【900～万円】Associate Director Product Quality Quality Informati…

日本イーライリリー株式会社での募集です。 メディカルGQP・GMP・品質保証・…

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
日本イーライリリー株式会社

Job ID
1591867

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Hyogo Prefecture

Salary
9 million yen ~ Negotiable, based on experience

Work Hours
08:45 ～ 17:30

Holidays
【有給休暇】初年度 10日 2か月目から付与及び使用可能 ※入社月により変動します 年途中で入社した社員に対する年次有給休暇は…

Refreshed
May 14th, 2026 15:55

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2379475】
【Scope】
The Associate Director Product Quality Quality Information （PQQI） sets the strategy and leads the PQQI function for Lilly Japan with direct accountability for both the Product Quality and Quality Information teams and their respective staff including the QI Team Leader.

The role ensures compliant effective and efficient operations across the full product lifecycle ・ spanning pre market through post launch phases ・ with particular emphasis on GQP governed activities product launches and quality information management processes. The Associate Director is accountable for maintaining robust GQP operations driving operational excellence and fostering cross functional alignment in a dynamic and rapidly evolving business environment.

【Specific functions duties or tasks】
Leadership Team Management
・Determine the strategic direction and execution plan of the PQQI team aligned with the overall Japan QA strategy set by the Japan affiliate quality leader to ensure success of ELJ 2030 and Accelerate Reach and Scale at the affiliate. ・・
・Partnering with the Japan affiliate quality leader （Hinseki） determine execute and continuously improve PQQI strategy for today and future business needs
・Lead the PQQI team directly managing both the PQ function and the QI Leader （M1） who reports directly to this role. Serve as the single accountable leader for all GQP related operations across both teams.
・Drive organizational effectiveness by integrating PQ and QI functions exploiting synergies to improve quality outcomes speed and operational efficiency.
・Lead the team through a high period of growth and a rapidly changing business environment model adaptability clear prioritization and resilience.
・Manage all people related responsibilities including performance management talent development resource allocation diversity and inclusion and recognition for direct reports and the extended PQQI team.
・Ensure team members are appropriately qualified and trained; maintain and continuously improve training curriculum maps covering GQP QMS GMP and Japan regulatory requirements.
・Foster a culture of accountability continuous improvement and high performance; support Q unit members in maintaining a healthy work life balance.

GQP Compliance Quality Management
・Accountable for all GQP and QI operations within the PQQI team both pre and post product launch including product release complaint quality management quality information reporting and sourcing site oversight.
・Ensure the operational execution of PAI and GMP inspection readiness and support processes at all manufacturing packaging and supplying sites for Japan marketed products.
・Work with the P4 Inspection Readiness/Support Process Owner and GQP SME to ensure effective and efficient PAI and GMP inspection processes.
・Establish implement and maintain GQP/QMS and GDP standards and SOPs in accordance with the Pharmaceutical and Medical Device Act （PMD Act） and applicable corporate standards （LQS GQS CQP）.
・Manage Marketing Affiliate quality activities per GQS181 and applicable GSOPs; oversee and maintain agreements with sourcing sites; liaise with ELJ QA and sourcing site QA to uphold importing product quality standards.
・Create and maintain robust systems for final product release to market; review and approve proposed changes and deviations in accordance with GQP requirements.
・Serve as Product Quality Representative （PQR） per JQA00 01 “Quality Manual.” Lead JCS and JSC activities.

Process Excellence Operational Efficiency
・Drive the design and implementation of clear simplified and efficient processes across the PQQI team with well defined roles and responsibilities and strong cross functional alignment.
・Continuously improve QI complaint handling processes and PQQI quality systems; establish monitor and act on team metrics and corrective actions to ensure delivery against commitments.
・Monitor ELJ quality and regulatory activities; maintain and improve communication between Japan and sourcing sites; influence business partner processes to improve compliance and efficiency.

Product Quality Quality Information
・Ensure the PQQI team is launch ready for new products line extensions and process or product changes; provide timely quality feedback to project teams to support pre launch quality preparedness.
・Oversee the provision of accurate timely and trustworthy quality reports to customers through APRC and QI support call center with technical and quality information.
・Periodically review and communicate quality and performance metrics and trends; propose product process and service improvements to appropriate functions.
・Build and sustain strong working relationships with ELJ QA call center manufacturing and packaging site quality teams ELJ regulatory and other internal and external partners.
・Maintain awareness of and ensure alignment to the latest corporate policies procedures and local regulations; propagate “Japan Quality” standards to overseas sourcing sites.

Required Skills

【Leadership Competencies （Critical for this Role）】
・Demonstrated ability to set strategy lead develop and inspire multi functional teams proven track record as a people leader in a regulated pharmaceutical environment.
・Proven ability to drive organizational integration and exploit synergies across functions; experience leading teams through high growth or rapid change.
・Strong process design and simplification skills; demonstrated ability to define clear roles and responsibilities and remove ambiguity in complex cross functional environments.
・Deep understanding of GQP/QMS/GMP/GDP regulations and applicable Lilly corporate standards （LQS GQS CQP GSOPs）; ability to interpret and apply regulatory requirements with practical business judgment and quality risk management principles.
・Strong cross functional influencing and stakeholder management skills （including global teams and stakeholders）; capability to build and sustain productive relationships with internal and external partners including sourcing sites call center regulatory and senior leadership.
・Strong critical thinking and problem solving capability; ability to lead teams to root cause resolution based on sound technical and scientific understanding.
・Demonstrated ability to coach and develop direct reports including 1st line leaders; experience building team capability and succession depth.

【Qualifications】

・Bachelor’s degree or higher in pharmacy chemistry biology engineering or related health science field; advanced degree preferred.
・Substantial experience （minimum 5 years） in GQP/QMS/GMP/GDP quality operations within the pharmaceutical industry with progressive leadership responsibility.

【Education and Work Experience Desirable to Perform Role】
・Strong oral and written English and Japanese communication skills.
・Demonstrated leadership experience with multi functional teams.
・Experience in Marketing Affiliate quality operations and sourcing site management; knowledge of Lilly marketed products compounds in development manufacturing processes and complaint investigations preferred.
・Experience managing through organizational change and business growth; proven ability to deliver results in dynamic evolving environments.

Company Description

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