Computer Systems Validation (CSV) Project Manager



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- Leading Pharma Company in the West of Ireland
- Excellent career progression opportunities along with a generous package

Oradeo Recruitment is presently seeking interest for an experienced Computer Systems Validation Project Manager to join their European Team for our clients located in Mayo. You can work remotely or on site. Reporting to the Associate Director, Instrumentation Optimization this role will be responsible for building and maintaining the project management framework for Charles River validation projects

Main Duties & Responsibilities:

- Coordinate with other departments to ensure all aspects of each projects are achieved
- Provide guidance to operational areas on processes with global validation (Master Validation Plan)
- Manage multiple projects and assist operational groups in the development of validation deliverables and use of project management tools.
- Write and assist in writing all validation deliverables within the Computer System Lifecycle, e.g. Validation Plans, Summary Reports, Configuration Specifications
- Responsible for developing and revising test validation procedures/protocols in accordance with appropriate regulatory agency

validation requirements, corporate & site quality management system and current industry practices

- Manage the full lifecycle of validation projects including defining and monitoring multiple project deliverables and timelines in parallel
- Maintain and provide project timelines and statuses in project management tool.
- Coordinate project meetings, steering committees, workshops and production of related documentation i.e. minutes of meetings, project plans etc.
- Assist other Biologics sites, domestic and global, in response to their validation requirements as required
- Participate in multi-site CSV initiatives through document development or other validation activities
- Ensure adherence to pertinent regulatory requirements and to departmental policies, practices and procedures [SOPs, safety procedures and biosafety protocols].
- Performs analyses and validate benefits related to selected projects.

The following are minimum requirements related to the CSV Project Leader position.

- BSc/MSc. in a relevant discipline.
- 5+ years' experience in validation & project management. Experience is preferable within the Pharmaceutical/Medical Device/CRO Industry but is not essential.
- Project Management certification preferable.
- Ability to manage multiple projects
- Ability to problem solve and work on own initiative.
- Proven communication and organizational skills required.

For more information about this position or other opportunities, contact Tara Ryan at Oradeo Recruitment confidentially on +353 1 687 7188 or apply in confidence.

About Oradeo — Oradeo Recruitment are specialists in the life sciences, pharmaceutical, construction & engineering sector. We are a leading service provider in Ireland, UK and Europe for professional recruitment services and the provision of managed labour in Construction & Civil Engineering, Data centres, Mechanical & Electrical, Life Sciences and Renewable Energies sectors