REGULATORY AND QUALITY SPECIALIST (MEDICAL DEVICES)

Company Description

AJL Ophthalmic is a Certified Medical Device Company, specialized in Ophthalmology, that designs, manufactures and globally distributes its final products. AJL is looking for a Regulatory and Quality Specialist that will be involved with its subsidiary in Chicago and will represent, take responsibility and support with the Quality and Regulatory activities at the manufacturing plant in Alava. This position functions as an organization liaison for compliance to international regulatory agencies and notified bodies, for a specific range of medical devices that are under the MDR 2017/745, 21CFR820, ISO 13485 and other ISO standards.

Information

Deadline: 2020-12-30
Category: Business
Province: Araba / Álava
Country: Basque Country
City: vitoria

Company

AJL Ophthalmic

Main functions, requisites & benefits

Main functions

To interact with the Notified Body representatives and regulatory agencies, for a specific range of products. To mantain products registrations and provides strategies and leadership for new products, line extensions, new markets and new requirements. To prepare annual reports, product certifications and various registrations. To mantain, review and update documentation related to the Quality System, such as Technical Files, SOPs, DOPs, etc... To manage internal, external and vendor audits. To process complaints and Routine Returns. To monitor Marketing/Field Feedback reporting, Post-market Surveillance Studies and Peer Review Studies.

Requisites

Bachelor Degree in Engineering or Life Science. Minimum 4 years of experience with Medical Devices in Quality Assurance / Regulatory Affairs. FDA, MDD/MDR, GMP and ISO Regulations: interpretation and use. Proficiency in English. Experience hosting, planning and executing audits. Computer, verbal and written skills essential, experience in medical writing a plus.

Benefits

Indefinite Contract. Remuneration according to value. Professional Development in a consolidated Entity.