



Mechanical Engineer

Location: Rome, Italy

COMPANY OVERVIEW

BVI® is a global ophthalmic medical device manufacturer with a mission to deliver high quality solutions and innovation for advancing eye surgery and improving the vision of patients. With nine decades of developing leading products and solutions, BVI partners with ophthalmic surgeons to improve the vision of millions of patients across the globe. Our team supports surgical teams, in more than 115 countries worldwide, either directly or through our network of trusted distributors. Our trusted brands include: Beaver® (Knives and Blades), Visitec® (Cannulas), Malosa® (Single-Use Instruments), Vitreq® (Vitreoretinal Surgical Products) and PhysIOL® (Premium Intraocular Lenses).

PURPOSE

To be included in the R&D / Technical Team as Project Leader of Medical Devices / Accessories.

RESPONSIBILITIES

To be a proactive member of the Operations team focused on development of new and current manufacturing processes, improving efficiency, utilisation and reduction/elimination of all waste forms through the use of lean tools and techniques.

Develop and manage capital projects aimed at improving site productivity.

To lead and/or participate in project teams responsible for all activities dealing with process validation of production equipment, from initial ideas to implementation of processes including costing and budget controls. To seek/source new technologies, suppliers and/or processes to support the continuous improvement strategy of the business.

- To discuss and draft projects specifications with the Team Manager and with the doctors / surgeons selected as opinion leaders.
- To create projects planning and budgeting.
- To develop and run projects in accordance with the approved project planning and budgeting.
- To develop and run projects in accordance with the approved technical specifications, the general technical standards and the specific medical device standards applicable.
- To generate the necessary documentation and deliverables for the products certifications (CE, FDA etc.) and registrations.
- Identify and develop capital projects and take through to completion. This will include development of solutions, evaluations with potential vendors, construction & presentation of Capital Justifications.
- Fully documented trials / validations in accordance with internal business procedures.
- Creation of formal project plans to determine improvement activities and quantify the savings gained through full data and current method analysis.
- Follow the development of prototypes and the testing phase, manage the industrialization of the product until it goes into production.
- The Mechanical Engineer will work with all employees at the plant level, their Direct Manager & local management, identifying Best Practice and staying abreast of all implemented solutions.



- In conjunction with Purchasing, oversee and monitor all order placement for capital projects.
- Actively use Lean Tools on C.I. projects to improve Plant Productivity & Reduce waste.

Additional Tasks

- Writing of validation protocols, validation reports and execution of validations
- Compile specifications, protocols, reports and standard operating procedures
- Equipment installation, commissioning and validation
- Organize investigatory testing as required
- Generate engineering change orders (ECO's) and progress through to implementation.

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Deep knowledge of the properties of the materials in general & specifically of the ones used in the Medical Device field
- Ability to carry out project related activities with little or no direct supervision.
- Medical or experience in a highly regulated environment
- Capital budget experience
- Sound knowledge of Cleanroom & Medical related manufacturing processes.
- Good understanding of CI (Continuous Improvement) principles to include Lean.
- Up to date with the latest Facility based regulations.
- Standards:
- ISO 9001
- ISO 13485
- MDR (plus)
- Good influencing and communication skills
- To be able to work dynamically treating tasks with a sense of urgency
- Proactivity
- Result-oriented

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- University Masters Degree - Mechanical Engineering or other Technical
- English - Fluent
- At least 6 years work experience in Design & Development (Micromechanics and precision mechanics sector) – preferably in the Medical Industry

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The above information on this description has been designed to indicate the general nature and level of work performed by employees within this classification. It is not designed to contain or be interpreted as a comprehensive inventory of all duties, responsibilities and qualifications required of employees assigned to this job.

Important notice to Employment businesses/ Agencies



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