MEDECINS SANS FRONTIERES

LA FONDATION

14-34 avenue Jean Jaurès
75019 PARIS

Paris, le 24/04/2023

The MSF Foundation is a specialized entity created by Médecins Sans Frontières (MSF) dedicated to medical innovation targeting patients living in contexts with limited resources. Ongoing projects relate, among other things, to the use of 3D printing to create personalized prostheses; the development of digital tools for epidemic control and surveillance; and the development of a smartphone application using machine learning to streamline and automate antibiotic susceptibility testing: **Antibiogo**.

The Antibiogo project will contribute to the fight against antibiotic resistance, a major public health concern that is expected to cause 10 million deaths per year by 2050.

Antibiogo is a free, open source, offline Android app, designed for laboratories in Low and Middle Income Countries (LMIC). It supports non-expert laboratory technicians in measuring and interpreting antimicrobial susceptibility tests (AST or Antibiogram), in order to help doctors prescribe appropriate antibiotics to their patients and to provide accurate results that can be used for surveillance purposes.

A first version of Antibiogo that was clinically evaluated across three different sites and countries (Jordan, Mali & Senegal) has been CE self certified since May 2022 (according to the In Vitro-Diagnostic Medical Devices Directive 98/79/EC) as a mobile device application used for the interpretation of antibiograms in resource-limited settings and is being deployed within MSF laboratories.

In parallel, a second version of the app integrating additional features is under development to be submitted for CE-marking according to the new In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746.

Different teams work in collaboration on Antibiogo under the responsibility of Antibiogo program manager, including the clinical team, the product and development team, and the regulatory & quality insurance team.

In this framework, we are looking for a **Regulatory Specialist for Software Medical Device (SaMD)** to join the Antibiogo team :

Regulatory Specialist for Software Medical Device (SaMD) H/F

Activities

The Regulatory Affairs Specialist for Software Medical Device (SaMD) serves as an expert for regulatory requirements as related to global Software as a Medical Device (SaMD). The Regulatory Affairs Specialist SaMD collaborates across functions on Antibiogo project with a focus on Software part to ensure software products meet safety, efficacy & quality requirements, and are readily available to users. He contributes with the Regulatory Affairs Manager to define regulatory strategies for key markets and is the SaMD regulatory point of contact.

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Under the hierarchical responsibility of the Regulatory Affairs Manager, the core activities/responsibilities will be to:

- Ensure The MSF Foundation is in compliance with current Software IVD medical device industry standards as well as local regulatory requirements to produce safe and effective products.
- Act as the technical expert for SaMD regulations (mainly CE, ISO, etc.) ensuring the proper processes and procedures are in place to obtain necessary regulatory approvals and maintain regulatory compliance.
- Compile the content of SaMD regulatory applications & files ; drafts the regulatory documents of the technical file and ensures their compliance with the requirements of the IVDR ; assess acceptability & completeness of documents; ensure timely retrieval of documents and identify non conform needs
- Work on development of pre-submission strategy/regulatory pathway, provide input on testing requirements for modified product; provide feedback on progress & RA questions
- Participate in Design Control projects to advise on SaMD regulatory requirements, identify risks, and communicate potential issues to the MSF regulatory management
- Keep abreast of regulatory procedures and changes as well as evolving regulatory landscape; Investigate regulatory history of similar products in order to assess regulatory implications for changes to existing product
- Provide regulatory review of product verification & validation documents, User Manuel, bench aid, and advertising materials
- Review and approve product design changes to maintain regulatory compliance for significant changes
- Actively participates in problem solving discussions and recommends solutions.

Profile

Experience and background:

- Bachelor's/Advanced degree in Software Engineering, Biomedical Engineering, or related field
- 5+ years of experience in medical device/IVD affairs, preferably in IVD or Medical Device engineering, Product Development or related functions
- In-depth knowledge of global regulatory/industry rules and guidance to drive the strategic approach to SaMD medical device approvals
- Experience with rules-based, machine learning and in diagnostics development and/or stand-alone software is preferred
- Experience with regulatory submissions including EU MDR / IVDR Technical File creation and maintenance
- Knowledge of low and middle income countries and emerging market is a plus

Languages : Fluent English (oral & written) is essential (B2). The French language is an asset.

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Competencies :

- Ability to work in a fast-paced/entrepreneurial environment
- Ability to work in a cross-functional, highly interdependent team structure
- Ability to comprehend principles of software development, basic microbiology and IVD use

Skills:

- Results and goal oriented
- Ability to work independently
- Excellent oral and written communication skills
- Willingness to seek out diverse ideas, opinions, and insights and apply them in the workplace

Starting Date : As soon as possible.

Status and Conditions :

Consultancy Agreement : 2 days per week

Location: Paris MSF HQ or remote (national and International travels might be necessary)

Duration: 12 months

Please send your application (motivation letter and CV) to the following address :
vanessa.lalouelle@paris.msf.org
Only candidates whose applications have been selected will be contacted
The announcement will be removed once the position has been filled.