



Position Title: Director, GxP Computer Systems Management

Reports to: Executive Vice President, Clinical Operations

Department: Clinical Operations

Created: April 5, 2021

General Summary:

- A hands-on technical subject matter expert (SME), responsible for leading TRACON's Computer Systems Life Cycle Program. This SME will implement and maintain controls for Computer Systems applications that support GxP systems used for Company Product Life Cycle including Clinical Operations, Product Manufacturing, Supply Chain, Quality, Data Management and Statistical Programming, Safety, Regulatory and other related functions, in accordance with 21 CFR Part 11, ICH E6 Good Clinical Practice, GAMP, and TRACON Standard Operating Procedures. This role will liaise with internal users, internal developers, external vendors, TRACON IT, QA and other department heads to ensure that all TRACON GxP software is maintained in continuous compliance throughout the product lifecycle.

Principal Duties and Responsibilities:

- Manage direct reports (all aspects of hiring, mid-year and annual reviews, promotions/demotions and termination).
- Represent TRACON as Computer Systems Technical SME both externally with vendors and internally across functional lines.
- As a hands-on SME, develop, facilitate, implement, and maintain controls for the comprehensive lifecycle of GxP computer systems. These controls include, but are not limited to, TRACON Computer Systems life cycle management SOPs, job aides, system design documentation, functional requirements, risk analysis methodologies, front and back end test protocols including user acceptance tests, system change control, initial and ongoing system validation packages, and system retirement processes.
- Perform and oversee all aspects of system validation for TRACON computer systems, whether vendor supplied or internally developed, including the integration of those systems, and the qualification of their underlying environments.
- Ensure seamless data integrity across GxP systems such that the provenance and transformation of data at every step of its lifecycle is audit trailed and documented appropriately, from its collection point to its final reporting and archival.
- Prepare and provide necessary training to appropriate staff to educate and raise awareness of GxP compliance requirements relating to Computer Systems lifecycle and data integrity e.g. 21 CFR Part 11, electronic signatures, change control, and validation.
- Assist in the identification, selection, and qualification of GxP Computer Systems vendors including vendor audits.
- Oversee and participate in the maintenance of all GxP computer systems throughout their lifecycles as related to validation activities, including bug management, patches, and release management.
- Work with internal and external software providers to identify and manage validation activities surrounding risks and bugs in GxP supporting software, from identification through production release and validation.
- Represent TRACON in communities, forums, and conferences related to GxP software, pursuing our interests in constant improvement
- Ensure that TRACON Computer Systems are always ready for inspection by regulatory authorities
- Identify areas of continuous improvement and take initiative to lead and implement corrective and preventative processes, systems, and controls for the Computer Systems Life Cycle Management.

Qualifications:

Education

Bachelor's degree in computer science

Experience/Skills

- Minimum of ten years of leading and hands-on experience with computer systems life cycle management experience in the biotechnology or pharmaceutical industry.
- Demonstrate understanding of all applicable regulations and guidelines governing drug development as they apply to GxP system selection and maintenance
- Excellent working knowledge of current Good Automation Manufacturing Practices (GAMP), Good Clinical/Manufacturing Practices; ICH guidelines; trial initiation and management practices and procedures;
- Excellent leadership, interpersonal and communication skills. Works efficiently with others to accomplish goals and resolve problems. Encourages cooperation, collaboration, and co-ownership of processes.

Position Requirements:

- Ability to work on complex problems where analysis of situations or data requires an in-depth critical thinking across functional areas and systems
- Willing to travel for training, vendor qualification, audits, and software related conferences and meetings or other purposes as necessary to support the implementation and maintenance of GxP software

NOTE: This description is not intended to be all inclusive or a limitation of the duties of the position. It is intended to describe the general nature of the job which may include other duties as assumed or assigned.