Digital Health Industry Regulatory Case Study

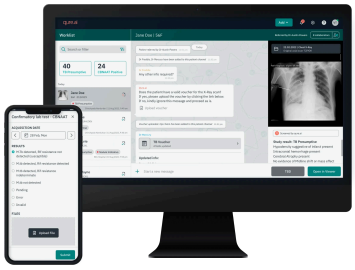
qure.ai

Bringing novel AI-powered devices to the US market

About Qure.ai

Qure.ai is a breakthrough artificial intelligence (AI) solution provider that facilitates automated interpretation of radiology exams for time and resource-strapped medical imaging professionals, enabling faster diagnosis and treatment. Their mission is to use AI to make healthcare more accessible and affordable. Qure.ai products include:

- *Chest X-ray reporting*
- *Lung nodule management*
- *MSK X-ray reporting*
- *Mammography scoring*



The opportunity

- Qure.ai's tuberculosis (TB) screening device has been deployed at 139 health facilities in India and over 2,000 sites globally since 2020.
- With the rise of TB cases in the US in 2021/22 during COVID-19, Qure.ai was keen to **meet patient and clinician needs in the US**.

The challenge

- Amidst the **shifting landscape of regulations** for AI/ML-enabled medical devices, Qure.ai sought to deepen its understanding of these evolving standards. They aimed to ensure their AI-powered TB solution, qSpot-TB, not only adhered to current requirements but also remained at the **forefront of compliance and innovation**.
- qSpot-TB is a second-read computer-aided detection and diagnostic device to analyze chest X-rays and localize all noted radiological signs suggestive of TB. The system provides a conclusion for the presence or absence of TB.

The approach

- Seeking clarity on the US market, **early engagement with the FDA** enabled them to **strategically position their product** and understand the US regulatory landscape and market entry requirements.
- Through multiple **pre-submission meetings**, they pinpointed the optimal requirements and specifications for their pathway, identifying **breakthrough designation as an optimal regulatory** path due to their product's unique capabilities in analyzing chest X-rays for TB detection.

The success

- ✔ **FDA granted a breakthrough designation** to Qure.ai's qSpot-TB, followed by regulatory clearance.
- ✔ Qure.ai achieved successful market access in US health systems and partnered with a large AI radiology company on commercialization.

> "Throughout our numerous engagements with the FDA, we have witnessed firsthand the value of openly sharing product aims, questions, and insights with the agency. It's important to be honest and transparent and never be afraid to ask the FDA questions in pre-submission meetings."

— Bunty Kundani

Chief Regulatory Affairs Officer, Qure.ai

DiME