JOB PROFILE

Job title:	QA Associate Documentation Controller
Reporting to:	QA Manager
Department:	Quality Team
N° of Direct reports:	
Location:	Pencoed, South Wales
Job Details	
Job Purpose:	Initially performing QA duties to support the design, build and validation of a new GMP manufacturing facility. Collation and monitoring of related GMP document generation, filing and archiving within the Company's EDMS. Upon completion of the project this role will become focused on supporting the Company's QMS, providing QA support as detailed below.
Main areas of responsibility:	• EDMS administrator • QA review of GMP documentation to ensure compliance with the QMS • Collation and analysis of metrics that reflect performance of the GMP building project and then ongoing operational performance • Working pro-actively with the Facility build team to ensure documentation is in place at the required time • Manage the documentation system for the Facility build project ensuring all documentation is controlled, maintained and available when required • Responsible for archiving GXP documentation • Responsible for monitoring key elements of the QMS specifically non-conformances, change controls, CAPAs etc • Post-Facility build: • Maintenance of product specification files • Liaison with 3rd party vendors and transmittal of controlled documents • Provide QA support for audits and regulatory inspections • Perform internal and external audits and regulatory inspections

	• Perform internal and external audits • Work effectively within project teams, providing QA input where required – escalating issues to the QA Manager where appropriate • Review batch records, QC data etc associated with the product release and provide, in conjunction with the QA Manager, disposition packs to the QP and Head of Quality.

Person Specification		
Qualification/ Experience required	**Essential**	**Desirable**
	• Minimum of 1 – 2 years' experience in QA or in a similar role in Engineering i.e. Document Controller	A relevant scientific degree (or equivalent)
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Skills and Competencies required	• Able to demonstrate a commitment to quality including a good understanding of QA • Computer literate • Knowledge of current GMP guidelines • Able to work as part of a team and individually • Excellent attention to details • Effective planning and organisational skills. • Effective communication skills within a traditional engineering environment.	

• 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: