

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals, and branded generic medicines. Our 109,000 colleagues serve people in more than 160 countries.

ABOUT ABBOTT

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Manufacturing Line Quality Engineer

We are recruiting for a MANUFACTURING LINE QUALITY ENGINEER to join our team within our Infectious Disease Developed Markets business unit located in Scarborough, ME. In this role you will provide support for contract manufacturing, product quality assurance, change management, process improvements, and quality system programs.

WHAT YOU'LL DO

- Support production with resolution of quality issues in accordance with established procedures.
- Support production on the manufacturing floor, ensuring adherence to procedures and ensure appropriate device history record (DHR) documentation. Supports line clearances, reworks, and inspections as required.
- Support the NC and CAPA processes by completing risk assessments, root cause investigations, and action plans.
- Perform Risk Management activities using the Failure Mode and Effect Analysis methodology (e.g. dFMEA, pFMEA). Support peers in the development of mitigations for failure modes and verify the effectiveness of these mitigations.
- Supports the change control process by reviewing proposed changes, performing risk assessments, and assessing the adequacy of verifications and validations.
- Reviews qualifications, validations, and other studies for technical content, statistical and sampling rationale, unintended impact and clarity. Act as the Quality representative for qualification and validation approvals for all validated equipment.
- May participate on design transfer and improvement project teams.
- Demonstrates commitment to the development, implementation and effectiveness of Quality Management System per ISO, FDA, and other regulatory agencies.
- Responsible for exhibiting professional behavior with both internal/external business associates that reflects positively on the company and is consistent with the company's policies and practices.
- Understands and is aware of the quality consequences which may occur from the improper performance of their specific job. Has awareness of device defects that may occur in their area of responsibility, including product design, verification and validation, manufacturing and testing activities.

• Other duties as assigned, according to the changing needs of the business.

EDUCATION AND EXPERIENCE YOU'LL BRING

REQUIRED

• Bachelor's Degree in Engineering, Chemistry, Biotechnology, Life Science or other technical field or the equivalent combination of education and experience.

PREFERRED

• Certified Quality Engineer (CQE) or Certified Quality Auditor (CQA) Certification

COMPETENCIES

• Knowledge of ensure and Agile programs.

• Working knowledge of Database software; Internet software; Inventory software; Spreadsheet software and Word Processing software.

• Working knowledge of FDA, cGMPs/QSR and ISO quality system requirements

• Strong technical writing skills and effective communication skills

WHAT WE OFFER

At Abbott, you can have a good job that can grow into a great career. We offer:

• **A FAST-PACED WORK ENVIRONMENT** where your safety is our priority

• Production areas that are **CLEAN, WELL-LIT AND TEMPERATURE-CONTROLLED**

• **TRAINING AND CAREER DEVELOPMENT** , with onboarding programs for new employees and tuition assistance

• **FINANCIAL SECURITY** through competitive compensation, incentives and retirement plans

• **HEALTH CARE AND WELL-BEING PROGRAMS** including medical, dental, vision, wellness and occupational health programs

• **PAID TIME OFF**

• **401(K)** retirement savings with a generous company match

• **THE STABILITY OF A COMPANY** with a record of strong financial performance and history of being actively involved in local communities

An Equal Opportunity Employer

Abbott welcomes and encourages diversity in our workforce.

We provide reasonable accommodation to qualified individuals with disabilities.

To request accommodation, please call 224-667-4913 or email corpjlat@abbott.com