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| **Role Title:** | Principal Pharmacist Aseptic Quality and Stability (HPN and Small volume) | **Department:** | Clinical Pharmacy Services  | **Budget:** | NA |
| **Direct Reports:** | N/A | **Reports To:** | Head of Clinical Pharmacy  | **Version:** | V1.3 |

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| **Role Purpose:** | **Key Accountabilities**  |
| To oversee the clinical dimensions of aseptic quality and stability, ensuring regulatory compliance, advancing compounded medication protocols, optimizing prescription workflows, and collaborating with stakeholders to provide patient-focused, safe, and high-quality pharmaceutical services that enhance care outcomes | 1. Ensures compliance of all aseptic processes and compounded medications with all UK regulatory standards, including Yellow Cover Documents (YCD), MHRA guidelines and Good Manufacturing Practice (GMP), maintaining the highest standards of patient safety and product quality2. Drive efficiencies in clinical pharmacy workflows by reviewing, updating, and enhancing stability protocols, prescription processes, and associated standards for compounded medications, ensuring safe, effective, and patient-centred outcomes 3. Drives innovation through advancements in compounded medication stability through research, development, and implementation of innovative practices4. Delivers a robust pharmacy quality assurance framework by conducting risk assessments, managing incidents and non-conformances, and driving continuous improvement to uphold clinical and operational excellence5. Increases capability across LPCH around aseptic quality and stability – acts as the subject matter expert, providing guidance and training to colleagues and customers where appropriate 6. Builds relationships and working closely with internal stakeholders to deliver the highest standards of service, supporting and identifying commercial opportunities and building customer relationships  |

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| **Key Accountabilities:** | **Key Measures of Success:** |
| 1. **Ensures compliance of all aseptic processes and compounded medications with all UK regulatory standards, including Yellow Cover Documents (YCD), MHRA guidelines and Good Manufacturing Practice (GMP), maintaining the highest standards of patient safety and product quality**
* Conduct regular audits to ensure adherence to Yellow Cover Documents (YCD), MHRA guidelines, and GMP standards
* Develop and maintain comprehensive standard operating procedures (SOPs) for aseptic processes and compounded medications
* Uphold knowledge on regulatory changes and communicate updates to relevant teams
* Provide oversight and validation of aseptic processes, ensuring alignment with regulatory and quality requirements
* Ensure effective documentation practices to demonstrate compliance and support traceability
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| 1. **Drive efficiencies in clinical pharmacy workflows by reviewing, updating, and enhancing stability protocols, prescription processes, and associated standards for compounded medications, ensuring safe, effective, and patient-centred outcomes**
* Evaluate and streamline existing stability protocols and prescription processes to eliminate inefficiencies.
* Implement tools or systems to automate and improve workflow accuracy and speed.
* Regularly review and revise standards for compounded medications based on the latest clinical and regulatory evidence.
* Monitor and analyse workflow metrics to identify areas for improvement and drive implementation of changes.
* Collaborate with multidisciplinary teams to ensure that patient-centred care remains the core focus of process improvements
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| 1. **Drives innovation through advancements in compounded medication stability through research, development, and implementation of innovative practices**
* Stays updated with emerging trends, new medications, and advancements in pharmacy practice
* Lead research initiatives on stability protocols and innovative compounding practices.
* Explore and integrate new technologies that enhance medication stability and quality.
* Collaborate with academic institutions or industry partners to stay at the forefront of advancements in aseptic compounding.
* Pilot new methodologies and evaluate their impact on safety, efficacy, and operational efficiency.
* Disseminate findings and best practices through reports, publications, and presentations within the organisation
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| 1. **Delivers a robust pharmacy quality assurance framework by conducting risk assessments, managing incidents and non-conformances, and driving continuous improvement to uphold clinical and operational excellence**
* Co-ordinates and delegates workload to meet operational requirements; including follow-up and feedback
* Conduct and document comprehensive risk assessments to identify and mitigate potential issues.
* Oversee incident reporting and investigation processes to identify root causes and implement corrective actions.
* Regularly review and update quality assurance policies and procedures to reflect current best practices.
* Lead training sessions to ensure colleagues understand and adhere to quality assurance standards.
* Promote a culture of continuous improvement through the implementation of lessons learned from non-conformances and audits
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| 1. **Increases capability across LPCH around aseptic quality and stability – acts as the subject matter expert, providing guidance and training to colleagues and customers where appropriate**
* Provides structured mentoring support for Technicians as part of their programme to become qualified
* Develop and deliver training programmes to build expertise in aseptic processes and stability among staff.
* Provide on-the-job mentoring and act as a resource for colleagues seeking advice on aseptic quality matters.
* Create and distribute educational materials to reinforce best practices and new standards.
* Support professional development opportunities for staff through workshops, seminars, and certifications.
* Actively participate in industry forums and share insights with the broader team to enhance internal capabilities
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| 1. **Builds relationships and working closely with internal stakeholders to deliver the highest standards of service, supporting and identifying commercial opportunities and building customer relationships**
* Engage with internal stakeholders to understand service requirements and align pharmacy operations accordingly.
* Actively participate in cross-functional meetings to foster collaboration and ensure cohesive service delivery.
* Identify and support commercial opportunities by providing clinical expertise to business development teams.
* Build strong relationships with customers, providing clear communication and tailored solutions to their needs.
* Monitor customer satisfaction and gather feedback to drive service enhancements and reinforce trust
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| **Enablers to the Role (Skills, Knowledge, Experience)** |
| **Skills*** Advanced understanding of aseptic processes, including sterility assurance and quality control
* Strong communication and collaboration skills for engaging with internal and external stakeholders
* Analytical and problem-solving skills to identify process inefficiencies and implement improvements
* High attention to detail and accuracy in monitoring and maintaining quality standards
* Project management skills to plan and oversee aseptic quality initiatives effectively
* Proficiency in applying regulatory and GMP requirements to aseptic environments
* Ability to interpret and apply stability data to support compounded medication quality
* Capability to innovate and adapt to advancements in aseptic and pharmaceutical practices

**Knowledge*** Comprehensive knowledge of Good Manufacturing Practice (GMP) and MHRA guidelines for aseptic production
* Understanding of pharmaceutical stability studies, including compatibility assessments
* Familiarity with quality assurance systems, including incident reporting and root cause analysis
* Awareness of health and safety standards related to aseptic environments
* Knowledge of UK-specific regulatory frameworks for compounded medications and homecare settings
* Understanding of aseptic processing technologies and equipment
* Awareness of advancements in medication stability and aseptic techniques
* Familiarity with risk management processes related to aseptic production

**Experience*** Significant experience working in aseptic pharmacy or pharmaceutical manufacturing.
* Proven track record of ensuring compliance with GMP and regulatory standards.
* Hands-on experience in optimizing aseptic workflows and processes.
* Practical experience conducting and applying pharmaceutical stability studies.
* Experience supporting audits and quality assurance reviews in a regulated environment.
* Demonstrated success in delivering projects related to aseptic quality improvements.
* Familiarity with the operational challenges of homecare pharmacy services.
* Experience collaborating with multidisciplinary teams to achieve quality and compliance goals
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