

Applicable background checks will be conducted.

The University of Iowa is an equal opportunity/affirmative action employer. All qualified applicants are encouraged to apply and will receive consideration for employment free from discrimination on the basis of race, creed, color, national origin, age, sex, pregnancy, sexual orientation, gender identity, genetic information, religion, associational preference, status as a qualified individual with a disability, or status as a protected veteran.