



Manager, Advanced Manufacturing Engineering - Capital Equipment

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 Advanced Manufacturing Engineering (AME) leader serves as the lead operations representative on new product development and lifecycle management projects and develops and maintains manufacturing strategies for new products and technologies within the capital equipment related category of BVI's portfolio. The AME leader leverages capabilities in process and equipment design and development and design for excellence (manufacturing, test, service, procurement) to translate design outputs into products with best in class quality, manufacturability, and cost.

RESPONSIBILITIES

- Responsible for the overall operations strategy and execution for new products – seeking input from manufacturing, supply chain, sourcing, and other operations groups to develop optimal plans.
- Accountable for process design (including equipment and tooling), development, and validation (IQ/OQ/PQ) and capital/capacity planning.
- Oversees design controls operations related documentation such as plans/protocols/reports, test methods, work instructions, PFMEAs, control plans, and contributes to global regulatory submissions



- Voice of operations within the design cycle – performing DfX (manufacturing, service, test, etc.) reviews and ensuring they feed back into the design cycle. Ensure the application of lean manufacturing and operational designs from concept to industrialization and beyond. Accountable for ensuring that designs and plans align with cost of goods sold targets. Resolving variances within the design cycle prior to design freeze.
- Partnering with R&D project leadership to ensure that manufacturing infrastructure supports product design and overall project and business needs.
- Optimizing the cost structure of the product based on demand side (volume, mix) and supply side (material, labor, overhead) factors. Influence design and material sourcing, and lead plant network (internal / external), capital equipment and automation, and lean manufacturing initiatives to develop the most suitable operation for the business need.
- Build and develop site and organizational capabilities in process and equipment design and development
- Other duties as required

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- High-level understanding of ISO 13485, ISO 9001, IEC 60601, ISO 14971, FDA CFR part 820
- Demonstrated capability in driving design for excellence (manufacturing, test, procurement, reliability)
- Experienced in indirect leadership of suppliers and contract manufacturers
- Business-level fluency in English
- Strong developed business acumen – understanding of manufacturing cost structures and levers to influence them. Ability to translate between business problems and technical solutions. Ability to think at an organizational level instead of just a functional level.
- Excellent analytical skills (effectively supports decisions on factual data and analysis). Ability to make informed decisions on limited or imperfect data
- Process design and development expertise
- Strong engineering problem solving skills
- Ability to work internationally – understands and adapts approach to regional norms to build relationships and drive success
- Ability to adjust and cater message clearly in a variety of circumstances (e.g. executive, function, cross function, customer, supplier, international)
- Ability to evaluate, triage, and mitigate risks, both product and project. Ability to influence a highly decentralized organization without direct authority
- Comfort and courage to operate in new areas of the business with limited direction. A willingness to try, fail, and try again



MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- Bachelor's degree in an engineering discipline or related field and 7+ years relevant experience or equivalent combination of education, training and experience
- Experience working in a highly regulated industry (medical preferred - automotive, aerospace, etc considered)
- Experience in indirect leadership of suppliers and contract manufacturers

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.
- International travel a must to interact with contract manufacturers and multi-site partners. Expected travel is 25-50%

Interested? Submit a cover letter and C.V.
to TalentAcquisition@bvimedical.com



BVI is an Equal Opportunity/Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, or protected Veteran status.

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

BVI does not accept referrals from employment businesses and/or employment agencies in respect of the vacancies posted on this site. All employment businesses/agencies are required to contact BVI's human resources department to obtain prior written authorization before referring any candidates to BVI. The obtaining of prior written authorization is a condition precedent to any agreement (verbal or written) between the employment business/ agency and BVI. In the absence of such written authorization being obtained any actions undertaken by the employment business/agency shall be deemed to have been 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.