BIOTRONIK JOB FAIR

21 February 2019, 130pm

26 February 2019, 930am

Techview, 1 Kaki Bukit View, Lobby C, #03-24 Singapore 415941

Position: Medical Product Assembly Operator

PURPOSE OF THE POSITION

Operators are in charge of executing the production processes in a production cell. They have to be able to independently execute those tasks and are actively involved in achieving the production objectives. In order to do this they also need to actively follow the established Kaizen processes and the corresponding Working Instructions. Operators are trained on multiple processes and have successfully completed a cross training.

Operators are measured by achieving the given objectives in terms of quality, quantity and according to the deadlines. This enables the organization to meet cost, quality and delivery targets.

ESSENTIAL JOB FUNCTIONS

- Follows the currently valid guidelines (e.g. working instructions, process descriptions, hygiene rules, environmental protection guidelines, cGMP, clear table policies)
- Independent execution of different process steps and surveillance of process execution according to written working instructions, according to the training level of the employee
- Notifies the supervisor of any observed discrepancies (process and quality discrepancies, security breaches, outdated calibration data, deviations in the documentation)
- Maintains a correct and conform documentation (e.g. when completing move tickets or inspection protocols)
- Highlights any issues immediately to the supervisor or the HR department
- Participates actively in the KAIZEN process (e.g. minimize waste)
- Contributes to a positive working culture
- If needed, performs individual tasks defined by the supervisor which in their nature belong to the work responsibility of an operator and/or are a necessity to achieve organizational performance
- Maintain a safe work environment and ensure the maintenance and upkeep of the physical location.

BASIC QUALIFICATIONS

Education:

- Completed professional education preferred
- Fluent in English and other Asian languages
- No other specific requirements

Experience:

- Experience working in a clean room environment will be advantageous.
- Experience of working in a production environment, previous execution of inspection tasks or machine handling is preferable
- Previous work experience in the pharmaceutical or medtech industy preferred

Position: Quality Engineer

PURPOSE OF THE POSITION

The Quality Engineer is responsible to provide support to Senior Quality Engineer on quality related matters to ensure product safety and performance. The Quality Engineer shall support execution, maintenance, and improving quality operations procedures as well as quality responsibility of incoming material inspection, in process/outgoing product inspection and environmental monitoring on serial production of components and devices for BIOTRONIK Singapore. The successful candidate ensures safety and performance of the manufactured components and products as per BIOTRONIK specifications under cGMP and quality system rules. He/she

ESSENTIAL JOB FUNCTIONS

- Enforce and maintain quality operation procedures relevant for the production site, e.g. process validation, non-conformance management, trending, DMAIC
- Work with In house Microbiologist/external test lab on Planning, coordinate and oversee testing, analysis and reporting
- Conduct incoming inspection for material
- Generate and review reports on quality issues and change controls
- Apply six sigma principles and least burdensome approach in quality topics
- Ensure safety and performance of products manufactured at the site
- Contribute to continuous improvement and CAPA handling
- Training of quality relevant topics
- Contacts to suppliers and service providers

BASIC QUALIFICATIONS

Education:

- Bachelor Degree in Mechanical, Biomedical, Engineering or equivalent

Experience:

- At least two years' work experience in a quality function in regulated environment, ie. medical devices industry would be preferred
- Knowledge and experience of quality techniques: Six Sigma methods such as DFSS, DMAIC, DoE, FMEA, etc.
- cGxP Know-How incl. regulations ISO 13485, FDA 21 CFR 820, MDD 93/42/EEC
- Knowledge of statistical methods
- English and German/ local language is a plus

Required Skills:

- Cross-cultural awareness

Position: Quality System Engineer

PURPOSE OF THE POSITION

The Quality System Engineer/Specialist is responsible for Quality Management Systems (QMS) implementation and maintenance, in the areas of Supplier Quality Management, Documentation Control and Change Management. He/she shall also assist the Lead Quality System Engineer/Director of Quality management in the successful planning and implementation of Management Review, CAPA and Quality Audits (both internal and external).

He/She shall interface with the relevant quality departments/functions at the respective system houses in Change management and Quality System harmonization/alignment.

