Sr. Quality Engineer

With a vision to create a world without limits for people with diabetes, LifeScan is a world leader in blood glucose monitoring - globally more than 20 million people depend on OneTouch brand products to help them manage their diabetes. For over 35 years, LifeScan has had an unwavering commitment to improving the quality of life for people with diabetes by developing products defined by simplicity, accuracy, and trust. The business has worldwide hubs in Malvern, USA (Pennsylvania), Inverness, UK, and Zug, Switzerland.

The Opportunity:

The Senior Quality Engineer will provide Quality Assurance/Engineering support for Digital Solutions, including execution and facilitation of Quality Systems processes (NC, CAPA, Change Management, Audit etc.) for digital products. This role will Regularly interface with project team members of product development, clinical operations, regulatory, V&V, IT, PMO, and other stakeholders to ensure that the Design control, IT Systems Software V&V, and Quality Management & Compliance processes are followed. The Sr. Quality Engineer will also provide support for inspection readiness program to ensure Digital Solutions and their products are inspection ready.

This position can sit remotely, more preferably local to Malvern, PA or the East Coast.

Job Focus and Responsibilities:

Quality Assurance:

- Executes and serves as the subject matter expert in quality assurance and process management related activities in the development of new digital products and software management processes. Represents the mindset and principles of the Quality department and drives quality initiatives. Assures adherence to quality systems to achieve highest levels of compliance.
- Implements quality activities in projects and product teams in the medical device realm and executes activities like product risk management, privacy & information security risk management, process compliance monitoring, supplier quality management, change management.
- Utilizes effective and efficient Quality Engineering techniques such as risk analysis, test method development, design of experiments, statistical data analysis, and development of sampling plans throughout the product lifecycle to execute associated tasks in Quality Engineering
- Ensures product lifecycle deliverables meet the requirements of LifeScan's processes, regulatory reviews, and pass internal and external audits. Ensure audit follow-ups and findings are appropriately addressed promptly.
- Responsible for ensuring the projects' and programs' compliance to LifeScan Quality System and applicable regulations.
- Mentors team members during new employee onboarding stage and on specific quality topics.

Quality Systems & Compliance

- Executes implementation of Global LifeScan Quality System within Digital Solutions and associated partners.
- Provide management support for quality systems and compliance activities for associated areas (Field Action Evaluation and resulting field actions, Non-Conformances, CAPA, Audits etc.).
- Works with quality leadership and stakeholders in implementing significant activities within the quality system such as: change control, NC, CAPA, supplier monitoring, risk management activities, involving global or highly complex interactions.
- Oversees Digital Solutions suppliers and ensures they are managed per LifeScan processes.

- Participates in project teams as required to represent Quality.
- Maintain awareness of industry issues, trends and changes in quality regulations and policy and bring those to the attention of management.

Quality Assurance (IT Systems V&V Process)

- Leads IT Systems validation projects and assures and oversees the adherence to LifeScan validation processes and methodologies and medical devices industry best practices.
- Works with stakeholders and suppliers to ensure high quality, process compliant, and timely commissioning of IT systems.
- Identifies and implements ways to make the processes efficient while ensuring compliance.

Continuous Improvement of Quality:

- Identifying and improving problem solving and fault diagnosis processes within the engineering teams
- Identifying opportunities and implementing projects to continuously improve quality, cost, and time factors in our quality systems, processes, operations, and tools.

Requirements:

- 5+ years of experience in Quality within a regulated environment
- Expertise in Software Development Lifecycle in Agile and Software as a Medical Device
- Expertise in Quality Systems, Quality Assurance, and/or Regulatory Affairs in a Pharmaceutical or Medical Device GMP/ISO environment
- Preferable - Certifications in Quality (CSQE etc.)
- Preferable – Certifications in project, change, and/or process management (Lean, Six Sigma, PMP, CMMi etc)
- Project Management
- Technical Leadership
- Data driven decision making
- Proactive approach to issue identification and problem resolution
- Resilient and ability to work under pressure.
- Trouble shooting and problem-solving skills
- Change Management experience
- Administrating & trouble shooting regulated QMS applications

Location:

- Remote – preferable local to Malvern, PA or East Coast

If you want to be seen for the talent you bring to your work, be the driver of your own career, and work with others who share your passion for caring and success then this would be a fantastic role for the right candidate.