

# JOB PROFILE

<b>Job title:</b>	QC Microbiology Team Leader
<b>Reporting to:</b>	QC Manager
<b>Department:</b>	Quality Team
<b>N° of Direct reports:</b>	
<b>Location:</b>	Pencoed, South Wales
<b>Job Details</b>	
<b>Job Purpose:</b>	Establish the QC Microbiology laboratories. Lead the QC monitoring elements of the qualification facility (working with consultant to determine the overall qualification strategy), and clean utilities and then lead the routine monitoring of controlled cleanrooms, classified areas, personnel and operator qualification.
<b>Main areas of responsibility:</b>	<ul style="list-style-type: none"> <li>• Generate work practices and associated SOPs to enable compliant and consistent operation in the QC Micro labs</li> <li>• Qualify and maintain equipment.</li> <li>• Perform microbiological testing such as Total Viable Counts.</li> <li>• Initially lead the QC monitoring elements of the qualification of the facility and clean utilities, and then lead the routine monitoring of controlled clean rooms, classified areas, personnel and operator qualification, and provide trend data on process and personnel performance.</li> <li>• Maintain/prepare microorganism cultures used in testing procedures and perform Microbial identification through Gram stain and Biochemical analysis.</li> <li>• Establish and maintain relationships with external providers to provide accurate and timely identification of cultures</li> <li>• Record test results and supporting data accurately and in a timely manner.</li> <li>• Assist with deviation investigations, perform any additional testing, create reports providing trend analysis and technical investigation of all microbiology processes where required.</li> <li>• Ensure that all microbiology laboratory areas and equipment and properly qualified, cleaned and maintained according to established procedures.</li> <li>• Ensure that equipment is maintained correctly and any deficiencies or calibration requirements are resolved.</li> <li>• Complete other duties as assigned by manager.</li> <li>• Ensure compliance with EU and FDA current Good Manufacturing Procedures (cGMP), relevant pharmacopeia, and other regulatory requirements at all times.</li> <li>• Front QC Microbiology at audits and regulatory inspections and work with QC Manager to resolve any resulting observations.</li> <li>• Become in-house SME on mycoplasma, endotoxin and sterility testing.</li> </ul>

Person Specification		
	Essential	Desirable
<b>Qualification/ Experience required</b>	<ul style="list-style-type: none"> <li>Educated to degree level in a Microbiology / Bioscience discipline.</li> </ul>	
	<ul style="list-style-type: none"> <li>Previous experience in a similar environment and role, with the ability to prove competence in all requirements of the job.</li> </ul>	
<b>Skills and Competencies required</b>	<ul style="list-style-type: none"> <li>Ability to act autonomously</li> <li>Driven to excel.</li> </ul>	

<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: