Director, Quality

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

The Quality Director provides leadership, experience, direction and guidance to their respective team. This position will plan, develop and control in conjunction with Quality leadership, the Quality Management System to ensure that all the quality objectives are met, as well as the improvement in quality, in the operation, in the processes, and the development of products, and that the transfer of processes / projects are implemented in an efficient and effective manner. This position will be responsible for providing support and communication with our operations groups and clients to address design, manufacturing and other problems related to product issues.

RESPONSIBILITIES

- Assures that all local, national and international standards and regulations are effectively implemented at the site
- Assures the effective implementation of the BVI Quality Management System
- Addresses customer quality issues and internally improve cost and competencies in process control / validation studies, root cause analysis, failure mode and effect analysis (FMEA), and the use of process excellence tools.
- Manage training, document controls, internal audit and other required quality processes
- Maintain and control plant quality procedures
- Promotes and executes continuous improvement and excellence activities for transactional Quality Processes and manufacturing processes
- Develops and implements risk management methodologies
- Produces advanced quality planning documentation where applicable
- Actively manages all the goals and objectives defined in the quality management system
- Responsible for the maintenance of technical files
- Reviews and approves the validation of new / changes in production processes as necessary
- Designs and validates the processes of the Quality System where applicable.

- Participates in the design evaluations where applicable
- Solves quality problems and eliminates restrictions to ensure that project objectives are met
- Manages local Supplier Quality Management and sterilization, to improve quality through a review of prequalification, supervision and continuous audit, implementation of engineering changes, validation, product qualification and processes and other procedures and instructions.
- Analyzes QMS and manufacturing processes using valid statistical methods to assess trends and to assist the administration in the identification and resolution of problems and the effort to improve overall quality. Recommend KPI to measure compliance with quality standards and the effectiveness of corrective actions across all functions
- Ensures effective implementation of the CAPA; develop and implement initiatives to improve proactive processes
- Generates quality metrics and establish the measurements to monitor quality costs and cost reduction
- Ensures the effective handling of customer complaints
- Maintains the GMP requirements, including environmental and personnel controls
- Ensures that all Health, Safety and Environmental requirements are met
- Maintains detailed and accurate records of all activities
- Responsible for the maintenance of metrics to monitor the general performance of the department
- Manages external audits by Regulatory Bodies and customers
- Prepares Management Review
- Assures appropriate organization and resources to execute quality-related processes
- Manages staff in accordance with organization's policies and applicable regulations. Responsibilities include planning, assigning, and directing work; appraising performance and guiding professional development; rewarding and disciplining employees; addressing employee relations issues and resolving problems. Approves actions on human resources matters
- Other duties as required

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- Knowledge of FDA and EU medical device regulation is required
- Knowledge of advanced quality planning, and validation is required
- High level of knowledge in validations, Experience in SPC, Advanced Quality Planning, Product Validation, QSR 21CFR820, 21CFR803, 21CFR806 and ISO 13485, MDD/EUMDR, CMDCAS, JPAL. MDSAP
- Excellent communication skills, written and verbal in both English and Italian
- Flexible work practices and approach
- Ability to influence and negotiate
- Proficient in the Microsoft Office suite of applications

- Excellent project management skills
- High attention to detail, speed, solution and customer service
- High standardized work, well organized and meticulous
- Excellent planning and organization skills
- Highly competent in number management with good verbal reasoning skills
- Client Management Skills
- Expresses high leadership skills and emotional intelligence
- Ability to establish and maintain effective working relationships with coworkers, managers and clients

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- Bachelor's degree in Engineering or related field and 10 years relevant experience; or equivalent combination of education, training and experience
- 10 years of experience in a medical device manufacturing environment and 5 years of quality management experence

PHYSICAL REQUIREMENTS

- Extensive use of keyboard requiring repetitive motion of fingers.
- Extensive use of telephone and face-to-face communication requiring accurate perception of speech.
- Regular sitting for extended periods of time.
- May require occasional travel.

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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.

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performed without the consent or contractual agreement of BVI. BVI shall therefore not be liable for any fees arising from such actions or any fees arising from any referrals by employment businesses/agencies in respect of the vacancies posted on this site.