QUALITY & REGULATORY LEAD

Company Description

Innitius is developing novel patented medical devices based on torsional wave technology for the diagnosis of conditions or syndromes based on the consistency of the tissue being tested. The company's initial focus is on improving the outcomes and reducing the costs associated with preterm labor (PTL). The company was established in 2017 as a spinoff of the University of Granada (UGR) and the Andalusian Public Health System (SAS) born as a result of several research projects starting in 2012 that developed into the Fine Birth device for preterm labor diagnosis. The first product, Fine Birth is designed to facilitate an evidence based decision-making process relating to Preterm labor (PTL) using a combination of torsional ultrasound waves and artificial intelligence to measure the shear mechanical properties of the mother's cervix and provide a clear interpretation to drive decision making. The Clinical goal of the device is to differentiate between false pre-term labor and true labor and by doing so improve patient outcomes and lower the costs associated with the unnecessary hospitalization and administration of therapeutics to false preterm labor patients. The Fine Birth device will allow doctors to diagnose the risk of delivery in real time, and to detect false preterm labor, delivering substantial positive benefits to both patients, their families and payors.

Information

Deadline: 2020-08-15
Category: Business
Province: Bizkaia
Country: Basque Country
City: Bilbao

Company

Innitius

Main functions, requisites & benefits

Main functions

Innitius busca incorporar a un perfil para avanzar en el proceso regulatorio y de implementación de la ISO 13485. Definición de procesos y procedimientos para implementación de QMS. Gestión documental y redacción de especificaciones de producto. Aseguramiento de cumplimiento normativa Medical Devices en el producto de la compañía. Gestión de ensayos normativos del producto. Ejecución de la estrategia regulatoria (FDA & EMA). Project Management.

Requisites

Licenciatura o Ingeniería relacionada con Ciencias de la Salud (Biología, Farmacia, Química, Ingeniería etc.) Experiencia demostrable de mínimo 3 años en implementación de QMS en sector Medical Devices. Dominio de la normativa de aplicación al dispositivo de la compañía. Experiencia previa en procesos regulatorios con FDA & NF. Experiencia en gestión documental para construcción de DHF. Nivel de inglés alto, hablado y escrito. Experiencia mínima de 3 años en puestos similares. Referencias previas.

Benefits

Incorporación inmediata. Flexibilidad horaria. Salario acorde a mercado, en función del perfil del candidato.