Orthoplastics
A VIANT COMPANY
science making a material difference

Statistical Process Control Manager

We are a manufacturer of orthopedic components and materials manufactured to high specifications for the medical industry. Our main focus is to supplying high quality medical products to exacting customer and international specifications, supported by our Technical Department which is capable of testing polymeric materials to the highest standards. In order to support continued business growth we require an enthusiastic individual to join our business to work within our Technical Department.

KEY ACCOUNTABLE AREAS:

- Perform statistical studies to support all new product introduction activities.
- Undertaking and reporting of statistical studies within the area using Measurelink® and MiniTab® Analysis Software
- Initiate and develop training and development plans for Quality personnel.
- Establishing and revising existing policies and procedures in the area.
- Continuous improvement of the process in the area to support all Quality standards, ISO 13485 & 21 CFR Part 820.
- Identification of the appropriate measurement methods required for products being inspected.
- Perform monthly trending of all NC's and non-conforming product that arise within designated production processes
- Generate such data as is required for Dashboard reviews as they apply to designated production processes
- Where necessary, review, improve, update and approve Metrology methodology
- Ensure all assigned quality actions are investigated, have causes identified and action plans completed to the agreed schedule, regardless of source
- Lead investigations into product or process issues raised within designated production processes, identifying root cause and corrective action plans as required
- Partner with Medical Machining and NPI team during the definition and introduction of new or improved processes, ensuring all validation, calibration, risk management and documentation activities are completed
- Involvement in validation activities regarding IQ/OP/PQ completion
- Support Manufacturing and Medical Machining teams to ensure that Preventive and Corrective Maintenance activities are completed to schedule. Ensure that Critical System Changes are raised for all applicable changes
- Work with Manufacturing and Medical Machining teams to ensure that process improvement activities including Lean Manufacturing activities are identified and introduced in a compliant manner
- Ensure all activities are carried out with all regulations and laws governing business and quality operations and continuous improvement of the process in the area to support all Quality standards, ISO 13485 & 21 CFR Part 820.
- Ensure compliance with all local, national, internal and company regulations, policies and procedures for Health, Safety and Environmental compliance

THIS EXCITING POSITION REQUIRES A PERSON WHO IS:

- Methodical and meticulous in approach
- An effective communicator and a good team player
- Conscientious and has a self-disciplined approach
- Motivated and flexible in their approach
- Ability to self-manage as well as working as part of a team
- Excellent time management and multi tasking skills
- Capable of producing high quality written material by hand
- Computer literate

Agency CV's Are Not Being Accepted For This Position

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REQUIRED QUALIFICATIONS/KNOWLEDGE:

- Technical degree in Engineering or similar Scientific discipline; Bachelor's Degree preferred.
- Quality Management System and Techniques
- Supervisory and/or managerial experience in operating and understanding a metrology operation.
- International & British Quality Standards (ISO 13485, ISO 17025, ISO 14001, BS OHSAS 18001, FDA, QSR's and Medical Devices Directive)
- Good Manufacturing Practice
- Quality toolbox including FMEA, Process flows, Root cause investigations, Lean and Six Sigma tools & techniques
- Knowledge of statistical software Measurelink® & MiniTab Analysis ®
- Validation requirements (IQ, OQ, PQ)
- MSA & GR&R experience
- Knowledge of Metrology techniques with Mitutoyo CMM programming experience being advantageous
- Document and maintain records accurately
- Previous experience in similar role
- Strong understanding and ability to use statistical analysis tools
- Good verbal and written communications skills

HOURS OF EMPLOYMENT

- Monday to Thursday 08.30 – 17.00, Friday 08.30-13.30 (35 hour working week), which includes breaks.
- Duties and hours may vary dependent upon workload

Please forward your CV & salary expectations to Tandy Kehoe, HR Business Partner Manager by email: kehoe@orthoplastics.com

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