United States Jobs Expertini®

CMC Quality Control Writer / Reviewer

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Company: Tandym Group

Location: United States

Category: other-general

A California-based biopharmaceutical company is looking to add an experienced professional to their CMC Quality Control Department as a Writer / Reviewer. In this role, the CMC Quality Control Writer / Reviewer will be responsible for authoring, drafting. reviewing, and approving the Regulatory QC CMC sections of the company's IND/IMPD and BLA/NDA filings for one or more the company's programs.***This is a Hybrid opportunity requiring 2 days onsite in Brisbane, CA and 3 days remote work.***Responsibilities:The CMC Quality Control Writer / ReviewerAuthor, update, and revise CMC stability sections in support of regulatory filingsAddress CMC stability inquiries per regulatory inquiriesPerform review/draft of analytical release and stability data, data integrity, laboratory documentation, stability reports, specifications, specification setting reports, and other QC/analytical documentsParticipate in the qualification/validation of analytical test methods for all Product Quality parameters, specification setting, stability programs for clinical and commercial productsGenerate QC documents including, but not limited to, CoAs, reference standard qualifications and reports and risk assessmentsWork within QC and with QA and other departments to address review comments on regulatory and QC/analytical documentsManage/assist the document creations and reviews via Veeva Document SystemCreate and update batch analysis tables for release dataCreate Excel/JMP tables and graphs/charts for release and stability data trendingInitiate and manage change controls, deviations and CAPA with Veeva Document SystemAssist in closing Quality events/Deviations (OOS/OOT/OOE) and Deviation investigationsEvaluate existing analytical method validation packages for accuracy and compliance with current ICH/FDA guidelinesPerform other duties, as

neededQualifications:5+ years of Analytical / Quality Control experience in a GMP environmentBachelor's Degree in Biochemistry, Molecular Biology, Pharmaceutical Sciences or a related Life Science fieldPrevious experience in the Biotech and/or Pharmaceutical industryGood understanding of cGMPs, ICH and Regulatory Drug requirementsProficient in Project and Personnel ManagementMicrosoft Office proficient (Excel, Word, etc.)Great interpersonal skillsExcellent communication skills (written and verbal)Strong attention to detailHighly organizedDesired Skills:Experience with writing and reviewing of CMC filings for regulatory submissions, including IND/IMPD, BLA, and/or MAAProficient in Statistical Analysis software (Excel/JMP)

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