

QUALITY ASSURANCE MANAGER

SUMMARY OF POSITION

The successful candidate will be a highly motivated individual to supervise the local quality assurance and control activities for release of commercial product within the Amicus KK group.

The Quality Assurance Manager position will have demonstrated experience including quality systems and quality control or related experience in supporting the major activities and responsibilities as described below. The successful candidate will be responsible for the day to day quality control of the Japanese operations.

MAJOR ACTIVITIES AND RESPONSIBILITIES

- Develop and maintain a local quality system to support the release of a commercial product
- Conduct or supervision of quality assurance activities, including but not limited to, product release, self-inspection, training and handling of defects
- Conduct internal process audits and external supplier audits as necessary
- Control of documents related to quality assurance activities
- Development of local SOPs related to quality activities and review or approval of functional area procedures as needed
- Communication with necessary parties in the case of recall or discontinuation of manufacture or marketing
- Support the establishment with a compliant assurance department for investigational and commercial products
- Reporting of any quality related issue to the Marketing Compliance Officer

The role may also support the International management team with additional adhoc project management support.

ORGANISATIONAL STRUCTURE

A dual reporting line to the GM, Japan and Quality Director, International.

QUALIFICATIONS AND BACKGROUND REQUIREMENTS

Educational / Work Requirement

- A minimum of a BS preferably in chemistry or life sciences (or equivalent).
- A number of years' experience in a quality role in a control or related discipline

Professional Work Experience

- Life science industry experience required
- Experience of working independently in a quality control or related function
- Leadership and collaboration skills, including excellent verbal and written communication skills at all levels
- Experience conducting and reporting on audits of various GMP suppliers
- Demonstrated knowledge with the following regulations and guidance;
 - ICH Q10 – Pharmaceutical Quality Systems
 - Japanese GMP for Drugs
- Ability to work independently and to make decisions based on experience
- Ability to travel domestically and internationally

LOCATION

This position will be based at the Amicus KK office, Tokyo