PM Clinical

CSV Specialist

JOB POSTING #PMC-04-2017

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

Description:

SeQure is looking for a CSV Specialist, the Company office is in Verona; we offer a full time permanent position.
The purpose of this role is to ensure that computer systems are properly validated and maintained in a compliance status, through appropriate change control management and periodic review.

Principal accountabilities / responsibilities:

- To develop and manage GCP system lifecycle documentation, including Validation Plans, User Requirements Specifications, Functional and Design Specifications, Testing Protocols (IQ/OQ/PQ), User Acceptance testing, traceability matrix, system, Validation Reports, SOPs, Change Control Documentation, and Risk assessment reports in accordance to GAMP5 and internal SOPs.
- To conduct System Compliance Risk Assessment
- To manage and coordinate all aspects of the computer systems validation activities as they pertain to SDLC, including project planning, developing validation strategies, document development and document reviews
- To oversee system change requests and associated documentation
- To manage documentation logs and document storage
- To ensures that CSV SOPs are proper maintained in line with current regulations
- To determinates the validation requirements using a risk based approach
- To manage the project change control implementation in accordance with requirements, design and system changes
- To identify risks and clearly communicate them to project stakeholders
- To perform activities related to ISMS according to controls to mitigate risks
- To ensure that ISMS SOP, concerning CVS area, are properly maintained

Ideal Candidate:

- Bachelor Degree in Computer Science, Engineering (biomedical preferred), Mathematics and at least 2 years of experience as CSV specialist in Pharma industry
- English, Fluent
- Knowledge of CSV regulations and guidelines (21CFR part 11, Annex 11, GAMP5)
- Knowledge of pharma processes and GxP regulations
- Knowledge of quality risk management
- Knowledge of IT standards (ITIL)
- Knowledge of authoring and reviewing of computer validation documentation
- Knowledge of management of change control, documents and incidents on computer systems
- Knowledge of computer information requirements legislation (privacy regulations)
- Knowledge of ISO/IEC 27001:2013 and activities related to Information Security Management System
- Knowledge of information security controls related to the norm