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Manager GMP Vendor Quality Management

Hiring organization
Cerevel Therapeutics

Job Location
Boston, MA (Remote)

Base Salary
$ 60000 - $ 110000

Date posted
May 10, 2024

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Description

Role Summary:The Manager, GMP Vendor Quality Management will maintain and utilize processes, quality systems, and tools to qualify and monitor outsourced GMP activities and GMP Vendors that are utilized in the manufacturing, packaging, labeling, testing, warehousing, and distribution of finished pharmaceutical products and investigational medicinal products. nKey ResponsibilitiesSupport and maintain the Cerevel GMP Vendor Management Program. This includes arranging contract auditor(s), assuring training documentation of the auditors is obtained and sustained to meet training requirementsThis position is accountable for timely receipt of audit reports, organizing internal review or audit reports, issuance of audit reports to vendors, obtaining vendor responses, and closure of audits in a timely manner to support business needs and meet timing requirements of Cerevel proceduresEnsure assigned audits are 1) scheduled and conducted, 2) audit documentation is accurate and complete, 3) audit reports are sent to vendors, 4) acceptable responses are received from vendors, and 5) audits are closed out in Veeva as per respective procedures and timingEnsure all assigned GMP vendors are appropriately qualifiedManage assigned Quality Agreements including their initiation, generation, and approval. Ensure that Quality Agreements are written, approved and in-place for external GMP vendors. Manage periodic reviews of assigned Quality AgreementsSupport Sr. Manager, with execution of the GPQ Internal Audit ProgramEnsure compliance with Cerevel requirements as well as applicable regulatory requirementsProvide necessary inputs to support reporting of key performance indicators, metrics, and compliance status of GMP Vendors to Global Quality senior managementIdentify process improvement opportunities within the Vendor Management program to strengthen compliance and increase efficiency. Participate on continuous improvement projects related to the Vendor Management programSupport inspections and inspection readiness activities associated with the Vendor Management programAdditional Quality projects and responsibilities may be assigned based on business needs of a growing organizationRequired QualificationsAt least 5 years of relevant Quality Assurance Vendor Management experience in a pharmaceutical industryExperience in the qualification and management of vendors for oral solid dosage forms both Clinical and Commercial purposes. This includes CMOs/CDMOs, API manufacturers, primary/secondary packagers and labelers, contract laboratories, warehouses, and distributorsExperience supporting Health Authority InspectionsGeneral understanding of how the Drug Development Process impacts vendor qualificationsExperience working in an electronic quality management system (Veeva or equivalent)Highly motivated, flexible, and able to respond quickly to shifting priorities. Able to meet deadlines, with excellent organizational skills and keen attention to detailsStrong verbal and written communication skills to effectively communicate with business functions and vendorsAbility to partner and build relationships with technical operation stakeholders and external vendors to enable high quality outcomesAbility to travel up to 20% domestic travel, occasional international travel may be expectedDesired QualificationsASQ Certified Quality Auditor certification, or equivalentPrior experience qualifying vendors for sterile manufacturing a plusStrong team player with a solutions-oriented, customer-service, and continuous improvement mind-setExcellent interpersonal and problem-solving skillsAbility to coordinate timelines with internal customers and vendorsEducationBachelorâ??s degree in life science or engineering field; significantly more working experience in the relevant areas may be required for candidates without a bachelorâ??s degreenPlease mention the word

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Contacts
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