

Edwards Lifesciences

- **TYPE**Full time
- **LOCATION**USA, California, Irvine
- **JOB REFERENCE**Req-31272
- **POSTED FOR**15 Days

Sr. Engineer, Packaging

Innovation starts from the heart. At Edwards, we put patients first. We invest a significant proportion of our revenue towards research and development to drive and develop groundbreaking medical innovations for structural heart disease and critical care. As part of our R&D Engineering team, you will work closely with our Quality and Manufacturing teams to develop the latest tools and technologies to address significant, unmet clinical needs that impact patients' lives around the world.

Develop world-class capabilities and provide a competitive advantage to Edwards, through packaging design and project management.

You will make an impact by...

- Designing innovative packaging concepts for moderately complex projects, including new product launches and existing products throughout all stages of product development from concept to launch, including clinical trials, global and limited market releases, as well as key operations initiatives
- Developing protocols for, and implement, package design, packaging process validation, and package shelf life testing, as well as driving new packaging technologies and strategies with increased uncertainty and complexity, to improve time to market and advance the technology of package engineering at Edwards
- Developing plans for moderately complex projects working closely with cross-functional team members and outside suppliers
- Validating packaging equipment and packaging manufacturing processes to determine appropriate sourcing, purchasing, installation planning and specifications

- Providing guidance and coaching to lower level engineers
- Other incidental duties assigned by Leadership

What you'll need:

Bachelor's Degree in Engineering or Packaging Degree, minimum of 4 years' experience is required or

Master's Degree or equivalent in Engineering or Packaging Degree, minimum of 3 years' experience is required or

Ph.D. or equivalent in Engineering or Packaging Degree –No experience is required

What else we look for:

- Sterile barrier system packaging experience is strongly preferred.
- Medical device packaging design preferred. Experience in highly regulated industry
- Knowledge of sterilization methods and design requirements for medical device packaging is preferred
- Demonstrate a strong working knowledge of standardized package testing and good working knowledge of regulatory requirements, examples: ISO-11607, ASTM D4169, etc
- Successful work experiences with different packaging materials such as – Tyvek, or HIPS, or PETG, or Polycarbonate, or Polyolefins, or co-ex films as well as good knowledge of material forming processes such as thermoforming, or injection molding, or extrusion/extrusion blow, or FFS is desired ability to develop and execute protocols for packaging design, process validation and shelf-life studies; source, purchase and qualify equipment as well as develop and validate packaging processes
- Good understanding of statistical techniques and proven expertise in usage of related statistical knowledge for packaging
- CAD experience preferred
- Solid technical writing skills and knowledge of documentation requirements
- Ability to interact professionally with all organizational levels
- Ability to manage competing priorities in a fast-paced environment
- Must be able to work in a team environment, including the ability to manage vendors and project stakeholders
- Ability to build productive internal/external working relationships. Ability to interact with senior internal and external personnel on significant matters often requiring coordination between organizations
- Strong documentation, communication (e.g., written and verbal) and interpersonal relationship skills including consultative and relationship management skills

- Previous experience working with lab/industrial equipment required
- Substantial understanding and knowledge of principles, theories, and concepts relevant to Engineering
- Strong problem-solving, organizational, analytical and critical thinking skills
- Good leadership skills and ability to influence change
- Knowledge of and adherence to Edwards Environmental Health and Safety and Quality guidelines as they relate to department clean room medical device manufacturing
- Ability to interact professionally with all organizational levels
- Ability to manage competing priorities in a fast-paced environment
- Must be able to work in a team environment, including inter-departmental teams and key contact representing the organization on contracts or projects
- Adhere to all company rules and requirements (e.g., pandemic protocols, Environmental Health & Safety rules) and take adequate control measures in preventing injuries to themselves and others as well as to the protection of environment and prevention of pollution under their span of influence/control