Job Description

Associate QC

GCF Grade Level: 02/03 **Site: Amgen Singapore Manufacturing (ASM)**

Role Description

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics has changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives.

The QC Associate will support the laboratory activities including testing, systems and projects in compliance with laboratory and analytical methods ensuring quality, cGMP, health safety and environmental standards are met. This training is expected to train up individual in both the technical and soft skills aspects. The role will encompass a good understanding and execution of various test methods/ techniques/ instruments.

Responsibilities:

- Perform analytical testing on routine environmental, water, plant cleaning, raw material, in-process control, drug substance and stability samples in compliance with Specifications, Analytical methods, SOPs and Pharmacopoeia requirements.
- Support laboratory operations including but not limited to systems, equipment qualification, calibration and maintenance, reagent/ buffer preparation, chemicals/ consumables inventory, laboratory housekeeping and document archival duties.
- Support in method verification and method validation/transfer for new product introduction (when required)
- Participate in troubleshooting issues related to analytical testing, techniques and equipment.
- Participate in laboratory investigations and assist in timely closure of investigations, CAPAs and deviations.
- Perform periodic review of laboratory procedures and risk assessment.
- Ensure proper handling, storage, disposal of all chemicals used in the lab.
- Author of SOPs/protocols/reports.
- Support regulatory inspections.
- Project management / Involvement in continuous improvement initiatives and projects.
- Other responsibilities that are not included in the above but are related to quality control and in accordance to internal guidelines and SOP.

Basic Qualifications

- Bachelor's degree in Science
  OR
- Diploma and at least 5 years of directly related experience

Preferred Qualifications/Competencies:

- Undergraduate degree or diploma in Chemistry, Microbiology, Biological Science, Life Science or related technological field
- At least 1 years of relevant laboratory experience in the commercial manufacturing environment within the pharmaceutical or biopharmaceutical industry and analytical testing experience preferred.
- Direct experience with bulk manufacturing of biopharmaceuticals/API preferred.
- Knowledge and understanding of GMP pharmaceutical production, pharmaceutical plant operation and associated testing methods.
- Experience with Quality Control testing, System and laboratory operations for common testing methods and equipment (e.g. including but not limited to LIMS, LMES, CIMS, Trackwise, Empower, LC, GC, LOD, KF, Autotitration, wet chemistry, FT-IR, conductivity, TOC, Potency, ELISA, Capillary Electrophosis, DNA, bioburden, endotoxin, microbial identification, environmental monitoring, microbial limits, growth promotion, biological indicators)
- Good communication skills (technical writing and verbal communication/presentation)
- Interact effectively with variety of communication and working styles and ability to work well in teams
- Ability to manage multiple simultaneous activities in a rapidly changing environment
- Problem solving skills and troubleshooting skills with the ability to apply logic and assess data to reach decisions and solutions related to compliance and product quality
- Fluency in written and spoken English
- Strong passion for training who always strive for continuous improvement
- Ability to work in a fast paced / dynamic work environment
- A fast learner with “Can-do” attitude
- Self- directed with strong written and oral communication skills
- Good time management skill, great attention to detail, ability to multi-task across concurrent projects.

Additional Requirements

- Work on shift schedules may be required