

Quality Manager

Company

The company is a manufacturer of medical devices with a factory located in Bangkok.

Responsibilities

Quality control

- Responsible of the quality controls of incoming, in-process and finished products

Quality assurance

- Fulfil the role of the site Management Representative for Quality (ISO 13485)
- Lead and manage the day to day activities of all quality assurance personnel and ensure the efficiency and effectiveness of all on-site quality system activities.
- Assure factory compliance with all company Quality System Procedures and policies.
- Establish effective corrective action plans for all operations department non-conformances. Drive towards timely closure and effectiveness.
- Manage 3rd party audits (ISO, Thai FDA, US FDA) and ensure the execution of corrective action and compliance with internal quality procedures and external standards.
- Manage the non-conformance and CAPA reporting system
- Management of the document control system
- Archive and scan the controlled document used in the QMS

Customer complaints

- Record and answer to customer complaints

Laboratory

- Monitoring microbiological tests
- Monitoring of the environment

Calibration

- Coordinate off-site calibrations with certified calibration companies

Various

- Represent Quality on cross-functional teams participating in various operational programs such as FMEA development, Risk Management activities, Master Validation Planning.

Profile

- Minimum 8 years of related experience in Medical Device industry.

Required Skills :

- Demonstrated use of Quality tools/methodologies.
- Working knowledge of ISO13485
- Fluent in English
- Supervisory experience required

Conditions

- Work Location: Bangkok
- Local Contract

Interested candidates, please send application to employment@francothaicc.com

Only shortlisted candidates will be notified.