

Senior Process Engineer

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.

The Person

You are qualified to degree level or equivalent in an engineering discipline and have at least 5 years' experience in a similar role, ideally in an oral solid dose manufacturing environment. You possess knowledge of the processes and equipment used in the manufacture and packaging of tablets and capsules, the management of small capital projects and an understanding of integrated validation approaches. Familiarity with Minitab or similar statistics software is an advantage while knowledge of cGMP, EU Annex and GAMP requirements is required.

You show excellent problem-solving skills and attention to detail with an ability to think outside the box. You are customer focused with strong communication, influencing and presentation ability. You are driven, accurate and timely in producing results and can manage tasks and schedules effectively.

The Role

You will provide process engineering support and project leadership to support internal customers in the day to day operations of the organization and site capital projects, enabling delivery of high quality process centered projects safely, on time and within budget.

You will:

Process Engineering

- Act as lead engineer for one of our manufacturing suites, leading a small group of engineers
- Support Eirgen's NPI system and capacity expansion project
- Identify and manage process improvements and projects
- Lead in the procurement, introduction, commissioning and qualification of process equipment and subsequent process validations
- Ensure qualification methodology is clear and integrated into the project from URS onwards
- Ensure documentation, training and handover meet the internal customers' expectations
- Life cycle cost considered in designs for maximum long term efficiency and reliability
- Plan and execute process validation schedules for manufacturing and packaging processes
- Write and execute documents for the validation of new and existing processes

- Liaise with contractors/customers when external resources are required to complete validations
- Liaise with relevant EirGen departments to organise resources/materials/ equipment/facilities/etc and ensure validation activities are planned and executed in line with applicable deadlines
- Assist with submission/audit/deficiency responses activities when required, in a timely manner.
- Draft/revise/review validation related documents e.g. SOPs, protocols, reports etc.
- Generate, analyse and interpret statistical data to verify acceptable criteria has been met and support process validations, CPVs
- Develop testing strategies and rationale for manufacturing and packaging process equipment qualification and process validation
- Provide technical support/troubleshooting for process and equipment issues.
- Investigate/resolve deviations associated with validation activities
- Utilise structured problem solving in support of process issues & problem resolution

Health & Safety

- Comply at all times with the Health, Safety and Environmental policy and associated procedures, legislative requirements
- Continuously promote a positive safety culture by challenging yourself and others to prioritize safety in everything you do
- Ensure safety management is paramount in project delivery processes
- Lead by example and take ownership of EHS matters in relation to engineering activities you are involved in

Quality Compliance

- Ensure all work carried out is in compliance with the required standards, conforming to company policy, cGMP, SOP and regulatory guidelines
- Lead by example and take ownership for quality compliance in relation to engineering activities you are involved in
- Ownership of equipment qualification and process validation from a quality compliance perspective

Contractor Coordination

- Ensure contractors are budgeted, approved, scheduled, qualified and permitted for the work they perform under your behest
- Develop relationships with contractors, ensure they understand our business and are compliant to site procedures

Reporting and Governance

- Report covering schedule, cost control, project scope and risks / mitigations, compiled at appropriate intervals
- All project and equipment related information stored centrally
- Ensure clear, concise communications with internal & external stakeholders

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 including the job title in the subject.