Position Title: Quality Systems Engineer
Department & Cost Center: Quality & Documentation 1060
FLSA Status: Exempt
Supervisor: Manufacturing Quality Manager
Grade Level: (HR Use Only)
Date Approved by HR: 8/5/2010

Position Overview:
This person is primarily responsible for engineering and executing business system improvements at Laerdal. They utilize statistical thinking and methodologies to identify opportunities, plan improvements, execute those plans, and then follow up to ensure business results have been statistically improved and sustained, especially with regard to meeting customer expectations. They are in-house consultants to all departments to facilitate and lead improvement activities. They support engineering efforts that relate to quality improvement. They participate in and support activities involving compliance with applicable regulatory and Quality Management System requirements. They coordinate and execute plans to maintain an ISO-certified quality system at Laerdal. They support the maintenance and development of the customer corrective and preventative action (CAPA), internal non-conformance and Laerdal Quality Management Systems.

Essential Duties and Responsibilities:

- Provide quality service to Laerdal’s internal and external customers in all assigned tasks, while upholding Laerdal Values at all times.
- Evaluate business goals, identify improvement opportunities and apply scientific methods, statistics and problem solving techniques to improve and sustain product quality and process effectiveness.
- Plan and execute projects and team activities to facilitate changes that have a statistical impact on business results, especially as it relates to meeting and exceeding customer expectations.
- Establish programs, policies and procedures to evaluate precision, accuracy and capability of processes, products, production equipment and testing, measurement, and analytical equipment and facilities.
- Provide technical expertise in product development projects, design reviews, verification, validation and manufacturability involving R&D, Product Group, Procurement, Manufacturing and other departments.
- Support the maintenance and improvement of the Laerdal Quality Management System.
- Schedule and perform audit activities, to include pre-audit planning, audit execution and evaluation and post-audit follow-up and recommendations.
- Assist operating units with development and implementation of corrective and preventive action plans to improve overall ISO compliance and quality results.
- Present to managers on improvement projects and activities.
- Compile & write training material and conduct training sessions on improvement tools & methodologies.
- Ensure applicability of current quality policies, procedures and objectives by keeping informed of the latest updates/ modifications related to ISO quality systems.
- Support the development and administration of the customer corrective and preventative action (CAPA), internal non-conformance and Laerdal Quality Management Systems.
- Perform other related duties as assigned.
Responsibility and Decision Making Authority:
  • Act independently; Decision making within Company policy.

Management/Supervisory Responsibilities:
  • Not Applicable.

Qualifications/Competencies/Position Requirements:

Knowledge, Skills, and Abilities:
  • Ability to understand and apply statistical and business improvement tools to improve and sustain business results.
  • Strong organizational, practical mathematical (statistical) skills, analytical and problem solving skills.
  • Strong communication, presentation, interpersonal, and organizational skills.
  • Ability to conceptualize, analyze, plan and organize projects.
  • Reasoning skills for problem identification and resolution.
  • Knowledge and ability to understand and apply process audit principles (ISO/ASQ).
  • Experience in quality control program operations, to include standards & measurement techniques.
  • Ability to apply quality control theories and principles to an operational environment.
  • Six Sigma or Lean skills and tools exposure advantageous.
  • Computer literate; able to utilize MS Office Suite, MS Project.
  • Database experience beneficial.
  • Must excel at working in a team environment.
  • Ability to communicate detailed, technical initiatives to non-technical people.

Education and Experience:
  • Bachelor’s degree in engineering or equivalent specialized experience.
  • 3+ years experience with Quality Assurance programs in a corporate environment preferred.
  • Low volume manufacturing environment experience advantageous.

Licensing and Certification:
  • Quality/statistical related certifications advantageous (ASQ, Six Sigma, Lean).
  • Professional auditing experience preferable. Quality certification, or RAB certification, preferred.
Working Hours:
• Hours may vary and will require evening and weekend work depending on business needs and will require working overtime.

Working Environment:
• Works in both an office and manufacturing environment.
• Exposure to shop elements such as noise, dust, odor, chemicals, solvents, and fumes.

Tools and Equipment Used:
• Personal computer, copier, fax, phone, and other standard office equipment.

Travel:
• Ability to travel as required by role.

Physical Demands:
• Digital dexterity and hand/eye coordination in operation of office equipment.
• Light lifting and carrying of supplies, file, etc.
• Ability to speak to and hear customers and/or other employees via phone or in person.
• Body motor skills sufficient to enable incumbent to move from one office location to another.