



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.

About you

If you are a Process Engineer qualified to a minimum of degree level in an Engineering discipline and have 5+ years' experience working in a clean room, Pharma, medical device or similar manufacturing and/or packaging environment we want to hear from you.

Ideally you will have experience in process validation (including statistics training) and the management of small capital projects along with knowledge of the processes and equipment used in the manufacture and packaging of tablets and capsules. Knowledge of cGMP, EU Annex and GAMP requirements, an understanding of integrated validation approaches and familiarity with Minitab or similar statistics software is an advantage.

You possess excellent written & verbal communication skills, including strong technical writing skills - you present complex data in a clear, understandable format. You have a customer focused mindset with strong attention to detail and problem solving - previous experience in leadership roles, direct or indirect would be an advantage.

You are results oriented and possess energy and drive. You will draw from many skills including adaptability, planning, multi-tasking and time management. You have the ability to form positive relationships and enjoy collaborating, gaining knowledge, continuous improvement and applying innovative ideas.

About the Role

In this 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 projects safely, on time and within budget.



You will :

- 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
- Consider life cycle cost 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.
- 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
- Report on schedule, cost control, project scope and risks / mitigations at appropriate intervals
- Store all project and equipment related information 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.

Closing Date is 31st July 2022