

Analytical Development Chemist - Validation

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? A growing and innovative company based in Waterford, Eirgen Pharma develops and supplies specialty care medicines to patients in more than 50 countries worldwide. Our guiding principle is to improve and enhance the lives of patients, whether they be reached directly or through our contract manufacturing and development customers across the pharmaceutical industry.

Eirgen's Waterford campus consists of a state-of-the-art and globally-accredited manufacturing environment which provides tableting, capsule, soft gel manufacturing and packaging capabilities. Our R&D Team accommodates our development and analytical scientists working on the next generation of treatments for the company and its clients.

About the Job

You will support product development and clinical supply by transferring and validating analytical test methods.

You will:

- Transfer and validate robust, sound analytical methods.
- Draft/review test methods, validation protocols and reports as applicable.
- Prepare submission documentation in support of license applications.
- Take part in/lead laboratory investigations.
- Liaise directly with customers and contract laboratories and attend conference calls as required.
- Attend internal project review meetings as required.
- Assist in the preparation for customer/ regulatory inspections.
- Identify and make recommendations for improvements as part of a team within or outside the department in order to ensure continuous improvement.
- Analyse all raw materials, in process samples and finished products in a timely and efficient manner to ensure quality and efficacy of the product.
- Ensure that all work is carried out in compliance with the required standards conforming to company, cGxP, SOPs, regulatory regulations and guidelines, safety and environmental guidelines.
- Complete all documentation correctly, in line with data integrity guidelines, free from errors, omissions or defects in order to achieve a high level of customer service and cGMP. To peer review documentation as required.
- Perform additional team tasks as agreed to support effective running of the Business.
- Support all other on-going laboratory functions & requirements.
- Ensure the requirements of EirGen's Safety Statement are implemented, report any defects/hazards and continuously promote a positive safety culture by leading by example.

About you

You are qualified to a minimum of degree level in Analytical Chemistry/ Pharmaceutical Science or a related discipline and have at least two years' experience working in a related technical environment.

You are competent in a range of analytical methods (HPLC/Dissolution), with excellent knowledge of GMP and ideally project management skills. You have working knowledge of Empower lab software &

electronic document management systems, possess excellent written & verbal communication skills, with a broad understanding of regulatory requirements for submission of dossiers in EU, USA, Japan and other jurisdictions.

You will draw from your many skills such as adaptability, planning, multi-tasking and time management. You have the ability to form positive relationships and enjoy collaborating, gaining knowledge, continuous improvement and solving problems.

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 up to date CV to opportunities@eirgen.com including the job title in the subject.