ESSENTIAL JOB FUNCTIONS

- Ensure the compliance of QMS towards applicable medical devices regulations
- Create, update and develop the training material for QMS.
- Consolidate Monthly Quality Data Analysis from Process Owners as input for the Site Quality Management Review
- CAPA Coordination and facilitator of the site CAPA Review Board meetings
- Assist Lead Quality System Engineer/Quality Director in planning and execution of both internal audits and external audits
- Serve as the organizational focal point for Change Review and Change Management in close collaboration with all stakeholders. Ensure that all QMS and Design/Process changes are properly captured, reviewed, deployed and documented and be the Change coordinator/Analyst for site, in collaboration with the change review board from the system houses.
- Maintain the Quality Documentation through the use of the documentation control system.
- Serve as the organizational focal point for Supplier Management matters, including supplier qualification and supplier continual assessments

BASIC QUALIFICATIONS

Education:

- Technical / scientific degree at college / university level (mechanical, biomedical, polymer engineer-ing, natural sciences)

Experience:

Occupational experience

- At least five years' work experience in a quality function in regulated environment (medical devices/pharmaceutical industry)
- In depth know-how of QMS regulations: ISO 13485, 21 CFR 820, ISO 14971, MDD, AIMD, applicable local regulations.
- ISO 13485 auditor Certification
- Experience as lead/auditee in third party audits (FDA, Notified Bodies, Competent Authorities)

Special knowledge, expertise, experience

- Desktop applications, analytical tools, presentations, document management.

- Documents and Quality Records lifecycle management
- Good communication skills with people from all levels in the organization
- English(spoken and written), German is a plus
- SAP and Success Factor User experience is a plus

Required Skills:

- Cross-cultural awareness

Position: Production Engineer VI

PURPOSE OF THE POSITION

The Production Engineer develops and improves administration and coordination of production engineering projects, policies, processes, methods and procedures designed to improve operating performance, reduce waste and delays and otherwise promote cost reductions on a company-wide basis. He/she will be supporting production transfers and introducing process optimizations. The Production Engineer establishes and maintains effective communication with employees, manufacturing and quality department, management and other stakeholders.

ESSENTIAL JOB FUNCTIONS

- Evaluate and improve manufacturing processes and reduce costs using knowledge of manufacturing processes, tooling and production equipment, assembly methods or quality control standards.
- Activities involve using time-study or standard data for a variety of machines, assembly and hand operations, production methods, equipment layout, material handling, and manpower, equipment and material utilization in order to improve operating performance.
- Determine root causes of failures using statistical methods and recommend changes for problem solving, product specifications and process optimizations.
- Provide technical expertise or support related to manufacturing.
- Develop new methods and processes and support product development activities.
- Train production personnel in new or existing methods.
- Communicate manufacturing capabilities, production schedules or other information to facilitate production processes.
- Prepare documentation for new manufacturing processes or engineering procedures.
- Apply continuous improvement methods such as lean manufacturing to enhance manufacturing quality, reliability or cost-effectiveness.
- Design layout of equipment or workspaces to achieve maximum efficiency.
- Design testing methods and test finished products or process capabilities to establish standards or validate process requirements.
- Analyze statistical data and product specifications to determine standards and establish quality and reliability objectives of finished products together with the manufacturing and quality department.
- Confer with vendors, staff and management personnel regarding purchases, procedures, product/process specifications, manufacturing capabilities and project status.
- Prepare reports by collecting, analyzing and summarizing information and trends
- Analyze technology, resource needs and market demand, to plan and assess the feasibility of projects.
  Develop and implement policies, standards and procedures for the engineering and technical work performed in the department.

BASIC QUALIFICATIONS

Education:

Bachelor's Degree in Electrical, Mechanical or Industrial Engineering or equivalent.

Experience:

- Prior Engineering Management experience in medical devices industry is required.
- Experience with manufacturing processes and methods, Lean, Kaizen, Kanban and other advanced manufacturing methodologies, tools and concepts.
- Familiar with ISO13485 and GMP.
- Proficient in SAP and MES.
- Ability to demonstrate time management and leadership skills.
- Strong organizational, communication and intercultural skills.

Position: Production Control Specialist

PURPOSE OF THE POSITION

As part of the production controlling team based in Singapore, the Production Control Specialist is supporting the Production Control & MES Manager to provide reliable and customer oriented production controlling services for the manufacturing of components for CRM leads supplied to the system house CRM in Berlin, Germany. In order to provide efficient services, he/she executes lean manufacturing projects and practices in close alignment with the production controlling team at the headquarters. He/she is responsible for production controlling activities such as WIP/work order analysis, expediting work flows and forecasting of output performance in the manufacturing of medical devices.

