

GF Health Products, Inc. Job Description

JOB TITLE: Quality Engineer, (CQE)
DEPARTMENT: Quality
LOCATION: Basic American Metal Products, Fond du Lac, WI
REPORTS TO: Corporate Quality Engineer/ Manager

SUMMARY

Responsible for developing and maintaining Quality engineering, inspection and process methods ensuring that the *GF Health Products, Inc.*'s Wisconsin Facility complies with *FDA* regulations including state and local requirements. Ensures quality products are manufactured and distributed consistently according to established standards and specifications, which meet or exceed customer expectations.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Compliance to FDA QSR, cGMP, ISO 13485-03.
- QSIT Subsystems: Management Controls, Design Controls, CAPA, Production and Process Controls.
- Utilizes Quality engineering principles and problem solving skills to develop and optimize products and processes throughout the product life cycle.
- Effective risk management assessment of products preventing unanticipated failure modes and ensure capability (FMEA).
- Establish and maintain open lines of communication throughout the Organization and function as a Project Team Member in matters relating to Quality Engineering at GF's Wisconsin Manufacturing facility.
- Ensure active and thorough investigation of Quality issues, Root Cause Analysis, effective corrective and/or preventative action.
- Assists in the development, execution, and completion of new manufacturing growth including but not limited to MVPs, Risk Management, Equipment IQ/OQ/PQs, Process Validations, Test Method Validations, and software validations.
- Provide guidance and recommendations involving the implementation of Quality

- requirements (e.g., Quality System Regulation, Canadian Medical Device Regulations, EU MDD, ISO standards, etc.).
- Validates/audits Supplier quality systems (Supplier Evaluations).
 - Manage and perform product and process audits of the quality system and when necessary, at supplier locations.
 - Ensure effective change control and proactively communicate with Regulatory/Risk Management/Legal any changes in design or changes in process that could adversely affect product quality/design function.
 - Partner with Engineering and Suppliers to ensure the application of process validation, process control, process risk management and investigation/correction of process failures.
 - Assist Engineering (GF, Supplier, and third party testing labs) and Product Managers with investigating root cause, corrective action and trends to quality complaints and product concerns.

SUPERVISORY RESPONSIBILITIES

Coordinates and facilitates Quality Management throughout the manufacturing facility including but not limited to document control, NCMR, CAPA, and complaint investigations.

EDUCATION and/or EXPERIENCE

Bachelor of Science in Engineering, ASQC Certified Quality Engineer, Certified Quality Auditor (CQA), Quality Systems Management. Experience interfacing with Pacific Rim Suppliers a plus.

COMPUTER SKILLS

Proficient in Microsoft Word, Excel, and PowerPoint. Statistical software Minitab, CATSWeb, and SharePoint interface desired.

TRAVEL

May travel on limited basis to international and domestic off-site locations. Quarterly travel to corporate office required.

To apply for this position please send a cover letter and resume to hr@grahamfield.com.

All qualified applicants will receive consideration for employment without regard to age, race, creed, color, national origin, ancestry, marital status, affectional or sexual orientation, gender identity or expression, disability, nationality or sex.

