## Job Description

- Company: HOLOGIC Japan
- Position: Regulatory Affairs Specialist
- Report to: RAQA Manager
- Location: Tokyo

### HOLOGIC: The Science of Sure

Driven by our ethos, *The Science of Sure*, we're a diverse, dedicated, creative team that develops, markets and services some of the most innovative and accurate diagnostic imaging systems and surgical products on the planet. Our core business units are focused on breast health, diagnostics, GYN surgical, and skeletal health.

While we're focused on and passionate about our work, we never forget that what we're really doing is giving people greater confidence and peace of mind in their diagnosis—*enabling healthier lives, everywhere, every day*.

### Specialties: Breast & Skeletal Health, Diagnostic, (GYN Surgical Solutions=not in Japan)

- Website: http://www.hologic.com
- Industry: Medical Devices
- Type: Public Company
- Headquarters: 250 Campus Drive Marlborough, MA 01752 United States
- Company Size: 5001-10,000 employees
- Founded: 1985

### Role Overview

As a member of RA/QA team in HOLOGIC Japan, Regulatory Affairs Specialist takes the responsibility for regulatory affairs in applying for and maintaining regulatory licenses of products which focus on diagnostics and breast health business.

### Responsibilities

- Participate in cross-functional team for new product introduction to provide expertise in regulatory strategies for In-Vitro Diagnostic Drugs (IVD) and Medical Devices.
- Prepare for applications for regulatory documents for medical devices and IVD.
- Prepare for documents for QMS inspection and data reliability assessment.
- Monitor the progress of the review status, and update to the team and management at regular

basis.

- Complete reviews of technical reports which is provided by Hologic Inc. to ensure the compliance along with Japanese regulatory requirements.
- Develop and execute strategies for submission for assigned projects.
- Monitor and assess regulatory impacts of new and revised regulations, guidance, and standard.
- Support the daily operation of the team, such as reporting assessments, complaints assessment, information for use/user's manual preparation, and recall.
- Register and maintain regulatory licenses such as market authorization, manufacture both domestic and foreign country, repair and sales.
- Responsible for IVD sales license.
- Support quality activities such as preparing technical file (製品標準書)、reviewing quality procedures.

**Skills and Experience**

- Pharmacist License
- 3-5 years of experience in regulatory affairs for IVD and/or medical devices
- Good communication skills in English (written and oral)
- Good analytical and problem solving skills
- Self-learner type of attitude
- Being a good team-player
- Knowledge about QMS and ISO 13485 requirements are the "plus"