Job Description & Person Profile
Senior Analytical Development Scientist

Department: Product Development
Reporting to: Product Development Manager
Senior Manager: Head of Operations

Job Purpose:
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 investigations and analytical problem solving, in support of formulation development activities.
To supervise the day to day analytical development activities and the analytical development team.

Responsibilities:
- Developing and validating analytical test methods for the testing of pharmaceutical products for manufactured ‘specials’ to Good Manufacturing Practice (GMP) and ICH Q2 requirements.
- Developing and validating test methods for use during cleaning validation.
- Preparing analytical method development, validation and analytical investigation reports.
- Solving complex analytical chemistry problems.
- Transferring new analytical techniques to the Quality Control (QC) laboratory.
- Purchasing, validating and maintaining equipment for analytical development activities.
- 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 and analytical problem solving to facilitate product development activities, including accelerated and long term stability testing and process development.
- Contributing to and preparing CMC Analytical development sections for MAA applications.
- Participating in self inspections and regulatory inspections.
- Using laboratory chemicals in accordance with Health and Safety and Home Office requirements.
- Supervising, motivating, coaching and mentoring the analytical development team.
- Ensuring good relations and communications with all members of the team and responding politely and in a timely fashion to internal and external customers.
- 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) and Good Distribution Practice (GDP).
- Observing and complying with company Health and Safety Policies.
- Observing and complying with company Standard Operating Procedures (SOPs).
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- Undertaking any other duties, either for this department or any other department within the business, which may be requested by the Line Manager, for which training and/or an explanation has been provided and understood.

Person Profile:

- Essential Requirements:
  - Chemistry, pharmacy or scientific (with strong chemistry content) degree.
  - Impressive, demonstrable track record and skills/experience gained within a similar position(s), at a similar level.
  - Minimum of 5 years experience of pharmaceutical HPLC method development and validation.
  - Good knowledge/experience of analytical instrumentation and qualification procedures.
  - Experience of working in a GMP environment.
  - Coaching/mentoring experience.
  - Good IT skills e.g. Microsoft Office (Word, Excel and Outlook).
  - Credible and confident communicator (written and verbal) at all levels.
  - Highly customer focused and passionate about delivering excellent customer service.
  - Ability to achieve and maintain high standards with meticulous attention to detail.
  - First class planning, organisational and time management skills.
  - Ability to work accurately in a busy and demanding environment, adhering to strict deadlines/timescales.
  - Strong analytical and problem solving ability.
  - Self starter who can ‘hit the ground running’.
  - Good team player.
  - Self motivated with the ability to work proactively using own initiative.
  - Hands on approach with a ‘can do’ attitude.
  - Committed to learning and development.

- Highly Desirable:
  - Good understanding of the pharmaceutical market, including the unlicensed medicines sector.
  - People management skills/experience.

Training:
You will receive on the job training and other specific training, as agreed and required.