

Validation Specialist

POSITION SUMMARY

One of the top manufacturing in the pharmaceutical industry located in Haikou, Province of Hainan, is looking for technical professional to add to its continuously expanding workforce, offering professional growth and advancement. The company has an ambitious pipeline to develop many new drug products for export into the U.S. market.

The Validation Specialist will manage, and will lead, coordinate, and supervise validation activities in the company. The Validation Supervisor will lead group activities to ensure that all production equipment and processes are qualified and validated per cGMP regulations, regulatory guidelines, and consensus standards.

MAJOR AREAS OF RESPONSIBILITIES

- Oversee all IQ, OQ, PQ of Equipment and Critical systems, Computer systems, Sterilization, Cleaning and Process Validation activities.
- Manage requalification and revalidation programs to ensure a continued state of compliance.
- Provide direction, feedback and guidance to validation assistants and technicians.
- Write validation protocols, including Master Plans; determine required validation testing based on guidelines (FDA).
- Audit and approve protocols, drafts and executed reports.
- Assess process and equipment designs and writes pre-validation studies.
- Track, maintain & investigate (or designate an investigator) for validation deviations.
- Design and improve validation systems and SOPs.
- Supervise the work of third-party resources needed for the completion of validation projects, when required.

QUALIFICATIONS/SKILLS

- Degree in Engineering (Biochemical, Chemical, or Mechanical), Physical or Life Sciences.
- Minimum of 3 years Validation experience in a pharmaceutical environment.
- Sterile product experience, including both aseptic and terminally sterilized parenterals strongly preferred.
- Management or supervisory experience is preferred.
- Proficiency in Microsoft Office applications including MS Project.
- Must be fluent in Mandarin and proficient in reading, writing and speaking English.

Apply Now

Please send your resume in confidence to kjiang@acic.com, in English.

While we thank all applicants, only those chosen for interviews will be contacted.