Project Manager/Senior Project Manager

This position is responsible for project managing (scope setting, project planning, and execution) the

implementation of all manufacturing processes and associated supply chain systems to support the

development and commercial launch of new product programs on time, within budget, and to

required performance requirements. Working within the medical device quality management

system, this leader manages a cross-functional team of professionals, promoting collaboration and

alignment within the team while simultaneously interfacing with both Commercial and Operational

Leaders to maintain organizational alignment through stakeholder management.

This is an individual contributor role that requires the use of judgment in applying professional

expertise and is expected to work independently with minimal supervision.

Key Areas of Responsibility

• Delivery of the manufacturing element of new product programs, with a specific focus on scope

setting, project planning and management, product quality, budget management, product supply

management and DFM (Design for Manufacture).

• Provides strong, capable leadership to the project team, encompassing key professionals from

Quality, Sterilisation, Production, Packaging, Labelling, Materials, Logistics, Finance, Industrial

Engineering, HR, Process Engineering, Facilities & EH&S to ensure new product launch

deliverables are achieved. Assumes overall responsibility for assigned teams and operational deliverables.

• Collaborates closely with leadership at the manufacturing site during the design development phase to ensure that all new manufacturing processes are introduced into production compliantly, on time, within budget, are operationally successful, and in alignment with the broader plant manufacturing strategy. Ensures all required quality management system deliverables are met by the team to effectively transfer the product into commercialisation from the design development phase.

• Drives capital acquisition strategy through determining total capital expenditure and operational costs expense, acquiring internal approvals, supporting contract negotiations, and ensuring timely installation, qualification, and validation efforts.

• Develops a comprehensive communication plan and strategy to convey project status updates to stakeholders at both Commercial and Operational business forums.

• Liaises with Regulatory Affairs to ensure the project strategy is aligned with the required regulatory pathway and appropriate regulations are met.

Qualifications Knowledge Skills

• Bachelor's degree in engineering or a science discipline or equivalent required. Project management certification through an accredited organisation (preferred).

• Minimum of 4 years for the PM role/minimum of 7 years for the Senior PM role in engineering /

Project experience in a regulated industry essential. Has demonstrated ability to successfully plan, prioritise, multitask, and organise multi-disciplinary team(s) to successfully achieve project

deliverables.

• Has applied knowledge of FDA & International medical device regulations.

• Ability to lead, motivate, and influence a cross-functional team on moderate complexity projects that do not report directly to this position.

• Strong communication and interpersonal skills with the ability to express ideas and collaborate effectively with multi-disciplinary teams.

• Excellent analytical and problem-solving skills, including risk management experience.

• Experience in process validation preferred.

• Experience with delivering results through Six Sigma and lean methods is preferred.

• High level of PC skills required (MS Excel, PowerPoint, and MS Project).