Quality Supplier Manager

For a leading Medical StartUp company

Essential Duties and Responsibilities:

1. Work closely with key stakeholders & company management to define & follow up required procedures and actions
2. Ensure compliance to required standards re. CE – ISO 13485 and applicable US regulations, including IDE, De-Novo, PMA, GCP, GMP, QSR, etc.
3. Provide necessary QA input for R&D and Operations to ensure all activities and processes are in line with necessary standards
4. Manage and implement annual internal audit plan, Audits Response, support regulatory audits, Audit and certify suppliers to required standards
5. Responsible for Management Review – data collection and analysis, AI follow up and improvements
6. Analyze complaints and prepare response to related bodies.
7. Analyze production Yield & cost of Quality.
8. Overview follow up and guidance of routine QA/ QC activities such as CAPA, MRB, ECO, RMA, DA, SCAR, incoming inspection, in process inspection, final inspection, product release.

Additional Responsibilities:

1. Communicate engineering and manufacturing specifications to supplier technical teams
2. Actively manage suppliers to ensure there are no regressions with the implementation of new processes
3. Aide in the new, probationary and rejected supplier transition processes
4. Travel to supplier locations to resolve quality problems
5. Assure compliance to all applicable legal requirements pertaining to the environmental aspects and impacts. Work to help achieve the performance goals established in the environmental measurement areas. Offer suggestions that can lead to improved environmental performance whenever possible

Authority:

1. Establish, implement and manage Quality Management Systems, Review & Approve records.
2. Educate and/or counsel staff in compliance with the organization's policies and procedures. Initiate action to prevent the occurrence of any non-conformities relating to product, process, and quality systems
3. Verify the implementation of solutions
4. Approve suppliers

Qualification:

1. At least 4 years r e l a t e d experience in medical device and training in design & development, manufacturing environment & Suppliers management; experience in MDD, MDR, QSR, ISO13485, and ISO14971 …..
2. Understanding of project management(experience preferred)
3. Knowledge of various quality system methodologies 8D, Lean, 5 Why's, Pareto Analysis, Six Sigma, 8-D, DFMEA, PFEMA, PPAP, etc. preferred

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