

## JOB DESCRIPTION / ROLE REQUIREMENT

### I. Position Information

**Position Title:** Quality Systems Specialist III, Learning

**Department Name:** Learning, Document Management, Change Control

**Reports to (title):** Manager, Quality Systems

**Revision number and date:** V1 21Oct2020

### II. Position Summary

Under the direction of functional area management, the Quality Systems Specialist III will consult with internal partners to understand business goals and performance needs, develop and execute learning aligned to the business strategy. S/He will routinely engage with and influence with key stakeholders to ensure learning solutions support and positively drive desired outcomes. Primary responsibilities include the design and development of learning items (procedural documents, eLearning, on-the-job, instructor-led) to develop personnel and/or increase organizational effectiveness S/He may act as Subject Matter Expert (SME) on the Training process. Success in this role depends on the candidate's ability to work cross-functionally to discover and articulate the business' process and performance needs and translate them through the design and delivery of learning solutions.

*The Company's management reserves the right to add, delete or otherwise alter assigned duties at any time. To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.*

**III. Responsibilities:** Under limited supervision and in accordance with all applicable federal, state and local laws/regulations, the Companies' policies, procedures and guidelines, this position:

**Ensure quality and compliance in all my actions by:**

All employees

- Attend GMP training on the schedule designated for my role and as appropriate for my role.
- Adhere to strict compliance with procedures applicable to my role.
- Exercise the highest level of integrity in the tasks that I perform.
- In a timely and prompt manner, identify, report and seek correction for deviations noted in my workplace.
- Embrace a behavior of employee involvement and commitment to doing the job right the first time.

People Managers

- Ensure employees under your scope of responsibility are trained in required procedures for the execution of their role and maintain current with training requirements during the year.
- Promote an environment of employee involvement in the workplace.
- Seek prompt identification, reporting and correction of deviations in the workplace as noted by employees.

**Learning & Development**

- Review/approve training documentation to ensure best practices of adult learning are applied while meeting customer needs
- Demonstrate an advanced understanding of learning processes and methodology in order to provide appropriate learning solutions; identify alternate, non-training solutions when appropriate
- Consult with stakeholders to evaluate performance gaps, streamline existing business and operational flows, define process models, and create/revise associated training documentation and assessments
- Rapidly assimilate new information, quickly grasp complex technical concepts and make them easily understandable in text and pictures to design/develop: process flow diagrams, procedural document content, instructor-led, on the job (OJT) and eLearning
- Remain current on learning and development/industry-related tools, techniques, strategies and practices in order to provide relevant, informed consultative advice to clients; share learning best practices with teams and stakeholders
- Deliver training and/or support local Subject Matter Experts providing training, as needed. Including, but not limited to: GMP Orientation, Train-the-Trainer (T3) and routine GMP training courses
- Create/revise and help others develop departmental SOPs, work instructions, training guides and checklists as needed; provide training to new system users/team members

**Process/Strategy**

- Monitor the impact and effectiveness of learning solutions; evaluate learning programs & processes through LMS data, the development of surveys and other feedback mechanisms. Interpret data/feedback, discuss with stakeholders and/or Community of Practice (COP), and suggest improvements to further enhance learning program effectiveness and sustainability.
- Lead department/project meetings, track progress, ensure timelines are met and provide updates to team and management. Lead/Represent team in stakeholder meetings to ensure expectations

are clearly defined, risks are appropriately managed and implications/change actions are communicated and executed.

- Develop business and project plans, communications and content to support business process and training activities.

### **Quality Systems**

- Support/perform Quality Systems operational activities including: LMS transactions, document review and processing, change controls, maintenance and generation of reports
- Monitor quality systems to drive completion of tasks, maintain compliance, identify quality system performance/process gaps, drive continuous improvement processes
- Manage/maintain file libraries, SharePoint, shared mailboxes and network drives for organization and access
- Provide support as SME for Training and/or Document Control systems during audits and inspections
- Support the development, collection and tabulation of metrics related to Quality Systems and processes
- Apply knowledge of internal systems or tools to provide relevant insights to metrics. Present Quality Systems topics and data at COP, Team Meetings, Quality Council, and other forums as requested by leadership.
- Ensure timely response to audit requests for quality systems data or documentation and/or serve in an audit support team role (e.g., document runner, ATMS, scribe, etc.)
- Support all quality system upgrade/validation/migration activities
- Serve as CAPA Owner and/or Change Control Author
- Supports and executes other activities as required by functional area management

### **Core Competencies**

**Project/Time Management:** Ability to independently establish priorities, to take responsibility for follow through and completing multiple tasks on time.

**Decision Making and Critical Thinking:** Ability to use a broad range of methods, assumptions, frameworks, and perspectives when solving problems and making decisions.

**Oral and Written Communications:** Ability to express oneself to provide information to others effectively and in a succinct manner; advanced verbal, written, and presentation abilities; ability to ask thoughtful questions to gain insights, listen, and understand other perspectives.

**Creative Thinking:** Demonstrated skill in applying tools and techniques for grasping new concepts, acquiring new ways of seeing things, and revising ways of thinking and patterns of behavior.

**Leadership:** Demonstrated skill in applying approaches, tools, and techniques to gain the cooperation and support of others; ability to lead by example and foster collaborative relationships.

#### **IV. Requirements**

**Education:** Bachelors degree or equivalent

**Experience:**

- 4-6 years
- 2+ years work experience in pharmaceutical and/or biological manufacturing operation in Quality Assurance and/or Quality Systems.
- Experience with use of Quality Systems (e.g. document management, change control, training)

**Physical Demands:**

- Lifting and/or carrying <40 pounds occasionally
- May require frequent periods of sitting and standing
- Climb stairs and ladders occasionally
- Crouching/squatting, bending/stooping, twisting, above the shoulder or low level work, fine finger dexterity/ including grasping or pinching required

**Knowledge, Skills and Abilities:**

- Adult Learning: Experience in assessing competency gaps and identifying what people need to learn for successful individual and organizational performance. Advanced experience in developing and delivering training programs.
- Knowledge of the applicable regulations including GxPs and working knowledge of other major regulatory agencies regulations and guidances.
- Proficiency with MS Office, including Word, Excel and Power Point, Adobe, SharePoint and ability to learn new systems.

Preferred

- Experience with use of document management and/or training systems (LMS)
- Experience using tools such as Captivate or Articulate to develop interactive learning
- Process Mapping/Improvement expertise

**Certifications/Licenses:** N/A

**Global Leadership Profile Requirements:** N/A

**Other Requirements:** N/A

#### **V. Position Dimensions**

**Employees Supervised:** 0

**Exempt:** NO

**Non-Exempt:** YES

**Personal Contacts:**

**Internal:** With all departments and at all company levels

**External:** Contractors and service providers

**V. Position Dimensions (cont.)**

**Responsibilities:**

**Budget:** NO

**Other Dimensions:** N/A

**Work Environment and Conditions:** N/A

**Tools, Equipment, Machines, Materials:** N/A

**Environment Health & Safety:** Comply with the requirements established in the Environmental Health and Safety (EHS) Program

**VI. Approvals**

*The above statements are intended to describe the general nature and level of work being performed by people assigned to this classification. They are not intended to be construed as an exhaustive list of all the responsibilities, duties & skills required of personnel so classified.*

**Employee (Print):** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Employee (Signature)**\_\_\_\_\_

**Supervisor/Manager (Print):** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Supervisor/Manager (Signature):** \_\_\_\_\_