MedPharm Ltd
Job Description

Job Title:	QA Specialist (3 month Fixed Term Contract – with possibility of extension)
Location:	MedPharm Limited, Guildford, UK
Report to:	Senior QA Specialist

Main purpose of job

- To maintain Quality Systems for the site GLP and GMP activity and support batch release activities.
- To support and maintain Quality GxP compliance with Global Quality, GMP and regulatory requirements.

Significant internal and external relationships

- Regular interaction with scientists, study directors, technical managers, other technical personnel, subcontractors and suppliers.

Responsibilities

1. Review and approve of change controls, deviations, OOS, CAPAs, audit comments and other related quality records and providing QA input into their generation.
2. Support internal audits of facilities to ensure compliance to GxP and other applicable standards.
3. Maintain the quality programs for the QA department including but not limited to, document control, supplier qualification, Technical Agreement and internal/external audit program.
4. Development, review and revision of company standard operating procedures.
5. Assist with the issue of Quality documentation such as standard operating procedures (SOPs) and forms.
6. Support the management of retention and archiving of records
7. Training and implement QA procedures for compliance with GxP.
8. Participate in continuous improvement activities.
9. Audit R&D and QC raw data where appropriate to ensure that the work has been completed to GxP.
10. Liaise with all staff; communicating information and updates as appropriate.
11. Approve restricted document types on behalf of QA
12. Ensure that all documentation, computer data and records are stored appropriately.
13. Approve specifications, sampling instructions, test methods and other Quality Control procedures.
14. Review batch manufacturing records prior to manufacture.
15. Review and approve completed batch manufacturing records post-manufacture.
16. Review and monitor suppliers of materials.
17. Approve or reject, as appropriate, starting materials, packaging materials, and intermediate, bulk and

finished products.

18. Monitor compliance with the requirements of Good Manufacturing Practice.
19. Review and compile manufacturing batch records and associated data ready for QP batch release
20. To adhere to MedPharm H&S policy and COSHH regulations at all times and to ensure the safety of others in any procedures or tasks performed.
21. To perform any other tasks at the request of MedPharm senior management appropriate to the job function

Education	• Bachelors' or Masters' degree in a scientific subject required • Degree in QA Management desirable
Experience and skills	• Knowledge of batch release process and root cause analysis • Experienced in batch release support (review of BMRs, data etc) • Experience with QMS management including deviations, CAPAs and change control • Previous experience in pharmaceutical industry CMO, CRO or big pharma (exposure to manufacturing ideal)
Personal Attributes	• High level of attention to detail • Team player • Good time management skills *Applicants must be able to commit to ad hoc weekend work.*