

Anne Chege

Quality assurance inspector

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To add value to all tasks and assignments and contribute to team and business goals, and consistently deliver excellent customer service and quality work.

WORK EXPERIENCE

External Analyst II, Postmarket Surv .

St.Jude medical. - Minnetonka, MN - 2015-11 - 2017-02

- Initiates and manages the complaint file.
- Strong organizational and follow-up skills, as well as attention to detail
- Independently assesses the complaint to determine if a medical device report needs to be filed with various global regulatory agencies (e.g., FDA, European Competent Authorities) and sends reports within required timeframes, consulting as needed with management.
- Prepares customer letters with investigation findings.
- Ability to leverage and/or engage others to accomplish projects
- Participates in cross-functional complaint review groups on a regular basis or as requested (e.g. cross-functional complaint teams, new product teams, risk management meetings).
- Communicates verbally and in writing both internally and externally to field representatives regarding information needed specific to product complaints (e.g. physicians, hospital personnel, sales representatives, international offices).
- Provide support to the Legal Department regarding product complaints
- Complies with U.S. Food and Drug Administration (FDA) regulations, other regulatory requirements, Company policies, operating procedures, processes, and task assignments .
- Supports the Quality Management Systems (QMS), Environmental Management Systems (EMS).
- Be able to ascertain when additional support may be needed from other teams based on product evaluation findings (e.g. potential manufacturing-related issues).
- Reviews external vendor/consultant evaluations and enters them into the complaint system.
- Reviews all pertinent information to complete the evaluation (e.g. photos, study or log files, field service reports, external investigations).
- Archives complaint records and retrieves information on closed investigations.
- Executes product evaluations to develop a well-documented and accurate root cause evaluation.
- Use procedures, judgement and experience to determine appropriate testing of returned products with minimal guidance .

Quality assurance inspector

- 2014-06 - 2015-10

Good problem-solving and proficient computer skills are required

- Multitasks, prioritizes and meets deadlines in timely manner.
 - Ability to travel approximately 10%, including internationally
- Quality assurance inspector.2014 june-2015 OCT.

- Inspection of incoming parts from different vendors.
- using SAP to store information on products.

- using windchill to follow the right process of inspection.
- good team work experience
- was chosen in 2014 as the head of Receiving inspection
- Ability to organize a team and work using FIFO and in a very efficient and quality way.
- ability to use inspection tools eg.lesser, ruler, microscope, micrometer, fluke, caliper etc.

Assembler/Quality assurance inspector/supervisor

Boston Scientific Inc - Maple Grove, MN - 2011 - 2014

Responsible for training file accuracy, ensured all employees in my area are following processes

- Ensured finished devices were within product specification prior to release
- Form and Fold, Coiling and VDT, Loading and unloading, Inspection and Packaging
- Proficient in SAP
- Selected as a member of CIS Team
- Participated in Kaizen Events, resulting in reduction of wipe by 60%, reduction of cycle time, and increased labor efficiency
- Completed leadership training
- Helped QE Tech with disposition of NCE
- Worked with ME and QE Techs to ensure new processes were suitable
- Trained employees on how to set up the machine by checking the water system, changing of sponges, changing of BIOSOLID Mix, and purging of R.O. water before working on the machine
- Coating of catheters, mixing of chemicals such as pre-mix and AIBN, measuring of the chemical to get the right quantity based on the requirement, loading and unloading of catheters, inspection of product to check for different unwanted defects, plasma treating of catheters, detangling of product to avoid scrap in the machine, and sorting of all products
- Laser scan micrometer and measuring the outer diameter
- Oven settings per PPS
- Braid Annealing
- Participated in the Kaizen Events/CIS
- Increased productivity, reduced cycle time, improved labor efficiency, Increased yield by 98%, reduced scrap

EDUCATION

Associate of Applied Science in Business Management

University of Nairobi (kenya) - Nairobi, KE

SKILLS

PowerPoint,Microsoft Office,Microsoft Access,Spreadsheets

ADDITIONAL INFORMATION

REF:

Supervisor Boston Scientific:

Fadumo Jama

612-986-0742

Henry Weru

Quality supervisor Abbott

763-516-7564

Melissa Wappel

Supervisor/Lead,

Postmarket Surveillance

Abbott

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