Lijo Philip

An Established Manufacturing Consultant with hands on experience in medical device industry. Provided positive solutions in manufacturing & packaging of medical devices & components. Evaluated & selected cost effective primary, secondary & tertiary packaging materials that meet industry standards for sterile barrier packaging systems. Provided technical expertise and project support to new product development teams by consulting within areas of packaging materials and equipment. Associated in NEW Product Development with in-depth knowledge in Manufacturing Process, Lean Manufacturing, Risk Management and Validation.

TECHNICAL SUMMARY

- Good understanding of standards like ISO 13485, ISO 14971 and ISO 11607. Knowledge of ASTM and ISTA Packaging Standards.
- Identified & supported packaging cost optimization, process improvement & packaging design optimization. Supported continuous improvement projects within the packaging department.
- Created or update packaging procedures and support change control process by reviewing, creating, or updating packaging specifications and documentation.
- Assisted in new packaging equipment procurement process, generating user requirement specifications, factory acceptance test and validation of new packaging equipment.
- Monitored and managed complete packaging development process, including the creation of packaging designs, prototype development, and performance testing.
- Troubleshoot new and existing packaging problems involving designs, materials and processes and provide creative, timely, and cost-effective solutions.
- Established standards and guidelines for supplier evaluation. Evaluate and select packaging suppliers. Assisted in purchasing of new packaging equipment.
- Experience with medical device compliance requirements based on FDA Quality Systems Regulations.
- Packaging development and qualification of innovative package designs as part of a cross functional new product development, sustaining engineering and quality remediation teams.
- New product lines setup and interplant transfers; equipment/process validation and qualification (Equipment Qualifications, Gage R&R, Test Method Validation, Process Validation).
- Supporting in drafting Standard operating procedure for Process Qualification and training operators on the execution of the process.
- Successful execution of Process Qualification for a new heart valve device

WORK EXPERIENCE

Edwards Life Sciences **March 2020 to Current**
Manufacturing Engineer

- Supporting NPI team and working with cross functional initiatives relating to New product design / development, validation activities, process qualification and transfer activities.
- Supporting in drafting and execution of Transfers and Qualification strategies, Master validation Policies/planning, Product/Process validation plan, Quality/process Control plan, Design/Process failure mode and Effect Analysis (FMEA) and Tools/fixtures installation Qualification (TFIQ)
- Lead in setup of Bill of material and routings, product drawings and revise assembly procedures as necessary in support of product design/production process transfers.
- Supporting packaging engineering validation efforts in support of product design/production process transfers and valve engineering projects.
- Lead in Manufacturing builds (feasibility, qualifications, commercialization) in cleanroom and be able to train and resolve manufacturing issues on the floor with sustaining engineers.
- Lead on Training of operators and Technicians on the production floors on the procedures.
- Manufacturing support for existing processes and for New product development, product changes, line extensions and enhancements, as well as related tooling and fixtures.
- Support validation of product, equipment, and processes.
- Interface with other departments to solve manufacturing production problems.
- Monitor equipment maintenance program.
- Investigation and testing of product processes.
- Support prototype and pilot production, facilities and planning, when appropriate.
- Lead manufacturing efforts associated with new product transfer between R&D and manufacturing.
- Evaluates, creates and initiates improvements to existing engineering and project systems.
- Provides support with execution of capital equipment build projects, including technical documentation (drawings, BOMs,specifications,reports) builds procurement and customer interaction.

- Works closely with prototype lab and Machine shop to provide clear documentation and communication, to allow for efficient fabrication.
- Develops documentation expertise related to equipment mechanical design and manufacturing processes.
- Searches and implements new technologies to improve manufacturing processes and equipment design.
- Performs other duties and responsibilities as assigned.
- Knowledge of statistics, DOE (Design of experiments) using Minitab.
- Preparing technical documentation, including manufacturing procedures, specifications, and engineering drawings.

Edwards Life Sciences **February 2019 to March 2020**
Packaging Engineer

- Monitored and managed complete packaging development process, including the creation of packaging designs, prototype development, and performance testing. Created and Reviewed Engineering change request and orders to the existing products, new product development and processes.
- Generated packaging specification profiles for existing and new products, which included primary, secondary and tertiary packaging.
- Troubleshoot new and existing packaging problems involving designs, materials and processes and provided creative, timely, and cost-effective solutions
- Conducted packaging distribution tests for new packaging design, selected best materials within budget.
- Created machine requirements and created IQ/OQ/PQ protocols with reports. Approved vendor created packaging tools.
- Established standards and guidelines for supplier evaluation. Evaluated and selected packaging suppliers. Assisted in conducting periodic Supplier audits.
- Responsible for the execution of packaging validations for new, or existing products, following ISO11607 regulations.
- Preparation and review of sterilization documentation, procedures, and specifications to ensure sterilization compliance with FDA and corporate requirements.
- The creation, revision, and control of customer labeling, with a primary focus on documentation control through all phases of the change control process. Reviewed product labeling for accuracy, completeness, content and regulatory compliance.
- Responsible for assuring all required design inputs are captured and incorporated into product labeling development and design changes for labeling content
- Documented test reports and specifications ensured the packaging meet quality requirements.
- Support design, new product development (NPD), validation and execution of test method for visual inspection of packaging for foreign matter and tensile testing of packaging pouches and trays. Involved in the equipment validation, which includes development validation protocols, performing testing and writing Validation Reports for various equipment's.
- Supported in new packaging development in early stage, worked with third party to conduct tests, documented test reports and supported in the packaging materials selection
- Prepared packaging validation protocols & reports to support packaging changes. Created packaging specifications for manufacturing.
- Performed all packaging validation testing (strength, integrity & microbial barrier) in accordance with ASTM & ISTA standards.
- Worked on Root cause analysis in CAPA and worked on redesigning, writing the protocol and executing the Design Verification and report.
- Worked as a Test Method Validation Engineer as a part of the Remediation project for the sterile barrier packaging process
- Writing test method validation protocols and trained inspectors on new methods prior to protocol execution. Performing test method validations as per FDA regulations and ensure product compliance
- Performed Gage R&R studies to ensure that the test methods are valid for their intended purpose.
- Execution and Documentation of IQ/OQ and PQ for process equipment, utilities, facility, manufacturing equipment and validation protocols.

