Job Description

Location: The majority of this person's time will be on-site in Taiwan
Date Needed By: ASAP
Expected hours per week: ~ 50
Expected Duration: ~ 18 month assignment

Responsibilities:

This individual should be an experienced and operational compliance professional well-versed in the requirements of: 21 CFR Part 820, ISO 13485:2016 and the EU-MDR. This person shall help to ensure Med Device client's Quality Management System (QMS) is complaint with each of these regulations while assisting the team with gap assessments of their Quality System, remediation action planning and execution as required. Key milestone activities will include a successful PMA inspection of the facility in Taiwan as well as the achievement of EU-MDR certification through a Notified Body.

Must have experience implementing a new QMS and aligning existing QMS with corporate and regulatory requirements.

This resource is being recruited to support a medical device manufacturing facility in Taiwan. There are no internal resources available at this time to support the project. Also, at the conclusion of the project, this resource will no longer be required.

Travel is reimbursed.