Lucy Chardon

Quality Assurance

New Haven, CT - Email me on Indeed: indeed.com/r/Lucy-Chardon/06b62b6c6f5a671f

Obtain a challenging position in where I can maximize the skills in management, quality assurance, product development/technical design and training that I have gained within the past 11 years working in global healthcare environments and in the fashion industry.
Authorized to work in the US for any employer

WORK EXPERIENCE

Quality Assurance Analyst II

Covidien Medtronic - North Haven, CT - June 2017 to Present

As Quality Assurance (QA), my job is to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer.
Conducts routine and non-routine analysis of raw materials and records and investigates out-of-specification and out-of-trend results and non conformances.
Perform the visual, dimensional, functional and physical testing of products/components in accordance with approved Inspection plan, Print, Master Inspection Characteristics and Departmental Standard Operating Procedures.

Performing analysis on raw materials, intermediates, standards and finished products

Creating CAPAs that arise within QA

Calculating results and reporting of data, including trend analysis as required
Carrying out routine maintenance activities for QC systems

Meeting quality and safety standards

Reporting and communicating to QC supervisor/manager

Participating in the preparation of QC reports

Job duties include:
1. Set up inspection lot includes moving/handling shipment packages through the Inspection process.
2. Perform visual, dimensional, functional and physical testing of components/products using various types of measuring instruments and equipment such as toolscopes, pin gages, calipers, cmm optical, microscopes, blade micrometers and micrometers.
3. Perform inspection on Vendor Inspect (VI) and Accept Per Certification (Client PER C of C) lots.
4. Ensure testing equipment is in proper operating condition and/or calibrated before use.
5. Read and interpret complex Engineer blueprints and specifications.
6. Review vendor/manufacturing traceability, supplier documentation (such as COC Certificate of compliance and Packing List), warehouse documentation and the operational computer system (BPCS and Agile).
7. Record inspection results and disposition lots in the operational computer system with accuracy and completeness.

8. Review vendor data, to ensure product is acceptable within material specifications and supplier control plans.
9. Scan certificate of compliance packet (Supplier, Warehouse, Incoming documentation) into the network folder and process through the Agile REC Workflow.
10. Issue nonconformance reports (NCR) and responds to customer regarding status of inspection lots.
11. Support the return to vendor process (RTV).
12. Support the VI/STS audit process.
13. Process various reference documents through the Agile Workflow.
14. Manage the record retention process.
15. Complete daily efficiency report in department database.
16. Provide hands on peer to peer training.
17. Perform departmental safety audits.
18. Follow plant safety procedures and PPE requirements.
19. Perform duties in accordance with current departmental operating procedures. Support and promote projects to implement and improve processes.

• Computer knowledge of software skills (Excel, Word, Power Point, etc.)
• Read and interpret engineering prints and specifications/Knowledge of GDT
• Ability to manage competing priorities.
• Demonstrated skills working independently with verbal / written instruction from Supervisor

• Knowledge of quality standards: ISO, GMP, and OSHA Rules and Medical Products Regulations.
• Knowledge and experience with medical device materials testing.
• Demonstrated excellent listening, verbal, and written communication.
• Knowledge of production policies, processes, procedures, and equipment use in routine Incoming receiving material testing.

• Knowledge of Client/CAPA/SCAR process.
• ERP BPCS experiences/knowledge.
• Agile experiences/knowledge.

Production Assistant

NEJ INC - Beacon Falls, CT - June 2016 to February 2017

As Production Assistant for Private labels I worked in collaboration with the Vice President of Private Brands, Technical design Manager, and the product development team in the creation of the Bills Khakis product line. Holding a large administrative position handling purchase orders and meeting multiple deadlines. A liaison with distribution centers and communicated details with many teams and vendors. Oversaw Domestic and International production. Managed WIP (Work in process) reports from tech issuance through bulk delivery. I requested, reviewed and submitted all POs through EMS system to domestic factories and mills.

Created core and seasonal fashion styles, assigned web codes, created fabric codes and entered fabric costs and trims costs in EMS. Built BOMs (Bill of matrials), cut tickets and provided factories with UPC and carton labels. Sourced all products. Ordered all trims and sent to factories as necessary; managed trim library and in-house trim stock. Negotiated trim costs and advised costing to Merchandising and Finance. Managed fabric shipments from mill to factory. Managed packing guidelines by brand. Requested delivery updates on production orders. Scheduled factory audits. Managed packing list and made updates when necessary.