GE Oil & Gas, Vadodara, Gujarat, India **(2013- 2014)**
Project Engineer

- Worked as a Safety/Project Engineer for a Terminal Automation Project at Indian Construction Corporation Ltd at Karnataka, India
- Job was to implement ANSI, ASTM, ASME and understand the Mechanical and Civil Drawings & completed, Erection & Installation of systems such as Radars, Power Distribution Panel, Programmable Logic Controller, Safety systems, Meters, Valves & Actuators
- Work with manufacturing, Quality, Regulatory and Compliance, to insure complete and thorough investigations.
- Expert at assessing and evaluating workplaces for safety/ergonomic hazards, creating and documenting assessments making recommendations for effective hazard control management.
- Experience of doing IQ, PQ and OQ of slot and v2 machines. And equipment testing on gauge R&R, Vernier, test method validation etc. and verification according customer needs or complains.
- Participate in the supplier material related processes which include such as Material Review Board (MRB)
- Maintains safety files and records. Provide Safety Training. Study and analyze hazards and accidents.

Elster – Instromet Pvt. Ltd, Vadodara, Gujarat, India **(2014-2015)**

Quality Engineer

- Evaluates suppliers' internal functions to assess their overall performance and provides feedback in assessment of their operation
- Collaborate with other functions to assure the resolution of all nonconformances raised and ensure highest product quality.
- Ensures that suppliers deliver quality parts, materials, and services.
- Work with project team to properly document component/product transfers
- Routing and review validation (IQ, OQ, PQ), TMV, V&V, Master plan validation & report and GRR protocols and report. Responsible for FMEA, PFMEA.

EDUCATION - MS in Mechanical Engineering, Gannon State University, PA

Cell # 313-329-1237
Email – ljp0790@gmail.com

Lijo Philip

- Tustin, CA, USA

Contact Information

- uuz-c5f-0v6@mail.dice.com (Preferred)
- 3133291237 (Preferred)

Work History

Total Work Experience: 7 years

- **Manufacturing Engineer | Edwards Life Sciences**
  Mar 01, 2020 - Dec 01, 2020
- **Packaging Engineer | Edwards Life Sciences**
  Feb 01, 2019 - Feb 01, 2020
- **Quality Engineer | Elster-Instromet Pvt Ltd**
  Oct 01, 2014 - Dec 01, 2015
- **Project Engineer | GE Oil & Gas**
  Mar 01, 2013 - May 01, 2014

Education

- **Masters**, No Dates Provided | Gannon University

Skills

- **engineering** | 5yrs | 2021
- **verification and validation** | 4yrs | 2021
- **manufacturing** | 3yrs | 2021

- **qa** | 3yrs | 2021
- **documentation** | 2yrs | 2021
- **fmea** | 2yrs | 2021
- **investigation** | 2yrs | 2021
- **mechanical engineering** | 2yrs | 2021
- **product development** | 2yrs | 2021
- **technical writing** | 2yrs | 2021
- **change request management** | 2yrs | 2021
- **corrective and preventive action** | 2yrs | 2021
- **manufacturing support** | 2yrs | 2021
- **ncr** | 2yrs | 2021
- **standard operating procedure** | 2yrs | 2021
- **drawing** | 1yrs | 2020
- **document management** | 2yrs | 2019
- **iq** | 2yrs | 2019
- **oq** | 2yrs | 2019
- **pq** | 2yrs | 2019
- **autocad** | 1yrs | 2019
- **design management** | 1yrs | 2018
- **osha** | 1yrs | 2018
- **business requirements** | 1yrs | 2015
- **inside sales** | 1yrs | 2015
- **project engineering** | 1yrs | 2015
- **sales** | 1yrs | 2015
- **sales engineering** | 1yrs | 2015
- **technical sales** | 1yrs | 2015
- **programmable logic controller** | 1yrs | 2015
- **management**
- **validation**

Work Preferences

- Likely to Switch: Most Likely
- Willing to Relocate: Yes
- Travel Preference: Up to 100%
- Work Authorization:
    - US
- Work Documents:
    - Employment Auth Document
- Desired Hourly Rate: 45+ (USD)
- Desired Salary: 90000+ (USD)
- Security Clearance: No
- Third Party: No

- Employment Type:
    - Contract - W2
    - Contract to Hire - Independent
    - Full-time
    - Contract to Hire - W2
    - Contract - Independent

Profile Sources

- Linkedin: http://www.linkedin.com/in/lijo-george-philip-4790
- Dice: https://www.dice.com/employer/talent/profile/6fb95dd6f8aaad817e007d8cbb0d133c18eb9f09