

Position: Diagnostics Program Manager

Daktari Diagnostics, Inc. is a Boston-based company developing innovative diagnostic tests for global health conditions. The core technology combines microfluidics with electrochemical sensing. Our initial product, a point-of-care CD4 testing system for use in HIV disease staging worldwide, will provide a CD4 cell count result in less than 8 minutes from a finger stick of blood, anywhere in the world. This handheld system includes a disposable assay cartridge comprised of molded plastics, microfluidics, integrated sensors, and chemistry, and a low-cost electromechanical instrument.

The successful candidate will be responsible for development of the CD4 immunoassay with on-board quality controls, and transfer to manufacturing. This position will report to the VP of Product Development. Emphasis will be placed on the ability to build and manage a lab team, planning and execution of research plans, and communication across functions in a focused start-up environment. Ability to drive projects through to completion is of paramount importance.

In more detail, the responsibilities include, but are not limited to:

- Lead a team of 3-5 scientists and technicians through the development and validation of a stable and robust microfluidics-based point-of-care assay including on-board dry reagent (antibody) and wet reagent (buffer) chemistry
- Work with Daktari's management team to develop schedules and resource plans for current and future development programs
- Design and conduct assay optimization experiments and analyze experimental results
- Design and execute studies to assess reagent and kit stability
- Write Standard Operating Procedures, and transfer technology to production group
- Perform all duties in compliance with appropriate quality system regulations and GLP standards
- Support data collection and documentation of reagent and kit stability for submission to regulatory agencies

Requirements:

- Degree in biology/immunology, chemistry, or related field
- 15 years or more of experience in commercial immunoassay development and/or validation, with at least 5 years managing a team in a medical products company pursuing FDA or related product approvals
- Demonstrated successful team and project management skills and the ability to contribute to strategic decisions, while driving detailed implementation plans
- Experience with development of microfluidics-based systems strongly preferred
- Ability to work independently in a start-up environment

Salary commensurate with experience; potential equity participation.

Daktari Diagnostics is a dynamic, start-up environment committed to bringing the highest quality medical diagnostics to everyone, everywhere.

Please contact work@daktaridx.com for more information. Please reference code RD3.