

## J O B P R O F I L E

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<b>J o b t i t l e</b>	Q C A s s o c i a t e
<b>R e p o r t i n g t o</b>	H e a d o f A n a l y t i c s
<b>D e p a r t m e n t</b>	Q u a l i t y T e a m
<b>N ° o f D i r e c t r e p o r t s</b>	0
<b>L o c a t i o n</b>	P e n c o e d , s o u t h W a l e s
<b>J o b D e t a i l s</b>	
<b>J o b P u r p o s e</b>	C o o r d i n a t i n g t e c h t r a n s f e r o f a s s a y s f r o m R e N t o G M P c o n t r a c t t e s t i n g h o u s e s ( C T O s ) a n d b e t w e e n C T O s . P r o v i d i n g o n g o i n g Q C o v e r s i g h t a n d s u p p o r t t o C T O s . R e p r e s e n t i n g R e N Q C i n p r o j e c t m e e t i n g s .
<b>M a i n a r e a s o f r e s p o n s i b i l i t y</b>	<ul style="list-style-type: none"> <li>• R e v i e w a l l Q C p a p e r w o r k f o r a s s a y s e n s u r i n g c o m p l i a n c e w i t h t h e m e t h o d .</li> <li>• W o r k i n g w i t h C T O s t o e n s u r e t i m e l y i n i t i a t i o n o f t e s t i n g a n d a n y l a b o r a t o r y i n v e s t i g a t i o n s / O O S s .</li> <li>• W h e n n e c e s s a r y w o r k a t t h i r d p a r t i e s i n s u p p o r t o f t e c h n o l o g y t r a n s f e r a c t i v i t i e s a n d d i r e c t t h i r d p a r t y w o r k</li> <li>• C o l l a t e , a n a l y s e , c o n c l u d e a n d p r e s e n t d a t a a n d a u t h o r / r e v i e w / a p p r o v e t e c h n i c a l r e p o r t s</li> <li>• E n s u r e t h a t e x p e r i m e n t a l w o r k i s r e c o r d e d i n a p p r o p r i a t e l y c o n t r o l l e d l a b o r a t o r y b o o k s o r p r o t o c o l s i n a c c o r d a n c e w i t h t h e r e q u i r e m e n t s o f G x P</li> <li>• P e r f o r m a n a l y t i c a l t e c h n i q u e s i n a n o n - G M P e n v i r o n m e n t i n r e a d i n e s s f o r e s t a b l i s h i n g a n d t e c h t r a n s f e r r i n g m e t h o d s i n t o c o n t r a c t l a b o r a t o r i e s .</li> <li>• A c q u i r e a n d m a i n t a i n a b r o a d k n o w l e d g e o f t h e s c i e n c e b e h i n d a n a l y t i c a l m e t h o d s a n d c e l l c u l t u r i n g f o r s t e m c e l l t h e r a p y .</li> <li>• W o r k w i t h t h e H e a d o f A n a l y t i c s t o p r o v i d e r e q u i r e d t e c h n i c a l s u p p o r t t o G M P Q C a c t i v i t i e s .</li> </ul>

	<ul style="list-style-type: none"> <li>• Author G M P documentation as appropriate .</li> <li>• Review G L P technical documentation from Contract testing laboratories as appropriate .</li> <li>• Own technical aspects of G M P investigations relating to Q C testing methods .</li> <li>• Contribute to Quality processes/initiatives at a local and Company level where required . To follow and assist in the implementation of G M P standards which contribute to the Company and site objectives</li> <li>• Coordination of stability studies and generation of associated protocols and reports</li> <li>• Develop and tech transfer test article preparations for assays</li> <li>• Generate tech transfer protocols and reports</li> </ul>
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**Person Specification**

<b>Q u a l i f i c a t i o n / E x p e r i e n c e r e q u i r e d</b>	<b>E s s e n t i a l</b>	<b>D e s i r a b l e</b>
	<ul style="list-style-type: none"> <li>• 3-6 years working in an analytical lab or similar scientific role .</li> </ul>	<ul style="list-style-type: none"> <li>• Experience working with third parties</li> </ul>
	<ul style="list-style-type: none"> <li>• A good understanding of Cell based assays with experience in a comprehensive range of assay platforms .</li> </ul>	
	<ul style="list-style-type: none"> <li>• A knowledge and understanding of working to G M P</li> </ul>	
	<ul style="list-style-type: none"> <li>• Aseptic cell culturing and cell counting (manual and automated)</li> </ul>	
<b>S k i l l s a n d C o m p e t e n c i e s r e q u i r e d</b>	<ul style="list-style-type: none"> <li>• A motivated individual committed to being an integral team player in the Q C .</li> <li>• Good communication skills, both verbally and written, comfortable to meet with all ReNeuron staff.</li> <li>• Knowledgeable and capable of presenting ideas and sharing information appropriately .</li> </ul>	

	<ul style="list-style-type: none"><li>• Be able to analyse and interpret data generated using standard computer programmes.</li><li>• Individual roles may be predominantly lab-based or predominantly focused on supporting GMP QC activities, or balanced between the two; depending upon the current business need.</li><li>• Some UK and international travel to meetings, conferences, and third parties (e.g., CMOs, CTOs, and collaborators) is expected.</li></ul>
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<ul style="list-style-type: none"><li>• To carry out any other tasks or duties within post holders capability as requested by the Company to meet business needs.</li></ul>
<ul style="list-style-type: none"><li>• 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.</li><li>• Information contained therein is not exhaustive but describes key elements of the function.</li></ul>

Author:	Date:
Revised:	Date: