CareerCross

Sr Validation Subject Matter Expert ・ Computer Systems Validati…

> **武田薬品工業株式会社での募集です。 製造技術・生産技術（電気・PLC制御）のご…**

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
武田薬品工業株式会社

Job ID
1469016

Industry
Pharmaceutical

Job Type
Permanent Full-time

Location
Osaka Prefecture

Salary
5.5 million yen ~ 11 million yen

Work Hours
08:00 〜 16:45

Holidays
【有給休暇】初年度 12日 1か月目から 完全週休二日制（土・日）、祝日、メーデー、年末年始、他 特別有給休暇、リフレッシュ休…

Refreshed
May 9th, 2024 00:00

General Requirements

Career Level
Mid Career

Minimum English Level
Daily Conversation

Minimum Japanese Level
Native

Minimum Education Level
Technical/Vocational College

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2207746】
Acting as Computer Systems Validation （CSV） engineer in the Engineering workstream of the project he/she will:

■Report to the CQV Lead/Validation Manager.
■Develop and execute validation plans protocols and reports for computer systems.
■Ensure that computer systems are compliant with regulatory requirements including FDA regulations GxP guidelines and industry standards.
■Collaborate with cross functional teams to identify and mitigate risks associated with computer systems.
■Conduct risk assessments and develop risk mitigation strategies for computer systems.

■Develop and maintain standard operating procedures （SOPs） for computer system validation.
■Provide training and guidance to end users on the proper use of computer systems.
■Participate in audits and inspections to ensure compliance with regulatory requirements.
■Keep up to date with industry trends and best practices related to computer system validation.
■Manage vendors/contractors related to CSV activities.

Required Skills

■BA or BS degree preferably in the engineering or science field. ■5+ years of validation experience・for non mgr role.
■Experience in validation of GMP manufacturing process control systems （e.g. Allen Bradley PLC Delta V BAS Siemens）
■Experience in control systems validation as part of a large capital project （e.g. new facility installation） is a plus.
■Experience in Plasma manufacturing is a plus. ■Prior experience in use of KNEAT （paperless validation system） in a validation project is a plus. ■Prior experience interacting with the FDA and other regulatory agencies. ■Excellent verbal and written communication skills in English and Japanese.

Company Description

医薬品、医薬部外品等の製造・販売・輸出入