



BTL India is looking for an experienced Project Lead (8 to 12 yrs) for its R&D Medical devices Improvement & Support (I&S) team. The Project Lead will manage investigational activities and support key areas to ensure safe and effective medical products. This includes the analysis of complaints, review of trends, ownership of investigations to determine root causes and proposal of possible solutions. Additional tasks are the ongoing required maintenance of such investigations for design changes and periodic reviews. The role includes close work with internal interfaces such as engineering teams, production, service, quality assurance and regulatory.

ROLES AND RESPONSIBILITIES

As part of the R&D I&S team, the individual should be able to perform following duties:

- Performing reviews for serviceability on prototype and early manufacturing builds.
- Take ownership to Manage & Carry out engineering design change activities by working in close coordination with engineers & cross functional teams of QA, RA, certification agencies Production & Service.
- Own the project/Task at a system level by planning the project timeline & working with the Hardware / Mechanical & Software engineers to execute the project.
- Drive the investigations of complaints & trending alerts that exceed threshold. This requires defining containment, and leading investigational activities to determine potential root causes. You will review complaint and field data, use problem solving tools, and partner with a global engineering team across BTL Industries and implement appropriate corrective and preventive actions for the safe and effective use of BTL Medical products.
- In collaboration with the Project engineering team during product development to determine if program scope contains potential reasons for failure and the residual risk. Participate in the technical evaluation of impact using risk mitigation tools such as failure models and effects analysis (FMEA)
- Own and maintain root cause investigation matrix documents on a routine basis in accordance with evolving trends identified in complaint data.
- Keep a watch on components obsolescence & provide timely solutions to prevent production stop situations.
- Continuous Improvement of Released products w.r.t updated Regulatory Standards.
- Maintain a database of Engineering Design reports & be familiar with critical functions.

- Support Production Technologist with Production transfer from one site to another.
- Support Regulatory department with Country Registrations.
- Support Quality and Regulatory audits as needed.
- Own the Technology know-how transfer from NPI released projects.

ESSENTIAL QUALIFICATION AND EXPERIENCE

QUALIFICATION:

- Engineering degree or above in Electrical/Electronic from an accredited university or college.

TECHNICAL COMPETENCY:

- More than 7 years of experience in Embedded Device Product development in the capacity of designer or Tech lead, with exposure to Project planning.
- Hands on Expertise in Hardware design with good exposure to other domains (mechanical and software) high level design, development & verification principles.
- Ability to work independently and connect the dots by interacting with teams globally (Engineering, Manufacturing, Services, Quality, Certification, Regulatory, Sourcing)
- Ability to work on multiple projects at once using project planning tools focusing on schedule and quality of results.
- Excellent Analytical & problem-solving skills. Has ability to use judgment to analyze and process data and draw the appropriate conclusions.
- Exposure to product safety testing & certification (Ex: CB Certification of medical devices).
- Exposure to value engineering of products w.r.t cost & technology.

BEHAVIOURAL COMPETENCY:

- Self-motivated and passion to finish (fire in belly/Ownership).

The 2013 incepted BTL India R&D center in Bangalore is the second largest R&D center and an important arm of the 1993 founded established brand, BTL originally from the Czech Republic, a global innovator of Medical and Aesthetic Solutions. BTL India is a complete R&D center focused on medical product developments in areas of Cardiology, Physiotherapy and Aesthetics.

BTL boasts 50 plus unique products in the market with its in-house marketing and sales in 55+ countries across the globe. BTL has four R&D centers and two manufacturing units in Europe while BTL India R&D center was started 8 years ago to add more products under the BTL product portfolio to support its growing market demands.

The philosophy of the company is to create technologically unique products with high added value, top quality and original industrial design.



- Big picture / Clarity: Ability to see the design from top to bottom. Ability to gain full clarity/ seek required information before execution.
- Assertiveness & Constructive communication : Ability to take decisions & express the same to other stakeholders by clarifying the reasoning in a constructive way
- Flexible, hands-on and willing to learn new technologies.
- Good team player with good collaboration skills.
- Fluent verbal and written English communication.

ADDITIONAL QUALIFICATION AND EXPERIENCE (DESIRABLES)

- Exposure to Medical devices product development will be an added advantage.
- Exposure to Medical devices standards/regulations, Design controls or similar regulatory environment and QMS will be an added advantage.

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