Singota Solutions

Job Description # JD182

Job title: Computer Systems Validation (CSV) Specialist
Department: Information Technology
Position Type: 40 hours/week
Reports to: Senior Technical Analyst

General Description including Skills:

1. Works across departments to support computer validation activities for the site for initial and revalidation activities for instruments, equipment and software implementation.
2. Supports the creation and maintenance of SOPs pertaining to validation and controls.
3. Reviews and approves software coverage assessments and assists with the development of impact assessments, FMEAs and user requirements specifications.
4. Works with process owners to develop test plans, data migration plans, develop and/or approve OQs and PQs and assist with protocol testing and exception investigation.
5. Creates and maintains the software validation program framework and master plan, including the trace matrix and validated software inventory list Validate GMP software applications per that framework and manage change control for validated systems, network equipment and be on-call if an emergency change control should occur.
6. Manages third party validation contractors to ensure they are meeting the requirements of our systems.
7. Works as a team lead and/or member during enterprise software implementations to ensure the needs of the program are being met by the software and its configuration.
8. Responsible for reporting status of validation activities to the departmental management as required. This would include key metrics, project status, improvement activities, etc.
9. Approves software IQs, review Engineering IQs, develops summary reports, executes 21 CFR Part 11 test scripts and performs periodic reviews.
10. Acts as primary contact for client, internal and regulatory audits for validation packages, GAMP 5 and 21 CFR Part 11 questions and takes ownership of all audit responses, as needed.
11. Supports management in training activities related to validation activities, including 21 CFR Part 11, GAMP 5 and process / system owner requirements.
12. Interprets and monitors FDA, MHRA and other applicable global regulations and trends to the development of computer systems supporting regulated business processes relevant to the validation program.
13. Complies with quality and safety management systems including requirements for documentation, training, system use, SOPs, processes and procedures.
14. Maintains demonstrated working knowledge of 21 CFR Part 11, GAMP 5 and other relevant compliance regulations.
15. Possesses general knowledge of ERP, QMS, labeling and lab systems or equivalent, validated for use in a life sciences and/or quality related industry.
16. Must possess a high-level of proficiency in Microsoft Word and document management skills.

Characteristics required include:

1. Trustworthiness, personal integrity; able to maintain a high degree of confidentiality
2. Positive attitude and good judgment
3. Connected and involved in life sciences and/or quality related industry initiatives
4. Excellent information/regulatory research, organizational, technical writing, self-starter and self-learner skills
5. Must be internal and external customer service oriented.
6. Strong verbal and written skills are essential.

Work Experience and Education Requirements:

- Minimum 5 years of experience in Computer Systems Validation, Quality Assurance, IT or related field.
- Minimum of Associates Degree or equivalent experience in life sciences and/or quality related industry.

Singota Solutions is an Equal Opportunity Employer