

PineTrees

Regulatory/Quality specialist

PineTrees is a stealth startup developing a novel point-of-care platform for nucleic acid diagnostics in healthcare with the goal of spreading molecular biology to every home and workplace and ending unknown disease. This technology was developed by scientific pioneers at top-tier institutions, including MIT and the Broad Institute. With rapid, affordable testing that can be performed daily, we believe we can end the COVID-19 pandemic and save lives for many diseases beyond.

We are seeking a regulatory and quality specialist to join our talented team for managing the regulatory process for our diagnostic product as well as necessary usability and quality studies. The role will involve working with the FDA and regulatory consultants, ensuring necessary studies are being conducted, managing usability studies, managing quality consultants, and implementing QMS within the company. Ideally, the candidate has experience with the EUA/510(k) regulatory process as well as QMS and can help manage consultants for necessary filings.