GLAXOSMITHKLINE
Job Description

An Organization chart must be attached

Job Title: Responsible Person Slovenia Rx	
Reports to: Country LOC Quality Lead Slovenia	**Job Creation Date:**
Business Level 1: Pharma Quality Slovenia	
Business Level 2: Pharma EU Central Europe Cluster	
Business Level 3: Pharma EU Regional LOC Quality	
Business Level 4: EU & EMAP Pharma Supply Chain Quality	

JOB PURPOSE :

Provides effective and efficient quality assurance systems support to the Country Quality Manager, including supporting the implementation and maintenance of the QMS with specific focus on and distribution related activities.
As directed by the Country Quality Manager, performs the day to day work in line with the Responsible Person responsibilities to ensure that the quality systems required by the LOC element of the Supply Chain and Marketing Company LOC, for Pharma organization, are performed in a lean and efficient way and meet the compliance standards of the QMS and the local Regulator.

KEY ACCOUNTABILITIES / RESPONSIBILITIES :

- **Quality Strategy**
  - As Responsible Person, maintain a high level of QMS and local regulatory knowledge and awareness of changes within the commercial environment to seek opportunities and manage potential business adversity with regards warehousing and distribution activities. Act as a Responsible Person of GlaxoSmithKline Slovenia according to Medicinal Products Act, Official Gazette 17/14 and Rules on the system for the receipt, storage and traceability of medicinal products, Official Gazette 82/15.
  - As a Responsible Person, in line with EU and Local regulations, maintains a high level of QMS and local regulatory knowledge and awareness of changes within the commercial environment to seek opportunities and manage potential business adversity with regards GDP activities.
  - Gain an understanding of the Supply Chain and Commercial LOC Business and Quality Plan at a high as they potentially link to day to day and quality improvement activities.

- **Quality Systems**
  - As Responsible Person, support the LOC Quality Lead to ensure that internal procedures and systems related to warehousing and distribution are in place and in use in the LOC and the LSPs are compliant to GSK QMS, Guide for Commercial Companies and local regulatory requirements.
  - Responsible for performing day to day work to support systems that have an impact on the quality of imported products in line with the QMS and local Regulatory requirements including (but not limited to):
    - Maintains the relevant licenses and authorizations, in line with European and local regulations, to allow storage and distribution of Rx medicines in the Slovenian market;
    - Ensures all product specifications and related documents (e.g. CoAs, TTs) are maintained compliant to current registered details,

- Review quality of all incoming Pharma goods in MMW and in the local warehouse,
- Review quality of all repacked medicines at LSP
- Perform sampling when appropriate or requested,
- Ensure timely local Quality acceptance of imported finished Rx goods deliveries to or dispatched from the local LSP warehouse to the Slovenian market ,
- Resolve Quality-related issues arising from the above mentioned deliveries,
- Ensure appropriate process are in place for storage, including temperature monitoring and control, stock management (quarantined and rejected stocks) as well as withdrawal of medicinal products,
- Local Repacking – Support the Country LOC Quality Lead with communication to the GMS supplying sites, R&D and Cluster Quality as it relates to approval of repacking activities. Perform day to day work to support repacking requests ensuring regulatory and QA compliance, timely QA batch release of repacked orders before distribution and/or re-export. Ensure as appropriate documentation of batch records and retention of samples.
- Archiving and maintenance of all quality documents in line with GSK's Policy and legal requirements.
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- **Risk Management** - perform activities to support the risk management process to ensure effective management, timely reporting, review and escalation of quality risks identified in warehouse and distribution activities.

- **Management of Distributor/ Logistics Service Provider/ Contractor:**
  - Ensures there is a process in place to allow all new and existing suppliers/ 3rd party contractors/ service providers that have a direct impact on product quality to be identified and audited by either LOC QA Team or the appropriate Central Team (e.g. ESA). e.g. repacking contractors, warehouses, freight management, printed packaging component suppliers.
  - Train the LSP operators in relevant GDP processes as well as LOC members when involved in distribution.

- **Corrective and Preventative Actions (CAPA)** - effectively manage corrective and preventative action plans linked to warehousing and distribution, conduct root cause analysis to investigate deviations and develop CAPA's. Local process in place to track and review CAPA plans on routine basis.

- **Artwork management** - perform day to day work in line with the roles and responsibilities for quality as defined in the local artwork procedures.

- **Auditing -** perform day to day work to support the local process that is in place for for MM (Management monitoring) and IBM (Independent Business Monitoring) auditing. Work with the Country LOC Quality Lead to ensure
  - There is a process in place to ensure all new and existing suppliers/ 3rd party contractors/ service providers that have a direct impact on product quality are identified and audited by either LOC QA Team or the appropriate Central Team (e.g. ESA). e.g. repacking contractors, warehouses, freight management, off-site archive sites, printed packaging component suppliers, archiving companies.
  - Conduct audits or support corporate organization audits (as ESA) of artwork printers, printed packaging component suppliers, archiving companies and ensures that the contractors comply with GSK and regulatory requirements.
  - The GDP Quality elements of the Marketing Company are audit ready for any relevant Level 3 or 4 audits.

