



GXP COMPLIANCE TRAINING SPECIALIST

Status: Full Time, Employee
Location: Miramar, Florida - USA
Work Status: Will *not* consider sponsorship for work authorization
Job Number: 2010-392

Summary:

Under general supervision, assist the GXP Compliance Training Manager with the implementation and management of the corporate GXP (collective of GMP, GLP, GCP, and other regulatory compliance) training programs. Perform and/or support the weekly cGMP training of new hires, as well as periodic (e.g., quarterly) General cGMP training for all shifts. Manage and deliver trainer qualification program and support Learning Management System initiatives and implementation.

Essential Job Functions: *This is not intended as a comprehensive list; it is intended to provide a representative summary of the major duties and responsibilities. Incumbent(s) may not be required to perform all duties listed, and, may be required to perform additional, position-specific tasks.*

- Evaluates training needs
- Utilizes tools to measure training effectiveness
- Evaluates training materials prepared by authors and trainers
- Coordinates and schedules training
- Participates in development and delivery of training materials
- Contributes technical/cGMP training expertise
- Delivers New Employee Orientation GMP program
- Designs, develops, implements, and delivers periodic GMP and GMP related training programs, including participant guides, instructor guides and training aids.
- Designs, develops, implements and delivers instructor-led, e-learning, computer-based, and OJT training programs, including participant guides, instructor guides and training aids.
- Revises, coordinates and conducts existing training programs
- Supports the OJT program by working with OJT trainers and provides leadership and information to operations on recommended training programs, and evaluation of trainee's performance
- Evaluates, coaches and mentors OJT trainers to continuously improve their training skills
- Assists in developing curricula for on the job training requirements and works with area supervisors
- Manages projects and training initiatives to drive quality, compliance and effectiveness
- Keeps abreast of new regulatory/technical developments and training methodologies to support continuous improvement.

- Supports the training department in the implementation and maintenance of the learning management system
- Leads Group Representative Meetings and ensures training initiatives and requirements are communicated to the organization through Group Representatives and Authors of procedures.
- Provides coaching and guidance for departmental representatives related to training and curriculum management
- Performs periodic internal training audits to identify training and curriculum gaps.
- Performs special projects as directed by training manager.

Supervisory Responsibilities:

This position does not require supervisory responsibilities.

Required Knowledge and Skills:

Knowledge of:

- General principles of Training and Development; application of adult learning principles
- Developing and delivering training programs in current Good Manufacturing Practices (cGMP), FDA and other regulatory agencies' compliance requirements
- Principles of Quality Assurance and Operational Systems in a pharmaceutical manufacturing environment
- Understanding/working knowledge of manufacturing and/or quality positions within a biopharmaceutical/medical device environment
- Computer literate in a Windows environment with the ability to use electronic mail system, the Internet and the Microsoft Office Suite including Excel, Word, Power Point and Access.
- Learning Management Systems (Part 11 Compliant)

Skills in:

- Strong organizational and time management skills
- Ability to multi-task and use initiative
- Results driven, action oriented and motivated
- Ability to work under general supervision and rely on experience and good judgment to plan and accomplish assigned goals
- Group facilitation
- E-learning content and development
- Curriculum development
- Ability to write routine reports and correspondence
- Excellent interpersonal, written, and oral communication skills; able to communicate and work effectively with all levels of the organization
- Ability to adapt procedures, techniques, tools, materials, and/or equipment to meet special needs.

Physical Requirements and Working Conditions:

While performing the duties of this job, the employee is regularly required to sit; use hands to finger, handle, or feel and reach with hands and arms. The incumbent is frequently required to talk or hear and occasionally required to stand and walk. The incumbent must occasionally lift and/or move up to 10 pounds. Specific vision abilities required by this job include depth perception and ability to adjust focus.

Minimum Qualifications:

Bachelor's of Arts or Science degree (B.A./B.S.) from four year college or university in Instructional design, educational technology, human resources or scientific degree with training background. Requires a minimum of 5-7 years relevant experience with a solid GMP background and 21CFR §210,211.

For consideration, submit resume to: careers@avevadds.com.

No phone calls please.

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