



**Position Title:** QA Manager (or Director)

**Location:** Cambridge, MA

## **Company Description**

Cognito is a venture backed (Morningside Ventures) startup company translating scientific findings from MIT into therapeutic approaches for Alzheimer's disease and other neurodegenerative conditions. We are a fast moving, highly motivated team of people with the ambitious goal of helping the millions of Alzheimer's disease patients and caregivers around the world. With our patented gamma stimulation technology, we are committed to developing non-invasive device-based therapies. Developing this unique platform requires expertise across a range of fields. Engineering, Software Engineering, Regulatory, Clinical, Product Design, Data Science, QA, Business Development, Marketing, just to name a few. We are looking to grow our world-class team of scientists and medical device innovators who want to make a difference and improve people's lives on an everyday basis.

## **Summary of Role**

We are looking for a highly motivated QA Manager (or Director) to join Cognito based in our Cambridge, MA office. As a member of the CA/QA/RA team, you will have the opportunity to manage the Quality System to help get our innovative technologies into the hands of the 45 million people around the world with Alzheimer's disease.

For us to be successful, our Quality System must be sophisticated enough to facilitate the highly innovative technologies we are designing as well as the complex global clinical studies we are pursuing. We are moving fast, but principled. Our systems must embody this as well. We need you to continually maintain and improve our systems to world-class standards.

Our culture is very open and innovative, and due to the multidisciplinary nature of building a complex device, you will be collaborating with teams from a variety of fields, including neuroscientists, engineers, and medical device professionals.

## **Deliverables**

You will be responsible for:

- Ensuring that our products and services are available to customers (both internal and external) through new product design, design review, engineering, customer/vendor relations, manufacturing quality, inspection, calibration, training, customer complaints and MDRs.



- Ensuring compliance with relevant device regulations including QSR, ISO, EU MDD, and others
- Leading the regular quality planning and strategy setting process alongside executive leadership to ensure that future strategic goals are supported by well-integrated and world-class quality systems

### **Who You Are:**

You're someone who likes the pace and energy of a startup company and wants to influence your own development. You're looking for an early stage company with an exciting technology, where you have the opportunity to make a difference for patients around the world.

### **Minimal Qualifications:**

- BS degree in Engineering
- 7+ years of experience in quality assurance and 5+ years managing a team in QA
- Experience in building various components of a Quality System from scratch, including vendor selection, implementation, training, and validation
- Experience managing the evolution of a Quality System to a larger and more complex state
- Experience managing external audits and performing internal audits
- Excellent communication skills

### **Desired Qualifications:**

- Master's level Engineering degree
- Compliance certifications
- Six Sigma Black Belt certification and experience implementing Six Sigma and Lean principles

\*Director-level role decided commensurate with experience and relevance of prior roles

### **Contact:**

Interested? Send a short introduction and resume to [jobs@cognitotx.com](mailto:jobs@cognitotx.com)