



## Stability Team Lead

*Reach your career goals with Eirgen Pharma, your future could be here*

Would you like to be part of a company that has the courage, innovation, and capability to improve and enhance patient lives across the globe?

Eirgen was founded in 2005 and since then we have continually grown and now employ over 160 employees at our site in Waterford. Our strengths lie in our capability to rapidly introduce new products and add additional volume to existing products - ensuring supply for new product launches and expanding market opportunities.

What makes us different is that while we continue to grow our business we have still maintained that small company feel to our culture which enables us to ensure that our employees are always front and centre in everything we do. By creating a progressive and dynamic working environment, where hard work and enjoyment aren't mutually exclusive, we have created a high performing, people-centric culture which allows us to work in an environment where the focus is always on ensuring that the patient comes first.

### **About the Job**

In this role you will support Stability Testing of commercial and R&D products by ensuring that all project plans and milestones are delivered on time and in full and assist other Commercial and R&D Analytical groups in the testing of In Process samples if required.

You will also ensure all testing is performed to agreed schedules and in accordance with regulatory requirements and support the Laboratory Technician(s) ensuring duties are carried out in a timely manner and the equipment is ready to use.

Your areas of responsibility will include:

### **Project Planning:**

- Actively plan each Stability Program in conjunction with the GMP Lab Manager, relevant Team Leads and Project Manager ensuring major milestone targets for each project are visible to all team members and key stakeholders
- Determine tasks and resources in conjunction with the GMP Lab Manager required to deliver the Stability program milestones by breaking them down into tasks; identify equipment, materials and people needed
- Create, manage and review the budgeted cost and hours per project, for work that is required for R&D/CMO/CMDO projects
- Proactively build effective working relationships with core team and functional members. To attend project review meetings and to provide project plan information



- Ensure that all work carried out is in compliance with the required standards conforming to company, cGxP, SOP's, regulatory regulations and guidelines, safety and environmental guidelines
- Ensure high quality output- to vigilantly watch over job processes, tasks, work products and documentation to ensure freedom from errors, omissions, defects or data integrity issues in order to achieve a high level of customer service and cGMP.
- Initiate action to correct quality/schedule problems or notify others of quality issues as appropriate. If a procedure does not exist, devise one (through the appropriate channels); if a process needs amending, do so through the appropriate channels
- Trend and review data for Stability programs
- Lead Laboratory investigations (Incident Reports, Out of Specifications, Out of Trends etc)
- Assist in the preparation for customer /regulatory inspections
- Review test methods, protocols and reports as applicable
- Prepare or review Submission Documentation in support of licence applications
- Support and identify stability projects for external customers
- Work closely with contract laboratories and vendors to ensure all work is carried out to a high standard within the target deadlines
- Ensure that all stability program are carried in a timely and efficient manner and ensure quality and efficacy of the product

#### **Team and Continuous Improvement:**

- Identify and make recommendations for improvements as part of a team within or outside the department in order to ensure continuous improvement
- Manage day to day scheduling of laboratory activities and capacity management
- Perform additional tasks as agreed to support the effective running of the business for e.g. assist other groups in the testing of raw materials, in process samples and finished products
- Support all other on-going laboratory functions & requirements
- Coaching / Mentoring – support members of the team with problem solving and skill development to aid learning and early problem resolution.
- Recruitment – assist with recruitment of team members in line with resource requirements and to the job spec
- Identify training requirements and training of Chemists and organize training as required.

#### **Health and Safety:**

- Ensure requirements of Eirgen's Safety Statement are implemented
- Continuously promote a positive safety culture by leading by example
- Implement safety requirements as per site documentation including SOP's, Safety Statement and COP's
- Perform H&S inspections and attend relevant meetings.
- Report/ action any defects/hazard



### **About you**

You are a positive and inclusive leader qualified to a minimum of primary degree level in chemistry, pharmaceutical science or a related discipline and have at least 5 years' experience working in a related technical environment, preferably including experience as a Senior Chemist or Team Lead. You have a broad understanding of regulatory requirements for submission of dossiers in EU, USA, Japan and other jurisdictions and are proficient in the use of electronic document management systems.

You have strong planning and Project Management skills with prior experience of regulatory and customer inspections. You are adaptable and possess the ability to multi-task, have a quality/detail orientation and strong analytical ability.

You will draw from your many skills such as your excellent communication skills, ability to influence and form positive collaborative relationships, continuous improvement mindset and problem solving ability.

### **Working at Eirgen – What to expect**

At Eirgen, we have developed a diverse, people-centric, high performance culture where people are enabled to achieve their potential.

If you are working at Eirgen, then we think you've got something special. Our employees are high-performing and work as part of a cohesive team, they are dedicated people who are driven to succeed and are rewarded with competitive salaries and an attractive range of benefits including opportunities for career progression and continuing education.

***Apply for the above role by sending your CV to [opportunities@eirgen.com](mailto:opportunities@eirgen.com) including the job title in the subject.***

*Explore Energise Innovate*