SAP

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: 2019-12-31
Category: Business
Province: Bizkaia
Country: Basque Country
City: Bilbao

Company

Innitius

Main functions, requisites & benefits

Main functions

As part of the development plan, Innitius is hiring a QA/RA manager to join the company as soon as possible. The main duties & responsabilities are: Create a regulatory strategy & workplan. Regulatory pre-submissions to EMA & FDA. Establish a design history file Establish a risk management file. Build relationships with suppliers - manufacturers. Establish document controls. As Innitius is creating its own product, it'll generate plenty of records, and it's important to have a system for organizing and maintaining them - they'll later be reviewed by the FDA, ISO, and possibly others to establish Innitius compliance with medical device regulations. Technical File & FDA documentation drafting Establish, manage and maintain compliance with FDA QSR, including establishment registration, new product submissions, CAPA System. Establish, manage and maintain compliance with MDD 93/42/EEC directive, including CE Mark applications via Technical Files. Implement Manage and maintain compliance to ISO13485 requirements.

Requisites

5+ years' experience in Quality Assurance and Regulatory affairs within the medical devices field of use Understanding of European & American Health Authority regulations, guidelines, policies. Ability to maintain a high level of accuracy and attention to detail. Effective project management skills. Excellent planning, organization, interpersonal, time and change management skills.

Benefits

Salary: To be discussed with the applicant based on her/his profile. Home-based work is allowed. Innitius has offices in Granada & Bilbao, so being able to relocate in Bilbao in the future -not necessary immediately- will be considered as a positive point.