Bring your talent to a place where your work will fight cancer and save lives.

Join Varian's Oncology Systems team and your expertise will make a difference by helping to create a world without fear of cancer. We drive the development of products and solutions that innovate, support and simplify cancer-fighting solutions worldwide. Bring your passion to a company generating nearly $3 billion in revenue, and put your talent into innovating the latest cancer fighting technology.

Senior Quality Engineer-BSEE

A Senior Quality Engineer responsible for influencing design, development, sustaining activities and usability of new products within the new product development environment.

ESSENTIAL FUNCTIONS:

- Participate on cross-functional teams to review marketing requirements and to develop concise, unambiguous, non-conflicting, and feasible product requirements that support the market needs.
- Participate on cross-functional teams to develop product risk management file (risk management plan, risk assessments, DFMEA, and risk management report). Perform engineering risk analyses (14971) to manage technical difficulties encountered with new medical devices.
- Partner with Software Engineering, Hardware Engineering and Manufacturing teams to assess risk, develop software design plans and documentation, ensure code and integration reviews occur, and to demonstrate software capability and maturity.
- Assist in the creation of verification and validation plans, protocol and reports. Oversee testing and analysis for standards and product requirements compliance.
- Provide guidance and direction for sample size and statistical analysis of verification and validation test results.
- Ensure successful transfer of new products to production facility by assisting in the development of process validation requirements (FMEA, IQ, OQ, PQ) using appropriate statistical tools and techniques
- Participate and aid in the new product development process by identifying effective test methods.
- Analyze and interpret engineering test data collected during new device testing.
- Interface among multiple departments and teams including R&D (help define user needs-Design inputs), Manufacturing (Partner on Mfg. Plan and equivalence), vendors and senior managers to ensure time and or regulatory standards are met.
- Evaluates/improves the robustness of new products/line extensions through design and/or testing
- Predicts potential failure modes of new product design and offers input/improvements to cross functional design team
- Work hand in hand with service organization to gather use data to further develop and improve clinical knowledge, use cases, and potential applications and failure modes for medical devices
- Designs and/or implements methods and procedures for inspecting, testing, and evaluating the consistency and durability of products and/or production and/or test equipment.

- Ensuring that proposed designs meet or exceed defined user needs
- Perform and/or supervise validation of production processes and/or test procedures/fixtures
- Select, analyze, design, and improve mechanical and/or electrical manufacturing and/or inspection procedures for medical devices.
- Analyzes reports and/or returned products and recommends corrective action.
- Develop statistical process controls and analyze data. Optimize operating parameters.
- Analyze and improve computer test software, verification and validation equipment, inspection equipment, and process/manufacturing equipment
- Capable of mentoring junior quality engineers in providing quality engineering support for their medical device products as well as creating and/or modifying procedures as necessary
- DMR and DHR contributor
- Review Design History Files for conformance to applicable requirements.

Requirements:

- **BSEE** with 12+ years of experience in Quality/R&D/Manufacturing with minimum 8 years in Quality organizations
- MSEE with 10+ years of experience in Quality R&D/Manufacturing with minimum 7 years in Quality organizations

SKILLS/QUALIFICATIONS:

- Clinical experience desired
- Working knowledge of and auditing experience to the FDA Quality System Regulation, ISO 13485, and the Medical Device Directive.
- Good verbal and written communication skills including protocol / report development and technical presentations.
- Risk Management, ISO 14971, FTA, FMEA, HACCP.
- Comparative Statistical techniques, sampling plans, GR&R, K-factor, hypothesis testing, ANOVA, parametric and non-parametric analysis.
- Process Validation (IQ, OQ, PQ), DOE, SPC and capability analysis.Test plan development and root cause failure analysis.
- Previous experience working in a cross-functional team environment.
- ASQ CQE, CQA, CSQE and/or CRE certification.
- Familiar with statistical software tools (Minitab, Stat Graphics, Statistical)
- Stability, Biocompatibility, Sterilization, Ship Testing, HALT/HASS.
- Familiar with IEC 60601 and product specific industry standards.
- Familiar with DMAIC or DMADV(DFSS) methodologies
- DFSS / Lean Black Belt or Master Black Belt preferred
- Excellent written and oral communication skills
- Excellent organizational, problem-solving, and analytical skills

At Varian, our culture is centered on fostering the creative potential of every employee through teamwork and collaboration. Touching millions of lives every day inspires us to do our best work. Start with your talent, ambition and creativity and build a career that allows you to make a difference. You'll also enjoy an array of benefits, including: a 401K plan with a generous 6% match, an employee stock purchase program, wellness programs, fitness centers, comprehensive insurance plans, flexible paid time off, and so much more.

You're just one click away from the most impactful work you'll ever do. Apply now. Someone, somewhere, will be glad you did.
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