



## Formulation & Process Development Specialist

*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 180 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 develop robust, capable, cost effective & safe manufacturing processes, materials and products and support the efficient and effective transfer of new products & processes into commercial production.

The role includes management of the following:

In this role you will act as a Subject Matter Expert for the development and transfer of drug product formulations and process that meet patient needs

Primary responsibilities of this role include the following:

- Responsible for the in-house development of products and transfer of CMO projects into Eirgen. Actively participates in the selection of CMO or CDMO projects for oral product manufacturing. Prepares and reviews development protocols, reports, and production documentation. Verifies products for commercial suitability according to regulatory requirements. Leads the evaluation, improvement, and optimization of products and processes to ensure safety, quality, delivery, and cost standards are met.
- Actively lead development process runs with Process Technicians and Operators.
- Establishes effective and transparent communication with the Pharmaceutical Development department and other stakeholders across the company.
- Manages resources efficiently to achieve specific departmental and company objectives.
- Ensures that changes to existing processes or the implementation of new processes are documented and carried out according to approved change control procedures and in compliance with cGMP requirements.
- Works closely with R&D Analytical and R&D Formulation teams during formulation development and broader stakeholders during CMO product transfer.



- Works closely with Commercial Value Stream during development of manufacturing process, and leads knowledge transfer from R&D to Engineering, Maintenance, Production and Quality ensuring robust knowledge transfer.

#### **Health & Safety:**

- Ensure requirements of Eirgen's Safety Statement are implemented.
- Continuously promote a positive safety culture by leading by example & drive a high EHS, 5S & housekeeping standard in areas under the roles control.
- Implement safety requirements as per site documentation including SOP's, Safety Statement and COP's

#### **About you**

You are educated to a minimum of degree level in pharmaceutical sciences, chemistry or any related science, while a post graduate qualification is advantageous. Your 4plus years' experience is in Product Formulation and Performance, Process Development or Engineering with Pharma and New Product Introduction project experience included.

Operations, process /technical support, projects or validation-based experience of oral solid dosage manufacturing processes at lab scale, pilot scale and/or commercial scale is a requirement as well as experience with technical transfers (sending site) for pharmaceutical products and with packaging processes and technologies.

You exhibit strong capability of using DoE and other statistical software to analyze and correlate the data with process output and predefined critical quality attributes. You are also familiar with regulatory, validation and documentation requirements for product development, commercial production and site transfers.

As a positive team member you will draw from your many skills such as strategic thinking, business acumen, planning, multi-tasking, project and time management. You have the ability to form strong relationships and negotiate and influence cross functionally, you 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 further 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.***