POSITION DESCRIPTION

Title: Scientist II (Formulation)	Ref no: March 2021
Company: Acrux DDS Pty Ltd	
Reports to: Formulation Manager	

Purpose:

- Develop and characterise formulations for Acrux' specialty and generic portfolio to support an ANDA and NDA US FDA regulatory dossier filing
- Perform scale-up studies and manufacture laboratory scale pharmaceutical products to support stability programs
- Generate data to support patent filings
- Conduct experiments to evaluate the feasibility of product concepts

ACCOUNTABILITIES

Key Result Areas	Key Tasks
Product Development	• Perform thorough literature searches (patents, interpretation of regulatory information and dossiers, product labels, journal articles etc) to become the team specialist for the assigned project • Develop and optimise formulations in accordance to regulatory requirements through concept to scale-up phase of the program, as required (including process optimisation) • Develop and optimise methods to carry out physicochemical testing • Perform and evaluate in vitro studies and other studies to support product development activities • Support manufacture activities for stability studies and for clinical trial supplies as required • Contribute to pre-clinical, in vitro and bioequivalence activities as required • Conduct analysis according to the appropriate quality standard and in compliance with GLP or other regulatory requirements, as applicable • Apply appropriate scientific rationale and experimental design throughout development • Interpret, summarise and correlate results to formulation properties • Test potential primary packaging components as required • Write and review study protocols, characterisation and formulation development reports • Contribute to the identification and implementation of new formulation and processing technologies which could potentially achieve significant time saving and/or improve standard of work • Support method validation activities • Partake in technical transfer activities including input to technical package, RFQs, sponsor requirements documentation, review of documents from CMO and testing of Pilot and Exhibit batches • Attend and report at project meetings and work to project timelines • Support other projects/other formulation team members with the above key tasks as required
Intellectual Property and Basic Research	• Conduct experiments to support patent filings for new IP, patent litigation or to assess existing IP • Contribute to brainstorming sessions for new IP • Draft new patent filings by completion of an invention record

ACCOUNTABILITIES	
Key Result Areas	**Key Tasks**
	• Ensure laboratory notebooks comply with good record keeping requirements for new IP • Provide innovative research concepts
Quality and Continuous Improvement	• Prepare and review methods, specifications, plans, procedures, reports and other documents to a high standard • Ensure documents comply with GMP/GLP and any other industry or regulatory requirements • Support activities regarding installation, qualification, calibration and maintenance of equipment if required • Ensure SOPs, test methods and other guidelines are adhered to • Fully report all work and ensure any study conducted is documented as per SOPs • Provide training to new staff and participate in SOP training sessions • Check laboratory data of other staff and external contractors • Support laboratory maintenance and calibration activities • Participate in new laboratory and continuous improvement initiatives, as required • Promote safety and adhere to OHS requirements

QUALIFICATIONS / EXPERIENCE:

Essential:

- **Education, qualifications, special training:** BSc, BFormSc, BPharm, equivalent or higher degree
- **Skills:** Formulation development; logical approach to research and development challenges; able to search and interpret scientific literature. Strong report writing. Good presentation skills
- **Experience:** Strong product development in the pharmaceutical or cosmeceutical industry working with a commercial focus.
- **Knowledge:** Understanding of experimental design and problem solving techniques. Understanding of GLP/GMP; awareness of Intellectual Property

Desirable:

- **Education, qualifications, special training:** Design of Experiments, Quality by Design, statistics
- **Skills:** Formulation development of topical branded and/or generic products, use of Microsoft office.
- **Experience:** Development of new products in the Pharmaceutical sector. Semi-solid product development and scale-up, HPLC experience, in-vitro permeation studies
- **Knowledge:** Proficient in Intellectual Property knowledge and application to the product development process

Key Competencies:	
Communication Skills	• Excellent verbal & written communication skills. Ability to write high quality scientific reports and other documentation • Able to effectively communicate with staff at all levels • Ability to follow instructions and guidelines and seek clarification as required

Key Competencies:	
Work Style	• Proactive and flexible work style • Ability to work independently and as part of a project team • Ability to trouble-shoot and solve technical and scientific problems • Ability to share information and ideas within a team • Flexibility, attention to detail
Leadership	• Leads by example, supports team members and models teamwork • Excellent understanding of principles and methodologies of core activities
Champion Team	• To actively 'live' the Acrux Champion Team (RIOS) values

Working Relationships:

Internal:

- Formulation Manager – Regular meetings to determine overall team timelines and guidance. Feedback project progress regularly.
- Formulation Specialist - Consult to determine project priorities and issues pertaining to development programs. Feedback project progress regularly.
- In Vitro Specialist – Consult to determine project priorities and issues pertaining to development programs. Feedback project progress regularly.
- Senior Scientists – daily contact to determine priorities and issues pertaining to research and development programs. Feedback project progress daily.
- Formulation Team – Regular contact to ensure progress of work and assist in problem solving.
- Analytical Development Manager – Consult for troubleshooting with analytical methodologies.
- Technical Affairs Manager – Consult to discuss requirements pertaining to the materials and components. Consult with regard to manufacturing operations and schedule.
- Quality Department – Consult to communicate investigations and other issues requiring QA input and provide input to identifying corrective and preventative actions.
- Other departments – Administration, Intellectual Property, Regulatory, Finance, Business Development

External:

- Liaise with service/maintenance engineers, CMO and contract testing laboratories, as required
- Liaise with suppliers to source equipment considering pricing, availability and lead times
- Industrial and academic research partners and scientific consultants
- Contract development and testing resources

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