POSITION DESCRIPTION

Title: Senior Scientist (Stability and QC)	**Ref:** 12month contract
Company: Acrux DDS Pty Ltd	
Reports to: Analytical Development Manager	
Purpose: • To coordinate and support Stability and QC activities throughout the product development lifecycle. • To support analytical development activities including method development, validation and drug product characterisation studies if required. • To ensure adherence to pharmaceutical regulatory requirements and GLP/GMP compliance • To serve as Subject Matter Expert in technical meetings within Acrux and with external parties. • Ensuring on-time, on-budget and GMP/GLP-compliant delivery of completed projects for internal and external clients in accordance with agreed service levels and timelines.	

Key Result Areas	KEY TASKS
Quality Control & Product Development	• Supervise and perform QC release of drug substances, excipients, components and finished products. • Supervise and perform stability testing of investigative/laboratory and clinical or regulatory batches. • Maintain the stability schedule and co-ordinate stability testing. • Write and review QC, stability and validation documentation including protocols, reports, methods and specifications to industrial, regulatory and quality standards • Develop and implement testing protocols in accordance with the relevant regulatory guidelines • Evaluate stability data generated and make predictions/trending as required. • In consultation with Analytical Development Manager release data to external parties as required. • Coordinate or perform activities in accordance to validation master plan including computer and instrument qualifications. • Support GMP activities including cleaning validation studies for GMP Suite, manufacturing equipment and environmental monitoring as required. • Support manufacturing and analytical activities that may relate to other functions, including analytical development activities e.g. method development, validation, process validation and drug product characterisation studies. • Check work within the group and for other functional areas as appropriate. • Communicate scientific results and concepts in a clear and concise manner verbally, in written reports and through presentations
CMO activities	• Serve as Subject Matter Expert in technical meetings within Acrux and with external parties • Participate in stability and QC technical transfer activities to the Contract Manufacturing Organisation (CMO), including review of CMO documentation, attendance at meetings (including teleconferences) and international travel to oversee technical transfer as required. • Problem solve and troubleshoot relevant activities during stability programs at the CMOs

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	• Participate in launch and post-launch studies and activities • Review relevant sections of the Dossier, specifically the Chemistry, Manufacturing and Controls (CMC) documents and respond to the relevant regulatory agency filings as required (i.e. ANDA, NDA or IND).
Leadership	Supervise team members by: • Organising day-to-day planning and operational guidance of stability staff to ensure all timelines are met. This may include initiating, designing and delivering work programs and organising the use of equipment and materials. • Providing appropriate coaching and training to new and existing staff to maintain team knowledge and skill levels. • Making independent decisions regarding scientific policies and procedures within an overall analytical program and in area of responsibility. • Effectively interfacing with internal and external customers. • Assist the Analytical Development Manager with staff Performance Appraisals and personal goal setting • Assist Analytical Development Manager and act on her/his behalf as necessary.
Quality and Continuous Improvement	• Prepare for and participate in both internal and external audits. • Thoroughly and accurately write, check and review QC, analytical, stability and R&D study data, protocols, reports, methods, specifications and SOPs. • Ensure that all work is conducted according to relevant procedures, test methods, guidelines, regulations, safety policy and meets the necessary level of GxP compliance. • Participate in the implementation and maintenance of procedures. • Provide assistance in the development and implementation of quality systems affecting team activities. • Lead by example and ensure all team members follow all company OH&S policies, procedures and initiatives including Poisons Control Plan. • Ensure all laboratory OH&S incidents and hazards are handled proactively and corrective/preventative measures implemented to ensure the safety of staff.

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QUALIFICATIONS / EXPERIENCE:

Essential:

Education, qualifications, special training:

- BSc or equivalent degree with a sound understanding of the pharmaceutical industry stability requirements, including proficient use of HPLC and GC analytical techniques and other laboratory instrumentation.

Skills:

- Proficient in the use of software applications such as Excel, PowerPoint, and Word.
- Able to apply scientific rigour to the interpretation of data.
- Able to perform considerably autonomous professional scientific work, demanding a high degree of originality, ingenuity and judgement, and knowledge of or expertise in more than one field.
- Demonstrate a broad understanding of many technical areas that encompass recognition of external ideas and influences which may aid internal development.
- Highly developed troubleshooting/problem solving ability.
- Work to high quality standards in line with project milestones.

Knowledge:

- Solid understanding of pharmaceutical development programs and GMP/GLP.
- Experience in the development and validation of stability indicating assays.
- Instrument qualification/validation experience.

Other:

- Ability to work on more than one project concurrently.
- Be able to travel including internationally to facilitate technical transfer activities, etc

Desirable:

- Supervisory or team leader experience.
- Knowledge of the generics industry.

KEY COMPETENCIES

- To actively lead by example and 'live' the Acrux Champion Team (RIOS) values
- Ability to write high quality scientific reports and other documentation.
- Able to supervise and prioritise QC, stability and analytical testing activities.
- Actively participate in the team, share information and ideas, and coach team members to work towards common goals.
- Proactive, flexible and responsive work style.
- Ability to work in a high-pressure environment and to tight deadlines.
- Ability to trouble-shoot and solve technical and scientific problems
- Decisive, assertive with the ability to take ownership of the analytical programme.
- Excellent understanding of principles and methodologies of core activities
- Attention to detail and follow-up

WORKING RELATIONSHIPS:

Internal:

- Analytical Development Manager – Consult to determine project priorities and issues pertaining to analytical development and stability programs. Feedback project progress regularly. Identify and resolve complex issues pertaining to overall program. Receive guidance regarding staff supervision.
- Analytical development team – Regular contact to ensure coordination and progress of work to meet timelines and assist in problem solving

POSITION DESCRIPTION

- Stability and QC team - Daily supervision to ensure coordination and progress of work to meet timelines and assist in problem solving.
- Formulation team – regular contact to ensure project timelines and assist in problem solving
- Project Manager/s - Assist in the preparation of project plans with estimates of project timings, resourcing and activities. Feedback project progress at project meetings.
- Technical Affairs Manager – Consult to discuss requirements pertaining to the GMP suite and manufacturing equipment including manufacturing operations and schedule. Consult to discuss component QC testing requirements, sampling, deviations and OOS
- Quality Department – Consult to communicate deviations, investigations and other issues requiring QA input and provide input to identifying corrective and preventative actions
- Other Area's – Administration, Intellectual Property, Finance, Business Development, Clinical

External:

- Work with and coordinate contract testing, development, storage and manufacturing organisations
- Liaise with service/maintenance engineers to support ongoing laboratory calibration and maintenance schedules
- Liaise with suppliers to source materials and equipment considering pricing, availability and lead times
- Liaise with and contribute to discussions with external collaborators

Employee: _____Date: _____

Manager: _____Date: _____

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