Job Description

Research & Development Manager

We are currently recruiting for an experienced Research & Development Manager to join our growing team in North County Dublin.

Reporting to the Chief Executive Officer, the Research & Development Manager will be a senior member of the management team and will be leading and managing the Research & Development Team as part of Research, Development, and Innovation function within the company.

Working closely with a number of cross-functional departmental managers, in particular Scientific, Clinical & Medical Affairs, Regulatory Affairs and Quality Departments; the Research & Development Manager will be responsible and accountable for the internal product development pipeline and will manage and oversee personnel involved in project specific implementation and execution of planned development activities. Furthermore, the Research & Development Manager will provide technical support to cross-functional departments such as Regulatory Affairs and Quality Departments.

Central to this role, this position will be responsible for development project planning/strategy and project management across multiple approved company projects at any one time according to timelines and budget parameters. As projects move from a defined product concept into development, the Research & Development Manager will be working closely with the Scientific, Clinical and Medical Affairs Department. As a key member of the wider Research, Development and Innovation function this role will be responsible for promoting a culture of innovation both within the Research, Development, and Innovation Department and across the business.

The company is a fully integrated healthcare organisation, but manufacturing activities are virtual in that production is carried out by a network of established contract manufacturers. Research and development activities are carried out through third parties as well as an R&D lab managed by Kora healthcare. The company has a portfolio of healthcare products including medicines, medical devices, foods for special medical purpose and foods supplement. The company is accredited to Good Manufacturing Practices, Good Distribution Practices and holds a manufacturing license and wholesale license, as well as ISO13485 accreditation

Key areas of role responsibility lie within the areas of

Project Management:

- Set project direction, planning, goals, milestones and ensure project deliverables meet strategic corporate objectives.
- Plan and oversee projects budget.
- Manage stakeholders and third parties' activities.
- Deliver projects within the planned timelines.
- Lead R&D's projects overall risk assessment and issue management.

Product Development:

- Source and evaluate the capabilities and qualifications of contract developers/ manufacturers to prepare/process the intended formulation.
- Lead and organise product development activities within Kora Healthcare's lab or within a contact development lab or manufacturing facility, according to the relevant guidelines and best practices of each product (i.e. QbD for Medicines)

- Lead and organise any non-clinical, CMC, scaling up, validation, stability, and tech transfer activities.
- Define the formulation, raw materials (grades and specifications), Finished product specifications, testing methods as well as any additional or specific studies needed.
- Define and agree on the manufacturing process, assess the critical parameters, and provide technical input as required.
- Define the stability storage condition and manage the stability programme.
- Input in and prepare any R&D related documentation (e.g., module 3 CTD) required for product submission or required by any relevant party.
- Maintain the development documentation (hard copies and soft copies) within the R&D's department as per each product's relevant guidelines (i.e., CTD for medicines and ISO 13485 for medical devices).

Innovation and Forward Thinking:

- Market Research - thorough understanding of the key therapeutic areas of focus
- Review competitor products and old/new technologies with a view to identify opportunities for competitive advantage through innovative product development
- Lead the 'New ideas and innovation' meeting.
- Supports and acts as the point of contact for new ideas generated by others in the company and draft the required documentation to assess new ideas.
- Intellectual Property – review patents covering ethical products (medicines), non-ethical (medical devices) or competitor products with a view to securing intellectually property.
- Prepare/write up grant aid for new products including recording of time for grant claims and R&D tax credits.

People Management:

- Leads and motivates direct reports to achieve personal development.
- Sets impactful development objectives.
- Provides stretch assignments to develop talent.
- Drives innovation and continuous improvement initiatives through the use of delegation and associate empowerment

Reporting to

The Chief Executive Manager

Direct Reports

Senior R&D Specialist

Essential Requirements:

The Successful Candidate will possess the following:

- Educated to Masters level / PhD in Chemistry, pharmacy; must be technically competent.
- 8+ years of experience in the pharmaceutical and/or medical device industry. Experience in a similar/related role is essential.
- Experience in scale-up manufacturing (bench to industrial/commercial) development

- Knowledge of gel manufacture and/or dry granulation advantageous (Current technologies: – gels – one based on polycarbophil and the other based on lactic acid; dry granulation; liquid manufacture).
- Strong Project Management skills – certified training and experience/track record in project planning and execution.
- Knowledge within Intellectual Property (e.g. patenting) processes.
- Risk Management Training.
- Lead, manage and participate in internal and external auditing (certified training).
- Knowledge/Technology Transfer
- Good awareness of the development and manufacturing infrastructure internationally.
- Good financial and budgetary planning.
- Excellent organisational skills, ability to prioritise work and systematic approach to tasks.
- Thorough / attention to detail; excellent report writing skills required.
- Strong work ethic: Highly self-motivated, self-driven, "can-do attitude" and ability to multitask.
- Accountable and Responsible to established timelines and goals.
- Strong background from a development perspective in the application of ISO 13485, MDD, GMP, GVP and GDP standards.
- Pro-active approach to addressing compliance issues and assuming responsibility for compliance deficiencies.
- Ability and experience in gap analysis and actions plans.
- The company works with a number of stakeholders both inside and outside the company, the ideal candidate will demonstrate excellent interpersonal, communication and presentation skills, strong analytical and problem solving skills.
- Proficiency in speaking, comprehending, reading and writing English is required.
- Willingness to travel (approx. 10%).

Kora Healthcare offers good benefits and an environment conducive to professional growth and advancement. All qualified applicants will receive consideration for employment. Kora Healthcare is an Equal Opportunity Employer.

Company Values:

- Passion "Passion is the difference between great and ordinary performance"
- Enjoyment "Enjoy the journey"
- Effective "Together Everyone Achieves More"
- Courage "Be the game changer - it's not about ideas; it's about making ideas happen".
- Empowerment "Honesty and trust is the license to empowerment and responsibility and accountability is the price of empowerment"