B & S GROUP "Believe in us"

JOB DESCRIPTION

ROLE: Sr. Executive / Asst. Manager (ADL-QC)
REPORTING TO: Head of Regulatory Special Projects
LOCATION: Vadodara*****

PRIMARY RESPONSIBILITIES:

- To develop and validate robust analytical test methods to support formulation development, stability testing and quality control testing of new pharmaceutical formulations, ensuring delivery in accordance with project timescales and deadlines.
- To perform analytical testing, investigations and analytical problem solving, in support of formulations.
- To supervise the day to day analytical activities and the analytical development.

SECONDARY RESPONSIBILITIES:

- Developing and validating analytical test methods for the testing of pharmaceutical products for manufactured to Good Manufacturing Practice (GMP) and ICH requirements.
- Developing and validating test methods for use during manufacturing.
- Preparing analytical method development, validation and analytical investigation reports.
- Solving complex analytical chemistry problems.
- Transferring new analytical techniques to the Quality Control (QC) laboratory.
- Controlling laboratory chemicals required for analytical development activities.
- Planning and organising stability testing.
- Stability testing for products for new formulations.
- Writing/reviewing specifications and methods of analysis.
- Writing/reviewing of Standard Operating Procedures (SOPs).
- Analytical support with analytical problem solving to facilitate product development activities, including accelerated long term stability testing, process development and regular commercial batches.
- Contributing and preparing CMC Analytical development sections for MA applications.
- Participating in self inspections and regulatory inspections.
- Supervising, motivating, coaching and mentoring the analytical development team.
- Ensuring good relations and communications with all members of the team; responding politely and in a timely fashion to internal and external clients.
- Working with all members of staff to maintain and develop the positive progressive culture within The Specials Laboratory.
- Observing and complying with Good Manufacturing Practice (GMP), Good Laboratory Practices (GLP) and Good Distribution Practice (GDP).
- Observing and complying with company Health and Safety Policies.
- Observing and complying with company Standard Operating Procedures (SOPs).

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES:

- Master degree in Pharmacy/Science.
- Working as Analytical Development Laboratory (ADL)/Quality control (QC) with minimum experience 4-6 years.
- Sound knowledge about Analytical instruments.
- Good communication skills.
- Sound knowledge of cGMP, GLP, ICH, WHO and good documentation practice.

***** *Initially selected candidates will work at Vadodara (GRPL); afterwards they will be transferred to London (UK) as per business needs.*