Computer Systems Validation 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 ensure that site automated equipment systems are introduced, maintained and operating in accordance with cGMP's, site and regulatory requirements with a keen focus on Data Integrity, Security and Reliability. The focus of this role will be on CSV for equipment systems linked to pharmaceutical manufacture, but as a member of the IT CSV team you will collaborate with those responsible for CSV in the laboratory and general business systems, ultimately with an intent to standardize, leverage best practices and ensure business continuity.

The position will work closely with Engineering, Facilities and Operations in the preparation of validation related documentation, standard operating procedures, reports, system quality reviews, identifying deficiencies, preparing CAPA (Corrective Actions and Preventative Actions) documents, test scripts and change controls with regards to automated equipment systems validation.

Primary responsibilities of this role include the following:

- Own the policies and procedures in relation to automated equipment systems in terms of defining, implementing and reviewing these, ultimately to ensure compliance with cGMP's, site and regulatory requirements (21 CFR Part 11, Annex 11 EU GMP).
- Guide / engage team members and external equipment suppliers in relation to validation & compliance activities regarding current and future automated equipment systems (manufacture and facilities, including connections to MES / QBMS / EBR).
- Support regulatory inspections and internal audits with a focus on 21 CFR Part 11; EU GMP Annex 11, GAMP and Data Integrity requirements.
- Ensure the automated equipment systems landscape is documented and up to date in terms of additions or retirements, and triggers are in place for periodic activities as required.

- Engage with cross-departmental teams in authoring specifications, risk assessments, testing protocols, validation reports, standard operating procedures, work instructions, system quality reviews, identifying deficiencies, preparing CAPA's and change controls.
- Create and act on change Controls, CAPAs and deviations related to automated systems.
- Ensure periodic audit trail reviews (activities, users, system changes) are carried out.
- Assist in training end-users as appropriate and relevant.
- Prioritize, manage, and execute on multiple projects as relevant in relation to additions, retirements or updates / patches / modifications to software or hardware.
- Ensure that all work carried out is in compliance with the required standards conforming to company, cGxP, SOPs, regulatory regulations and guidelines, safety and environmental guidelines.
- Perform additional team tasks as agreed to support effective running of the Business
- Keep up to date with advances in the field, in the areas of regulatory, IT and equipment in particular.

About you

You are educated to a minimum of degree level in computer science, computer engineering, life science, or any other pertinent degree. Your experience includes computer systems validation within the Pharma industry and you have extensive knowledge of the validation deliverables associated with each step of the computer system life along with knowledge and proven application of established risk management.

You also possess cross-functional project experience and exhibit understanding of / interest in IoT (Internet of Things).

As a positive leader you will draw from your many skills such as decisiveness, compliance focus, 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 including the job title in the subject.