

**POSITION INFORMATION**

<i>Job Title:</i>	Document Management and Training Specialist	<i>Job Requisition #</i>	
<i>Department:</i>	Quality	<i>Report To:</i>	Quality Assurance Manager
<i>Location:</i>	STAQ Pharma, Inc.	<i>Travel Required:</i>	No Travel Required
<i>Level:</i>	Non Manager	<i>Position Type:</i>	

**JOB DESCRIPTION**

<i>Summary</i>	The Document Management and Training Specialist is responsible for oversight activities including managing the GxP Document Control, Labeling, and Training Systems while ensuring compliance to quality objectives and regulatory requirements.
<i>Roles and Responsibilities</i>	<p><u>Document Management</u></p> <ul style="list-style-type: none"> <li>• Manage the preparation, routing, review, approval, distribution, and archival of new and revised controlled/managed documents (i.e. batch records, SOPs, WI's, etc.)</li> <li>• Reviews documents submitted to ensure the correct use of templates and document types.</li> <li>• Leads the Label process.</li> <li>• Performs advanced word processing and assists personnel in resolving document format issues.</li> <li>• Collaborates with cross-functional departments to ensure timely implementation of document change requests.</li> <li>• Organizes and ensures accurate and reliable filing systems for all paper based GxP documents.</li> </ul> <p><u>Training</u></p> <ul style="list-style-type: none"> <li>• Collaborates with each department to ensure proper job level and task level curriculums are developed and assigned.</li> <li>• Collaborates with site functional managers and SMEs on the creation, delivery, and evaluation of training content (new employee orientation, classroom training).</li> <li>• Manages tracking of course revisions, history and training completion data.</li> </ul> <p><u>General</u></p> <ul style="list-style-type: none"> <li>• Develops, tracks, and communicates site metrics to management.</li> <li>• Supports audits (internal &amp; external) in order to verify that regulatory and quality requirements have been met.</li> <li>• Performs other duties as required.</li> </ul>

<p><i>Qualifications and Education Requirements</i></p>	<p>Minimum of 2 years of technical writing/document control experience in the pharmaceutical/biotech or equivalently regulated industry.</p> <p>Proficient with the Microsoft Office suite (i.e., Word, Excel, Visio, PowerPoint, etc.) and Adobe.</p> <p>Comfortable in a fast-paced small company environment with minimal direction and able to adjust workload based upon changing priorities.</p> <p>Demonstrates ability to perform detail-oriented work with a high degree of accuracy.</p> <p>Effective written and oral communication skills.</p> <p>Effective time management and interpersonal skills.</p> <p>Possesses initiative and is proactive.</p>
<p><i>Preferred Skills</i></p>	<p>Knowledge of training processes/systems and regulatory requirements (21 CFR Part 11/210/211).</p> <p>Familiarity with course design and development.</p>
<p><i>Additional Notes</i></p>	<p>To apply for this job, go to Indeed or email <a href="mailto:amathai@staqpharma.com">amathai@staqpharma.com</a> for more information.</p>