Head Compliance

Key responsibilities

Before Start up:

- Prepares and reviews all documents to be submitted to the Chinese SFDA authorities
- Establishes and maintains an excellent relationship with all relevant authorities
- Ensures compliance of the project design and of the execution of the project with Chinese regulation and GMP/FDA requirement
- Sep up QA management system
- Reviews all SOPS
- GMP/QA training
- Ensures the appropriate design of the QC department (equipment and staffing)
- Build up analysis method
- Design quality label system as key person together with other department
- Technical report to HQ

After Start Up:

- Prepares and reviews all documents to be submitted to the Chinese authorities
- Establishes and maintains an excellent relationship with all relevant authorities
- Pass GMP audit
- Pass FDA audit
- Keep efficiency and effective QA system
- Coordinate with HQ to improve QA system
- Response for customer complaint investigation and action plan implementation
- GMP/QA training
- New products application of GMP
- Coordinate with HQ to build up new analysis method
- Perform a regular quality meeting
- Technical report to HQ
- Others supervisor requested

Critical Experience and Skills

- Master in chemistry or pharmacy
- 10+ years of experience in intermediates and API manufacturing
- 10+ years of experience in dealing with Chinese authorities in SHE and cGMP related activities
- Excellent relevant network in the Nantong/Jiangsu province and/or