ESSENTIAL JOB FUNCTIONS

- Support Production Control & MES Manager by building consensus with engineers, production staff and business leadership to ensure that planning and production controlling processes of the CRM operations are executed in the most efficient and effective manner
- Provide and manage support for production controlling functions including SAP/MES interfaces at shop floor, issuing and tracking work orders, assessment of production progress, review of work schedules and systemize the delivery of raw materials
- Investigate production control issues, analyze root causes and provide solutions to emerging challenges and risks
- Analyze, plan and manage demand from customers with respect to capacity planning and material requirement to ensure 100% on time delivery of shipments
- Plan and monitor material flow in production cycle to ensure continuous operations
- Serve as local contact person pertaining to production controlling topics internally as well as with system house
- Assist with integration of global and local supply chain and production planning related matters. Such systems include ERP (SAP), Business Intelligence (Business Objects) and other planning tools
- Develop and drive continuous process improvements for inventory, manufacturing and production control systems to meet business objectives
- Work closely with inter-departments i.e. Supply Chain & Logistics, Production, Quality, Purchasing, Process Engineering and Equipment Engineering in identifying and resolving production planning related matters
- Provide accurate production performance data, work progress and other KPI reports as required
- Maintain accuracy and data integrity of production reporting systems (MES, SAP)
- Assist with software validation for enhancements or new solutions related to production controlling activities
- Willing to work 70% in office and 30% at production floor

BASIC QUALIFICATIONS

Education:

Minimum: Diploma in Industrial Engineering/Supply Chain, related engineering discipline or equivalent

Experience:

- Fresh graduates are welcome to apply.
- Diploma holders with experiences in handle production control activities using ERP tools are welcome to apply.
- Work experience with SAP, MES (CAMSTAR is a plus in a 24x7 manufacturing environment will be an advantage) and any others planning tools.
- Strong interest in manufacturing operation management or production, inventory control and capacity planning field.
- Experience in Lean concept and implementation is a plus.

- Experience with WIP expediting, ERP/MES system, quality/continuous improvement initiative is a plus.
- Knowledge of process modeling in computer system environment is a plus.
- Excellent interpersonal, communication and intercultural skills with strong problem solving skills desired.

Position: Shift Supervisor

PURPOSE OF THE POSITION

The Shift Supervisor is responsible for supervising and managing the shift and all direct staff. He/she manages the smooth running of the production processes to enhance product quality and maximise efficiency and performance enabling the products to be manufactured on time. The Shift Supervisor will ensure that all products are produced to the specified specifications; target and deadlines are met to achieve the orders. This position plans and assigns work, implements policies and procedures; and recommends improvements in production methods, equipment, operating procedures and working conditions.

ESSENTIAL JOB FUNCTIONS

- To take responsibility of the shift in terms of management of staff, management of production processes and quality targets
- To ensure the smooth running of the production processes and maintain a positive work atmosphere
- To take responsibility of the quality and product that is produced within the shift in line with company's quality systems, processes and procedures
- Coordinate daily production floor activities and delegate assignments to production personnel
- Manage and motivate direct reporting employees by communicating job expectations, planning, monitoring and appraising job results; initiating, coordinating and enforcing systems, policies and procedures
- Develop and maintain training programs to ensure that all personnel have the necessary skills to perform their duties safely and productively; and to ensure that training skills are met for current and future demands of the shift
- Monitor and enforce working time, break, attendance, absence and leave planning of the production floor personnel
- Conduct employee performance reviews and disciplinary actions
- Assist in the selection and training of direct reporting employees
- Monitor, measure and report on production related process performance and general issues
- To ensure good communication of clear expectations to production personnel, develop personnel growth opportunities and monitor employee work performance
- Maintain material and work flow throughout the manufacturing facility and ensure the workstations are supplied with material quickly and efficiently
- Ensure equipment and tools are in good working order and available for use when required
- To ensure that Health and Safety rules and regulations are adhered to during the shift and all matters relating to this are dealt with using the resources within the company
- Maintain compliance with established company's policies and procedures
- Address problems and provide solutions to resolve the issues
- To work closely with other Shift Supervisors to ensure production handovers are effective communication tools
- To have an active role in company's continuous improvement plan to achieve plans for future growth within the company
- Maintain housekeeping standards to ensure a clean and safe work environment at all times by educating and directing personnel
- To ensure company's resources are used in an effective manner to achieve best operating costs
- Be able to make appropriate decisions while following company's policies and procedures

BASIC QUALIFICATIONS

Education:

- Bachelor's Degree in Engineering, Manufacturing, Business Administration or equivalent.
- Continuing education in Production Management will be preferred.
- Fluent in English and other Asian languages.

