Job Title	Production Quality Associate	Reports to	Senior Pharmacist – Operations and Quality Assurance
Job Purpose	○ The Production Quality Associate will need to ensure that all operations are compliant with internal procedures and regulatory requirements in accordance with the General Pharmaceutical Council Regulations and Guidance for Registered Pharmacies preparing Unlicensed Medicines. ○ You will also support the provision and development of efficient and effective Quality Assurance (QA) processes. ○ Ensure safe and effective Pharmaceutical Compounding Services are delivered day-to-day. ○ You will ensure that all our products meet industry standards, design specifications and customer satisfaction measurements. ○ R&D experience in pharmaceutical compounding/ manufacturing is desired, especially with regards to formulations, lab automation, lab testing, and continuous process improvements in line with company's vision and direction.		
Main Duties and Responsibilities			
Safe and Effective Production	○ Write, review, and approve SOPs together with the Senior Pharmacist. ○ Ensure that Specialist-Pharmacy products meet all quality attributes, safety, potency and purity. ○ Ensure that the final products have the right quantity and composition of active pharmaceutical ingredients through documented reports produced by the electronic dispensing system. ○ Review and approve project risk assessments. ○ Review and approve analytical and compounding documentation prior to certification. ○ Participation in the change control process to ensure changes to processes, systems, equipment, and facilities are appropriately assessed and implemented. ○ Drive continuous improvement of core processes to ensure compounding quality is maintained while efficiency is optimized. ○ Participation in quality issue investigations and agreeing CAPAs. ○ Support the development and implementation of the company quality system as required. ○ Interpretation and communication of information (e.g., GMP requirements) and provision of advice on quality issues and safety to members of staff and clients. ○ Review and approve validation activities such as equipment and computer systems validations. ○ Involvement in regulatory inspections as required. ○ Review of analytical protocols, results, and investigations, ensuring data integrity. ○ Perform audits to monitor compliance of internal operations with internal procedures and regulatory requirements. ○ Together with the Production Supervisor manage the capacity and contingency planning process (scheduling), considering production staff numbers, time to compound, equipment, premises, and prescriber/patient demand. ○ Together with the Production Manager maintain an up-to-date Quality Management System which translates into operational excellence at the London Specialist Pharmacy Ltd (trading as Specialist Pharmacy). ○ Strive to deliver and maintain turnaround times of production as per the company's key performance indicators. ○ Together with the Production Manager run team briefing meetings on a regular basis to keep team updated and briefed on key matters relating to the quality of products manufactured as well as processes to ensure quality is achieved and maintained.		

	○ Ensure that errors, incidents and near misses are logged and reported accurately. ○ Observe the Safety at Work Act 1974 regulations and ensure compliance with the Control of Substances Hazardous to Health (COSHH) regulations protecting staff and the public. ○ Observe and comply with the General Data Protection Regulation (*(EU) 2016/679*). ○ Ensure a flexible approach to work to help assist other departments as and when required.
Upholding Compounding Standards	○ Uphold and comply with non-sterile compounding standards stated in the EU Good Manufacturing Practice, Good Laboratory Practice, Australian Pharmaceutical Formulary, British Pharmacopeia, Professional Compounding Chemists of Australia, Pharmaceutical Society of Australia standards and the United States Pharmacopeia. ○ Act as the main trainer together with the Quality Associate for all Compounders ensuring all adhere to, champion, and maintain all non-sterile compounding standards and ensuring all training and staff validation records are kept up-to-date and revised constantly as compounding processes are being updated. ○ Investigate non-conformances and discuss findings in team meetings. ○ Instill a culture of no-blame, transparency, and a continuous learning from non-conformances amongst production staff. ○ Action any Change Control (CC) forms and Corrective Action/Preventative Action (CAPA) forms identified by non-conformance reports and trends.
Planned Preventative Maintenance	○ Aid the Production Manager in actioning the planned preventative maintenance (PPM) programme for all laboratory equipment, compounding hardware and software, laboratory fixtures e.g., Air Handling Unit and portable appliance testing.
Good Stock Management	○ Together with the Production Manager and Production Supervisor assist Procurement Lead to ensure there is good stock management and a continuous supply of stock, ensuring that there are no stock outs of raw materials and primary packaging. ○ Stock management includes: ▪ Forecasting usage of SP stock for an efficient ordering process. ▪ Constant communication with the approved pharmaceutical suppliers to follow up on orders placed. ▪ Ensure continuity of supply through horizon scanning and accurate stock forecasting and analysis – communicating with the approved pharmaceutical suppliers. ▪ Confirm and approve input of stocks into the compounding software and ensure all certificates of analysis and any other quality control/assurance are obtained, checked by a pharmacist, and file appropriately. ▪ Ensure an effective stock rotation process is in place including expiry checks. ▪ Effective API waste management – ensuring wastage is kept to a minimum. ▪ Confirm and approve the monthly reports for stock counts produced by the Production Manager or Production Supervisor including current stock figures (stock levels and stock value). ▪ Participate in the safe and effective procurement process for Active Pharmaceutical APIs, Bases, Consumables, and any other items required in the compounding process.

Compounding Risk Register	○ Participate in all risk assessments of all laboratory equipment and processes. ○ Action any Change Control (CC) forms and Corrective Action/Preventative Action (CAPA) forms identified by risk assessments.
Service Improvement	○ Together with the Compounders, Production Supervisor, Production Manager, and the Senior Pharmacist strive to continuously improve the service by producing, gathering, and implementing initiatives using the change control process including methods of compounding, automation of process and any other process/safety initiatives
Staff Management and other Duties	○ Together with the Production Supervisor manage the rotas for compounding. ○ Supervise and participate in daily compounding meetings to discuss schedules of work and communicate any changes/solve problems effectively. ○ Strive to continuously develop compounders skills and promote good teamwork across all areas of the pharmacy service (Patient Care Team, Dispensary, Pharmacist Team and Production). ○ Participate in compounding duties as practicable. ○ Participate in dispensary duties including labelling, packaging, and dispensing when required.
Skills Required	○ Excellent people management skills. ○ Ability to work to tight deadlines. ○ Ability to follow instructions methodically with excellent attention to detail. ○ Ability to problem solve and action change effectively with minimum supervision. ○ Able to work with minimal supervision. ○ Pharmacy NVQ Level 3, GPhC-registered Pharmacy Technician or working towards ○ Basic computer skills essential. ○ Flexible and adaptable to meet the needs of SP, e.g., accommodating for part time / shifts would be required. ○ Production/Compounding experience is essential.
Colleagues at Gluck Holdings Ltd should be …	○ Able to Institute leadership, help people do a better job. ○ Customer Focused, at the forefront of providing service excellence. ○ Action Oriented, able to take on new challenges with enthusiasm. ○ Trustworthy, able to gain the confidence and trust of others easily and honour commitments. ○ Innovative, able to spot opportunities to do things better and share best practice. ○ Collaborative, building and maintaining strong working relationships and working with colleagues to meet shared goals. ○ Cultivating Innovation, embracing the concept that the business should never stand still, challenging the status quo and not settle for anything but #1. ○ Strategically minded, comfortable to shift their thinking between the short and long term to lead us towards future success. ○ Collaborative, modelling collaboration at all levels and promoting high visibility of shared contributions to goals.