United States Jobs Expertini®

Document Coordinator

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Company: Planet Pharma

Location: United States

Category: other-general

Summary: Provides support to the process for creating, reviewing, approving, distributing, controlling and maintaining documentation to ensure effective and efficient application of GMP.Documentation within this process includes, but is not limited to, manufacturing and packaging, laboratory, and general operations.Understands the basic principles and concepts of the documentation lifecycle and associated electronic systems. Performs departmental tasks under supervision. Essential Duties and Responsibilities can include, but are not limited to, the following:DOCUMENT STRUCTUREUnderstands the concept of document hierarchies and applies when executing document review.Performs document review against standard formats and requirementsUnderstands the approval process and provides guidance to customersEnsures appropriate cross-referencing, links, and other required meta-data for documentsDOCUMENT & WORKFLOW MANAGEMENTPerform intake review of documents for completeness and accuracy while maintaining document workflow.Coordinate review and revision of controlled documents.Owns single to a few pre-fixes or process across multiple areas within a siteExecutes activities associated with creation, retiring and unretiring, and periodic review of documentsProcesses document requests including intake, coordination, editing, review, and releaseEnsures collaborative review is completed prior to workflow activationMaintains document integrity as per procedurePerforms basic troubleshooting of workflowsRECORDS ISSUANCEExecutes the different steps associated with the lifecycle of a record (including but not limited to, Master Batch Records, Batch Sheets, Protocol Performance Copies, Labels, Logbooks, Keys): issuance, tracking, and reconciliation.Performs verification of records ensuring all required

information is present, accurate, and compliant against procedures prior to issuing to receiving areaMaintains an accurate and comprehensive inventory of issued documentationPROCESS PERFORMANCECollects and compiles data to support metric analysis required for understanding of system or process performance, or investigation activitiesGenerates reports and interprets data on a pre-defined basis needed to support process understanding, customer information requests, and visibility of organization activitiesCreates basis visual management information from data for different department activitiesRuns standing metrics reports for Quality Operations Systems Metrics meeting, Right to Operate meeting, and other performance review meetingsTECHNICAL SYSTEMSMaintains a basic understanding of the Electronic Document Management System EDMS for processing workflows, running reports, and performing basic information searches.Accesses and reviews QlikSense tools, file tracking P Databases, The Document Activation Management tool, SharePoint sites, and Servers to support execution of tasksMaintain departmental databases.INSPECTION SUPPORTParticipates in inspection and audits by supporting the associated logisticsSupplies requested information to Doc Control inspection teamCOMPLIANCE SUPPORTParticipates in investigationsGENERALIdentify areas for continuous improvement for processes based on experience and customer feedback.Participate in departmental project teams.Years of Experience: 1***Compensation within this range will be commensurate with level of experience***

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