PM Clinical

Senior CSV Specialist

JOB POSTING #PMC-03-2017

Job Department: Quality Assurance & Compliance Consultancy
Location: Verona, Italy
Job Type: Permanent, Full Time

Description:

SeQure is looking for a Senior CSV Specialist, the Company office is in Verona; we offer a full time permanent position. The purpose of the role is to manage and coordinate CSV processes, resources and projects in order to meet business goals and ensuring department productivity. The Senior CSV Specialist ensures that computer systems are properly validated and maintained in a compliance status, through appropriate change control management and periodic review.

He/She creates and maintains collaboration with stakeholders inside and outside the Company.

Principal accountabilities / responsibilities:

- To coordinate and manage the department within the framework of Company values, mission and strategies
- To Organize the department to ensure the Clients receive the requested services
- To manage the overall workload of the unit, ensuring target allocation rates and billability
- To coach and motivate direct reports
- To grant the compliance to the current regulations
- To develop and maintain excellent relationships with internal and external clients
- To ensure the department profitability
- To validate and manage the technical partnership
- To define and review the business case and requirements by regular reviews and controls to ensure the client receives requested services.
- To develop and execute documentation for validation and qualification activities to support various computer system validation projects. Documents to be authored may include: Project Validation Plan, Requirements Trace Matrix, Risk Assessment, IQ/OQ/PQ, Validation Summary Report, Data Migration , Change control, SOPs, etc.
- To support development of validation deliverables, such as Functional Specification (FRS), Design Specification, etc
- To manage system change requests and associated documentation
- To perform Periodic Review
- To ensure compliance of computerized systems to relevant regulatory requirements (e.g. cGMP/GCP/GAMP)
- To review existing CSV SOPs ensuring the compliance with current regulations

Ideal Candidate:

- Bachelor Degree in Computer Science, Engineering (biomedical preferred), Mathematics and at least 6 years of experience as CSV specialist in Pharma industry
- English, Fluent
- Solid understanding of GAMP standards, 21 CRF Part 11, and applicable regulatory guidelines.
- Good knowledge of pharma processes and GxP regulations
- Good knowledge of quality risk management principles
- Method
- Communication
- Quality Orientation
- Teamwork
- Client Orientation