Job Description

Job title	Qc Analyst
Department	Quality Control
Responsible to	QC Analytical Team Lead

Job Summary

To undertake the chemical and biochemical analyses to support the manufacture of PBL's licensed pharmaceutical products; as required by EU Directive 91/356/EEC for GMP compliance. To write quality documentation relating to raw materials, water and product testing where appropriate. To ensure that work performed within the laboratories is carried outin compliance with corporate statutory health and safety requirements

MAIN DUTIES AND RESPONSIBILITIES

- Operate the QC Analytical Services Laboratory in compliance with Porton Biopharma's safety policy and cGMP
- Ensure analysis, recording of tests and interpretation of data have been performed in compliance with cGMP. Communicate progress and escalate issues to line manager and/ or senior analyst
- Plan and complete assigned tasks within the required timeframe
- Responsible for testing raw materials, in-process, finished product and stability samples to ensure that they meet approved specifications.
- Verify analytical raw data and release results from the QC Analytical department as appropriate
- Write SOPs, protocols, reports and risk assessments as appropriate.
- Write quality records such as non-conformances, and devise CAPAs and change controls as appropriate.
- Liaise with external testing laboratories to arrange correct and timely testing.
- Work collaboratively with team to ensure business, regulatory and customer needs are met
- Maintain an up-to-date awareness of regulatory and scientific developments.
- Perform housekeeping of laboratories.
- Receive samples into the lab from internal and external customers
- Ensure all equipment within the QC department is calibrated and serviced
- Identify improvements

The above is only an outline of the tasks, responsibilities and outcomes required of the role. You will carry out any other duties as may reasonably be required by the Manager.

The job description and person specification may be reviewed on an ongoing basis in accordance with the changing needs of the organization

Communication and key working relationships

Internal –	QC Analysts | QC Senior Analyst | QC Team Leads | QC Analytical Manager | Quality Assurance personnel | Production personnel | Pharm Stores personnel | Validation personnel | Calibration personnel | Health & Safety personnel | Engineering personnel | Process Technical Group personnel
External –	Contract laboratories | Participation in audits by external customers and regulatory bodies e.g., MHRA and FDA. | Supplier of instrumentation and chemicals | Vendor engineers

Other

You should adhere to PBL values and behaviors:

- Passion
- Respect
- Integrity
- Diligence
- Excellence in Execution (E^2)

APPROVAL AND AGREEMENT			
	Name	Signature	Date
Line Manager			
Employee			

Job Title	QC ANALYST

Person Specification

	Essential	Desirable
Eligibility		
Current, valid Right to Work in UK	☒	☐
A good standard of written and spoken English	☒	☐
Equality and Diversity		
An understanding of and commitment to equality of opportunity and good working relationships, both in terms of day to day working practices, but also in relation to management systems	☐	☐
Qualifications		
Degree or equivalent qualification in Chemistry/Biochemistry or other related subject or previous relevant experience.	☒	☐
Higher degree or equivalent qualification in Chemistry orBiochemistry	☐	☒
	☐	☐
Knowledge and Experience Experience as defined by type/level (not length)		
Working Knowledge / Experience of cGMP	☒	☐
Working Knowledge / Experience of the EP and USP	☒	☐
Working Knowledge / Experience of ICH requirements	☐	☒
Previous experience of working in a similar position as a bench analyst following written instructions and comparing analytical results with set specifications	☒	☐
Knowledge / Experience of UV/Vis and FT/IR	☐	☒
Knowledge / Experience of analysing purified water andwater for injection by TOC	☐	☒
Basic experience of the out of specification process and carrying out laboratory investigations	☐	☒
Experience using standard analytical laboratory equipment such as pH meters, balances, pipettes	☒	☐
Knowledge / Experience analysing pharmaceutical rawmaterials	☐	☒
Knowledge / Experience of Waters HPLC systems andassociated software or equivalent	☐	☒
Skills and Capabilities		
Good communication skills able to communicate technical issues to Supervisors and understand technical instructions	☐	☒
Problem solving skills and ability to respond to suddenunexpected demands	☐	☒
Ability to work on own initiative, organise own workload and prioritise daily work with minimal supervision working to tight and often changing timescales	☐	☒
Ability to use technical software packages	☐	☒
Ability to work as part of a team	☐	☒
Good basic computer skills and literacy	☒	☐
A desire and ability to self-improve and to improve the department	☐	☒
An understanding of and commitment to equality of opportunity and good working relationships, both in terms of day-to-day working practices, but also in relation to management systems	☒	☒

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