

Person Specification

Job Title	Principal CSV Engineer
Job Holder	
Reports To	Qualification Group Manager
Date	July 2020

	Essential	Desirable	Method of Assessment
Educational Attainment A degree Software or related Engineering discipline	X		Application form / Certificate
Work Experience At least 5 years' experience of GAMP, risk based approach to validation	X		Application form / Interview
A good understanding of electronic records and signatures	X		Application form / Interview
Knowledge of data management and data integrity needs in a GMP regulated environment	X		Application form / Interview
Proven ability to work with others from multiple disciplines.	X		Application form / Interview
CSV tech review and sign off of lifecycle phase documentation	X		Application form / Interview
Defined validation strategy for systems upgrades or new systems implementations		X	Application form / Interview
Carried out supplier audits as CSV SME.		X	Application form / Interview
Experience of delivering training courses		X	Application form / Interview
Knowledge/Skills/Aptitude Business Standards & Integrity: Thoroughness and attention to details	X		Application form / Interview
Relationship Building & Customer Focus: Concern for Impact and good communication skills, Ability to influence, negotiate and persuade	X		Application form / Interview
Process Management: Proven tasks management and efficiency skills,	X		Application form / Interview
Analytical Thinking: Critical Information Seeking. Ability to use risk management techniques and effectively prioritise.	X		Application form / Interview
Planning, Effective planning and use of resources	X		Application form / Interview
Achievement & Results Orientation: Self-Motivation and Flexibility	X		Application form / Interview
Circumstances None			