- **LOC Quality Council** – support the Country LOC Quality Lead re organizing Council meeting with regular meetings. This support should ensure that the LOC Quality Council format, frequency and reporting are standardised to global requirements. In addition support should be provided re Quality metrics and reporting format/ system in place.

- **Change Control** - Support the Country LOC Quality Lead to ensure that an effective local change control process with the aim of ensuring all planned major changes impacting warehousing and distribution are effectively and compliantly managed. Processes in place to routinely review progress of changes and close out when completed.

- **Incident management** – Support the Country LOC Quality Lead to ensure that an effective local product incident process is in place to escalate and manage any product quality related issues identified in the warehousing and distribution activities. Assist the Country LOC Quality Manager in any investigations triggered by local warehousing and distribution incidents and in conducting LOC Incident Committees.

- **Complaints** - Support the Country LOC Quality Lead to ensure that an effective local complaints management process ensuring
  - the assessment of potential issues are determine as quickly as possible and linked to the adverse event reporting process and local product incident process if/as appropriate.
  - report and follow up on product complaints with manufacturing sites, customers and commercial teams

- Support the Country LOC Quality Lead to ensure that all **SOPs** are in place, updated & training has been conducted across the business. Also support on monitoring system in place for tracking training compliance and process for escalation of persistent non-compliance. Processes in place for delivering routine training for updates to SOPs, GQPs, and GQMPs as relevant.

- **Contact with Local Regulatory Agency:**
  - Report any counterfeit and non conform or rejected batches delivered to the local warehouse identified as not meeting the requested quality criteria,
  - Communicate shortage of stocks or supplies which would jeopardize fulfillment of orders within Slovenian market

- **Other**
  - Supporting the Country LOC Quality Lead to ensure a robust, sustainable and effective QMS (Quality Management System) through monitoring and reviewing the compliance status within the Slovenian Pharma are Marketing Company.
  - Promote QMS management principles and seek continuous improvement of the processes
  - Review, conduct impact assessments and implement any updates to QMS policies
  - Identify, Implement and Manage QA Objectives & KPIs
  - Establish and manage Annual Quality Plans

  Acts in the role of the Country LOC Quality Lead in his absence or when applicable in organizing and Charring effective LOC Quality Councils

- ***Reporting Line:***

1. *Report dotted line to – N/A*
2. *Report solid line to the Country LOC Quality Lead*

KNOWLEDGE / EXPERIENCE / SKILLS / COMPETENCIES REQUIRED :

Education and Experience:

- Successful completion of relevant tertiary qualifications – science degree of Faculty of Pharmacy
- At least 1 year of practical experience in one or more pharmaceutical companies thet are authorized to manufacture medical products, the activities of quality control of medicinal products, quantitative analysis of active pharmaceutical substances and analyzing and testing to ensure the quality of medicine
- Strong understanding of and experience in quality assurance systems particularly in the areas

of batch release, audits and repacking.
- Strong knowledge of regulatory requirements pertaining to GMP/GDP
- Good knowledge on effective quality documentation systems

Essential Skills and Abilities:
- Professional written and verbal communication skills
- Ability to deliver clear communications and foster excellent working relationships with peers and management
- Analytical mind, good problem solving skills within a structured process and good attention to detail
- Good team player – works well in cross-functional teams
- Ability to multi-task and work under pressure
- Good time management skills, with ability to multi-task and work under pressure
- Concise and persuasive in the description of the different QA situations
- Works with a spirit of continuous improvement and innovation, creatively open to new ideas and methods
- Flexible thinking – able to challenge and see views from different perspectives
- Ability to self-motivate and be resilient and focused under pressure
- Strong general computer literacy with Intermediate skills in Microsoft Word, Excel, Power Point and Outlook

JOB FACTORS

ACCOUNTABILITY:

Pharma Commercial operating business units, global QA and Global Logistics
- Technical expert within function, working with moderate supervision from Line Manager.
- Responsible Person in line with local Regulatory requirements
- Administers and executes policies, processes, and procedures and supports the development and implementation of policies and processes within specific area of expertise.
- Leads departmental projects.
- Usually no Line Management responsibility, but may supervise entry-level or skilled / hourly employees. May provide coaching and training to team members.
- Key role in ensuring overall quality targets are achieved for Rx organization within agreed timelines .
- Reports to organizational level 2 of Pharma CE Cluster Quality
- Has no managerial level as subordinate.
- No budget responsibility.

COMPLEXITY:

Solving issues:
The job operates in a defined environment where changes occur.
Assignments are task or activity oriented. Work is reviewed on overall quality and efficiency.
Identifies problems and implements solutions.
Diverging problems/ incomplete and uncertain information; a detailed analysis of the issue is necessary.

Interpersonal skills:
Interacts internally with and influences non quality colleagues. Primary purpose of liaison is information sharing and basic problem resolution.
Externally interacts with and influences customers, suppliers and vendors.
Communicates with the Authority.
Job holder must have an understanding of heterogeneous departments/ cross functions.

Job position is open for 0,5 FTE.

Organization chart