United Kingdom Jobs Expertini®

Validation Specialist

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Company: Hyper Recruitment Solutions

Location: Caerphilly

Category: architecture-and-engineering

Role Overview

Are you an experienced Validation Specialist looking for a new exciting job opportunity?

We are currently looking for a Validation Specialist to join a leading pharmaceutical company based in the Caerphilly area.

As the Validation Specialist you will enhance validation practice and compliance; support improvement to validation system; streamline processes. Identify risk areas and required mitigation to meet regulatory inspections e.g. MHRA, FDA, Notified Body etc. through routine compliance activities and specific validation projects.

Key Duties and Responsibilities

Your duties as the Validation Specialist will be varied however the key duties and responsibilities are as follows:

1. You will be responsible for ensuring that the Site Validation Master Plan is maintained accurately and Validation Plans are implemented for all relevant aspects of Equipment, Process, Cleaning, Computer Systems, Facilities/Utilities and Analytical Method validation.

2. Additionally, you will also be assisting with all validation activities on equipment before handover / return to system owner and updating all relevant records and schedules. You will be responsible for arranging specialist services to maintain, calibrate and qualify specialist

equipment.

3. Technical input into all Validation Lifecycle activities as part of a cross functional team. Provide guidance and support to other internal site departments ensuring compliance with applicable regulatory requirements (MHRA, EU, FDA, U.S., Notified Body and international), International Standards, and quality/validation regulations and guidance documents.

4. You will also prepare and present validation reports and Key Performance Indicators for management review. Review and monitor trends; initiate continuous improvement opportunities, communicate any matters outside the norm to the Validation Manager / Site Director of Quality.

Role Requirements

To be successful in your application to this exciting opportunity as the Validation Specialist we are looking to identify the following on your profile and past history:

1. Successful validation experience in a GMP environment (in the pharmaceutical, medical devices, consumer healthcare or semi-conductor industry) is essential for this position. Experience working in a sterile manufacturing facility would be highly desirable.

2. Demonstrated expertise in cGMP's, EU/FDA regulations, GAMP guidelines, assessment of risk and drafting of plans, protocols, reports and procedures.

3. Previous team leadership experience (direct or indirect) desirable, operating in a matrix organization.

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