



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:

- Carrying out Laboratory Scale-up, production trials, process validation, preparation of protocols and other required documentation to support the manufacturing team for successful product development
- Re-development of legacy processes to increase productivity, reduce manufacturing costs and eliminate quality defects
- Deliver cost-effective process development of the highest possible quality with enthusiasm, and a team ethic
- Build early-stage feasibility, technical, process optimisation and process validation studies
- Lead technical transfers and new product introduction (NPI) (receiving site) projects following a pre-approved project plan, schedule and current project management best practice. Ensure that important manufacturing systems and support structures are in place for major technology transfer and NPI projects and provide technical advice on process engineering requirements. Collaborate with technology transfer project counterparts at Eirgen
- Manage the technical transfers to provide a smooth transition
- Communicate with Production Operations and support to identify process support and improvement opportunities. Propose and implement sustainable solutions to resolve process issues, reduce processing times, improve yield, reduce defects and eliminate waste. Manage the associated Change Records, CAPAs and Deviations in Track wise



- Identify cost-effective opportunities for introducing the best manufacturing technologies. Design and introduce these technologies to manufacturing operations
- Work with local Regulatory Compliance function and Global Regulatory Affairs to support production submissions, Regulatory/Health Authority queries and compliance verifications
- Produce and review Change Records and Risk Assessments to document and control GxP changes and assess potential process and validation impact
- Use statistical software packages for data analysis and in the identification and reporting of shifts, signals and trends in process parameters and product quality attributes
- Provide regular progress updates (written and verbal) on activities within NPI and beyond the Manufacturing Sciences Team as reported in project communication plans or by the relevant partners
- Follow the compliance matrix of business processes and routine departmental tasks
- Comply with the relevant industry and Company quality standards and the cGMP about pharmaceutical production
- May assume other technical support responsibilities where applicable, from time to time and as directed by the Manager

About you

You are educated to a minimum of degree level in a science discipline, a post graduate qualification is advantageous. Your 3plus years' experience is in Formulations, Process Development or Engineering with Pharmaceutical industry and New Product Introduction project experience included. Operations, process /technical support, projects or validation-based experience of oral solid dosage manufacturing processes is an advantage as well as experience with technical transfers (sending site) for pharmaceutical products.

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.

As a leader you will draw from your many skills such as people management, planning, multi-tasking, project and time management. You have the ability to form strong relationships and have 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 including the job title in the subject.