Quality Control Auditor/Coordinator Techincal Design

Distinctive Apparel Inc. - Milford, CT - May 2013 to June 2016

Job Description:
Organize actions between 3rd parties and in house management to ensure completion of assignments per timetable requirements. Evaluate (T.O.P.) Top of Production and size set samples for Brand and Private label for quality purposes. Compare samples to approved standards for fit, wash, treatments, trims, labeling, marketing, overall workmanship and construction. Send approval/rejection comments to factories. Receive all bulk QC results notifications from overseas. Determine which styles need to be inspected at warehouse based on T.O.P. results & QC results. Work with Production department on how issues affect delivery. Work with warehouse to coordinate when goods arrive in order to inspect in timely manner without holding up picking/ packing depts. Work with Tech. Department to understand our fit and quality standards. Inspect bulk goods in warehouse for: measurements, wash, treatments, trims, labeling, marketing, & workmanship. Knowledge in RTV processes, working with 3rd party logistics and warehouse procedures. Coordinate with all parties regarding how to proceed once bulk has been inspected. Garment industry knowledge in inspection and control methods, techniques and documentation in Technical Design and Quality Assurance. Provide daily interaction with our Customer Service dept., ensuring the best customer service satisfaction solving quality problems and issues by meeting their needs.

Quality Assurance Inspector
PHILIPS RESPORONICS - Wallingford, CT - June 2012 to 2013

Healthcare

Job Description:
Receiving, in-process, final and pre-delivery verification and inspection of all company products.
Inspection of out-sourced products. Interpretation of drawings, blueprints and specifications. Use of standard measuring instruments to perform measurements on products and tooling, such as calipers and micrometers. Conduct a First Article Inspection Report. Ensuring that all documents, sign-offs, stamps, dates and part counts are accurate and properly recorded prior to accepting an operation as complete.

Quality Assurance Analyst
COVIDIEN - North Haven, CT - 2006 to 2010

Covidien is a manufacturer of medical devices, pharmaceuticals and medical supplies.

As QA (Quality Assurance) at Covidien, my responsibility included regulation of the quality of raw materials, assemblies, products, and components, services related to production, and management, production and inspection processes (including incoming, in-process and final inspection).
Duties included:

* Monitored, tracked, and trended surgical device product complaints to assure compliance with FDA and all competent Authorities worldwide.
* Performed in-depth trend analysis for Senior Management, leading multiple product teams and interacting with medical professionals.
* Mechanical testing with Instron machinery for suture and needle attachment on tensile, compression, flexure and peel testing.
* Plan, conduct, report and follow up an audit in accordance with ISO9001, AS9100
* Followed current departmental regulations on (SOP) Standard Operating Procedures, (CAPAs) Corrective and preventative action, (GMP) Good Manufacturing procedures, (GLP) Good Laboratory procedures, (GCP) Good Clinical practice procedures, Plant safety procedures and Personal Protective Equipment
* Use gauges, calibrated measuring equipment and other methods to ensure product conformance
* Oversee review of corrective and preventative action (CAPA) plans to assure completion.
* Abided with OSHA (Occupational Safety and Health Administration) rules and regulations.

* Practice Lean Manufacturing and training in 6 Sigma
* Operated in a clean room environment laboratory
* Document inspection results and inputting data into quality database.
* Generate NCP (Non Confirming Products) and CAR (Correction Action Reports) for non-confirming and/or rejected parts.

EDUCATION

Certification in Product Development Technical Design

FIT-Fashion Institute of Technology State University of New York - Manhattan, NY
April 2013 to Present

Bio Medical Engineer

Gateway College - New Haven, CT
June 2017

SKILLS

SKILLS * Microsoft Office - Outlook, Power Point, Word, and Excel 2010 * Certified in SOP (Standard Operation Procedures) database and Statistical procedure control * Trained in the following systems: * VERAX's Acquire and Analysis * Netscape * SAP * BPCS *EMS * PLM * Enovia, * Ecometry * Citrix * Order Trax * Circle Commerce (10+ years)

ADDITIONAL INFORMATION

SKILLS:

* Strong project management and interpersonal skills
* Self-motivated and independent; ability to work autonomously as needed
* Ability to manage working relationships effectively
* High level of professionalism with excellent verbal and written communications skills
* Strong attention to detail; highly organized
* Strong computer experience with proficient excel skills

* Multi-tasking ability in a fast-paced environment
* Possess strong commitment to team environment dynamics and demonstrate a positive attitude
* Works well hand in hand with Customer Service Quality related issues and customer requests
* Focused on meeting internal and external customer's needs and goals
* Great at solving quality problems using process planning, technical knowledge, teamwork, mathematics, and critical thinking
* Action-oriented by making timely decisions and resolving issues related to day-to-day activities
* Ability to adapt to change