

QA Team Leader Compliance (Pharma)

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Company: Piramal Pharma Solutions

Location: Grangemouth

Category: other-general

The role of the QA TL (Compliance) is to ensure governance and compliance of the Pharmaceutical Quality Management System (PQS) and maintain Regulatory Registrations/Licenses/Certifications at Piramal Grangemouth. The position holder will have responsibility to coordinate, maintain and promote compliance, leading continuous improvement of quality and regulatory systems. The role will support and ensure that the site and related functions are in compliance with GxP regulations and applicable quality guidelines, including, but not limited to UK/EU/US GMP/GDP, ICH and other region specific guidance. The individual will have ownership for key quality system elements and will support and execute site quality and compliance improvements, working closely with relevant stakeholders on site. Role Compliance governance of key quality system elements, including scheduling and completion of; Quality Management Reviews, Qualification of Vendors, PQRs, Audits (Self-Inspections, Vendor Audits, Customer Audits). Maintain site establishment registrations with regulatory agencies as applicable. Coordinate tracking of site compliance commitments and follow up actions. Coordinate and support the delivery of Quality Compliance Metrics/KPIs to key stakeholders. Identify GxP trends and communicate these to relevant stakeholders. Support compliance risk management activities and implementation of risk mitigation plans. Working with the wider site functions to drive down out of compliance events, identify and implement quality improvements. Coordinate QMS training for site employees and ensure this adheres to current regulatory requirements. Maintain responsibility as the site system owner for the Trackwise electronic QMS. Support and track regulatory findings and trends that may lead into a focus of regulatory inspections. Act as

Single Point of Contact between site and Corporate Quality Team as delegated by QA Manager. Assure compliance of procedures according to internal guidelines and UK/EU/US/ICH and other region specific guidance. Lead Quality Management Review meetings highlighting GxP areas of concern and working to support and track actions that are to be taken. Support quality related investigations, assist in the development and approval of effective CAPA in order to resolve product, audit and customer issues. Support effective pre-audit preparation, management and post audit follow up of customer audits and regulatory inspections. Escalate any significant breach of quality or regulatory compliance to the QA Manager (Compliance) and Head of Quality. Keep up to date and integrate current quality standards, guidelines and best practice on site. Ensure compliance by promoting understanding of the underlying concepts. Ensure productive working relationships are maintained between QA and other site personnel and stakeholders.

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