Experience:

- 5 to 10 years of relevant working experiences in the medical device technology or pharmaceutical industry with minimum 3 years in managerial or supervisory capacity in a manufacturing environment.
- Experience working in a clean room environment will be advantageous.
- Good understanding of production and manufacturing processes and techniques.
- Basic knowledge of Six Sigma will be advantageous.
- Familiar with ISO13485 and GMP.
- Proficient in SAP and MES.
- Strong intercultural experience and excellent interpersonal skills.

Position: Inventory Management Technician

PURPOSE OF THE POSITION

The Inventory Management Technician has the responsibility to manage raw material inventory, unfinished/finished inventory, disposition and storage, material preparation for production processes as well as analyzing inventory levels in accordance with operational requirements. The Inventory Management Technician proactively resolves inventory issues including aging inventory, bottlenecks, storage.

This position must utilize electronic systems, such as SAP, MES, bar code scanners, production schedules, and document management systems. This includes appropriate inventory transactions, inventory handling, documentations and administrative activities as assigned.

ESSENTIAL JOB FUNCTIONS

- Ensure continuous and proper flow of raw material, unfinished and finished inventory through accurate and timely inventory movement, documentations, labelling and transactions
- Disposition raw material, unfinished and finished inventory based on requests or requirements
- Conduct inventory investigations on aging inventory and bottlenecks to manage raw material, unfinished and finished inventories as directed by supervisor
- Facilitate prioritization and preparation of production materials
- Assist supervisor with coordinating daily activities and general inventory organization
- Act as subject matter expert in particular area as determined by supervisor and assist with training when needed
- Adhere to and promote proper practices and techniques which are consistent with current operating procedures, working instructions, training requirements, cGMP, safety practices and company policies
- Coordinate Quality decisions for dispositions or corrections and elevates to supervisor as necessary
- Execute all inventory movement transactions to assure accurate inventory levels and counts which includes appropriate use of bins, warehousing, and storage conditions based on inventory type, status and 5S efforts
- Notify the supervisor of any observed issues and/or discrepancies (process and quality discrepancies, safety and security breaches, deviations in the documentation and labelling)
- Participate actively in the KANBAN process
- Support cycle counting activities as directed by supervisor and reconcile and resolve cycle count discrepancies
- Other ad hoc activities as per assigned

BASIC QUALIFICATIONS

Education:

- Completed professional education preferred
- Fluent in English and other Asian languages

Experience:

- Experience working in a regulated manufacturing environment in a supply chain or inventory management related role preferred; experience in cGMP environment is a plus
- Previous work experience in a regulated, biotech or manufacturing industry preferred
- Ability to read and comprehend detailed procedures, written and verbal instructions in English
- Must possess strong communication and interpersonal skills to deal with various levels
- Ability to use a computer and possess working knowledge in Microsoft Office (Excel, Word)
- Must possess the organizational skills to multi-task and meet deadlines as needed

- Must be able to lift, push and pull and be able to use material handling equipment such as push carts and pallet jacks

Position: Production Engineer

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- Familiar with ISO13485 and GMP.

- Proficient in SAP and MES.
- Ability to demonstrate time management and leadership skills.
- Strong organizational, communication and intercultural skills.

Position: Equipment Technician

PURPOSE OF THE POSITION

The Equipment Technician is responsible, as member of the interdisciplinary operation team, to provide technical support for production operations in meeting output and quality. This includes transfer, document and repair. Further the Equipment Technician will support the Equipment Engineer in required training activities to ensure the processes will be correctly operated. Also his/her expertise will be required to optimize the infrastructure of the facility.

ESSENTIAL JOB FUNCTIONS

- Provide first level troubleshooting and resolve production stoppages due to equipment issues
- Minimise equipment downtime and ensure production meets target output and yield
- Document and report all production line stoppages due to equipment or technical issues
- Monitor machine output and ensure the required standards are met
- Replenish production auxiliary materials and tools in the respective workstations
- Perform process control check where necessary
- Participate in and execute preventive maintenance and calibration activities for production and measuring equipment
- Ensure work stations are in excellent housekeeping conditions
- Collaborate with engineers and production in continuous process improvement projects
- Maintain and build up relationships with local vendors
- Train and educate operators, technicians and other engineers
- Support operator training
- Other duties as assigned
- Able to perform shift work as and when necessary

BASIC QUALIFICATIONS

Education:

- Higher NITEC or Diploma in any Engineering discipline

Experience:

- At least 1 year of relevant experience, preferably in medical device industry
- Prior technical experience in Electronics / Manufacturing environment will be added advantage
- Meticulous, responsible, flexible, independent and customer oriented
    - Experience working in project environment with good problem solving skills