Validation Engineer (INT11)

This role is a full time (37.5hr) permanent position working onsite at our Lane Cove Facility.

The role of Validation Engineer sits within our Validation Team and within the wider Quality Team. The Validation Engineer is responsible for ensuring cGMP compliance relating to qualification, validation, change control, and assisting with new product introduction activities.

Major functions of the role include (but are not limited to)

- Ensuring execution of the Validation Master Plan, as per agreed schedule.
- Ensuring Critical Safety Reviews are completed in a timely manner.
- Ensuring all validation activities are performed in accordance with PIC/s Annex 15 requirements.
- Performing the execution of the IQ/OQ/PQ protocols, and preparation of IQ/OQ/PQ reports.
- Co-ordinating the sending of validation testing samples to external laboratories.
- Creation and implementation of validation protocols for all validation activities
- Generating final reports for validation and qualification activities in a timely manner
- Investigation of any failed testing / validation results via the laboratory investigation system.
- Development of terminal sterilisation cycles for new products as required.
- Assist with validation aspects of Change Control requests.
- Ensuring processes and cleaning validation activities are conducted in accordance with PIC/s Annex 15 for existing and new products for the facility.
- Ensuring all validation instruments are calibrated and reviewing calibration certificates.
- Organise cleanroom certification/recertification with service providers and review of all certificates.
- Equipment and process validation of newly built non-sterile manufacturing facility

To be successful in this role you will require the following

- Tertiary qualification in Chemical Engineering, Mechanical Engineering, or Chemistry
- At least 3-4 years of experience working in pharmaceutical validation within sterile product manufacturing.
- Knowledge and understanding of generating IQ/OQ/PQ protocols and reporting.
- Knowledge and understanding of PICs Guidelines in particular, Annex 1 and 15
- Understanding of terminal sterilisation cycles ***and*** Autoclave Cycle development experience - Preferred
- Experience with investigations of failed testing and validations– Preferred
- Experience working with deviations/non compliances.
- Extensive knowledge of GMP principles and practices
- Ability to write reports and technical documentation.
- Strong commitment to product quality and a continuous improvement mindset
- Ability to communicate well and build relationships with internal and external stakeholders.

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