JOB PROFILE

Job title:	Validation Manager
Reporting to:	Head of Quality
Department:	Quality Team
N^{o} of Direct reports:	
Location:	Pencoed, South Wales
Job Details	
Job Purpose:	The Validation Manager is responsible for the development and implementation of the strategies for the qualification or the manufacturing unit and equipment including compliance to GMP, specifically Eudralex Annex 11 & 15 and relevant FDA guidance for industry.
Main areas of responsibility:	• Lead the validation activities as part of the facility design, build and qualification project by hands-on work and support from specialist contractor(s) as required. • Close liaison with the building contractors, engineers and vendors of facility and equipment items to ensure full and appropriate information is provided, along with vendor qualification protocols. • Support FATS, SATs, IQ/OQ as appropriate of plant and equipment, reviewing documentation and advising team members to deliver best practice. • Responsible for the oversight of ongoing (DQ, IQ, OQ, PQ) validation activities once production has commenced. • Review of vendor protocols and creation or approval of in-house protocols and reports to deliver a complete package of qualification documentation. • As some validation activities will be outsourced, you will maintain these relationships, monitoring KPIs so that performance and value for money is maintained. • In addition to the contractors, manage other validation team member(s), including their performance, development, training and compliance. • As a key member of the Quality Team, contribute to the overall validation strategy for the site as well as act as a technical point of contact for internal and external stakeholders. • Key contributor in the project team to validate the manufacturing unit, working full-time on design, build and qualification activities. • Work effectively and supportively with other project team members to deliver the GMP manufacturing facility in accordance with the program • Draft and review GMP documentation including validation documentation, SOPs, and training documentation. • Train team members in procedures relating to validation as required. • Participate actively in the preparation for the Manufacturer's License as directed by Head of Quality. • Understand the production schedule, and work closely with Manufacturing and Engineering to build a qualification schedule that

	delivers minimum interruption to manufacturing output. • Work in a safe manner, ensuring full compliance to HS&E policies at all times. • Participate in and respond to inspections by Regulatory Authorities including MHRA and FDA, representing the validation function. • Participate in continuous improvement in the manufacturing facility to enable production effectively and efficiently. • Establish and maintain strong relationships with cross functional departments including Manufacturing, CMC, Engineering and Regulatory groups. • Actively maintain and update knowledge and expertise of current developments, standards and operating practices with the ATMP and pharmaceutical industries.
Person Specification	

Qualification/ Experience required	**Essential**	**Desirable**
	• Degree or equivalent in biological science, engineering or related area.	• Experience of participating in the introduction of new processes and equipment into a GMP manufacturing facility.
	• At least 5 years' of leading and conducting validation activities in a GMP licensed facility that includes aseptic and/or sterile manufacturing.	
	• Proven experience of manufacturing compliance to GMP regulations and guidance including specifically Annex 11 & 15. Current working knowledge of GMP, and with a deep understanding of validation of cleanroom manufacturing environments and related equipment.	
Skills and Competencies required	• Ability to work consistently and compliantly, following standard operation procedures and quality policies. • Able to generate GMP documentation to a high standard and relating validation policies, SOPs, protocols and reports. • Good communication skills: able to work with various team members across all functions. • Good understanding of Quality Management Systems, and having a controlled approach to identifying and reporting deviations and completing CAPAs.	

• The role holder will be required to operate across the facility including within Grade B and Grade C environments. These are restrictive environments that require careful and

controlled working methods, following a series of SOPs and wearing specialist clothing. • Weekend and out of hours working may be required from time to time. • Some occasional overseas travel may be required to visit other manufacturing sites or equipment suppliers. • To carry out any other tasks or duties within post holders capability as requested by the Company to meet business needs.
• The Company reserves the right to vary or amend the tasks and responsibilities of the post holder at anytime according to the needs of the Company's business. • Information contained therein is not exhaustive but describes key elements of the function.

Author:	Date:
Revised:	Date: