

Head, Knowledge Management and Quality Risk Management

Job ID: 00413806

Job Function

Management Quality

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Executive (Director/VP/SVP)

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

Accountable for developing strategy and program to establish processes and tools to manage technical product knowledge and information throughout the product lifecycle in accordance with Knowledge Management as an enabling element of the Pharmaceutical Quality system. Accountable for planning, leading and coordinating activities involved in the implementation, governance, and continual improvement of the Pharmaceutical Technical Operations (PT) Quality Risk Management (QRM) Program including standards, business processes, and tools within the Pharmaceutical Quality System (PQS) to ensure consistent and GMP compliant QRM practices. Engage in external interactions to influence the development of industry best practices in a manner that provides a competitive and strategic advantage to Roche; monitor the external environment for regulatory changes and emerging issues.

Lead Knowledge Management and Quality Risk Management function including organizational design and implementation, staffing, talent management, performance management, financial budgeting and financial performance, and execution to meet strategic and operational goal. Specific focus on developing organizational model to support PQS Knowledge Management program. Direct staff in setting operational objectives and business goals for their respective areas of responsibility. Establish and monitor performance

measures and objectives for the function.

Major Responsibilities

- Accountable for the development, deployment, full realization, and continual improvement of the PQS Knowledge Management Program in alignment with current regulatory expectations and in collaboration with the PT Supply Chain organization. Includes developing strategy and program to establish processes and tools to manage technical product knowledge and information throughout the product lifecycle in accordance with Knowledge Management as an enabling element of ICH Q10. Specifically includes implementation and maintenance of a Quality Requirement, Global Standard and Procedure, business processes, and tools.
- Accountable for ensuring that the PQS Knowledge Management program is integrated with other PT knowledge management and business intelligence initiatives. Influence across matrix to drive strategic approach and decisions at a functional and cross-functional levels.
- Accountable for the development, deployment, full realization, and continual improvement of the PT Quality Risk Management Program in alignment with current regulatory expectations and in collaboration with the PT Supply Chain organization. Specifically includes the following: implementation and maintenance of a Quality Requirement, Global Standard and Procedure, business processes, and tools
- Accountable for ensuring integration of QRM throughout the product and process lifecycle, and as an enabler within the Pharmaceutical Quality System (PQS).
- Responsible for proactive identification, assessment and management of Quality and Compliance risk across PT operation to ensure compliance and quality supply to patients.
- Accountable for partnering with customers, key stakeholders and senior management across PT Global Operational Units, Functional Units and sites to a.) communicate and escalate Quality risks, resolve conflicts, and drive value-add risk based processes, pragmatic decisions and practices and b.) ensure the Knowledge Management Program for PQS is appropriately integrated with other knowledge management and business intelligence initiatives across the PT organization.
- Serve as Quality representative to the Integrated Risk Management (IRM) Core Team. Accountable to work in conjunction with the IRM team to implement, maintain, and continually improve the RM Training and Certification Program. Ensure all roles involved in QRM activities across all levels of the organization are supported through the RM training and certification program.
- Accountable for implementation, sustainment, and continual improvement of processes that ensure proactive identification and management of Quality and Compliance related risks across PT operations to ensure compliance and quality supply to patients.
- Communicate regularly with appropriate management and decision makers to ensure potential quality or regulatory issues that may affect product quality, patient safety or regulatory compliance are escalated and managed adequately.
- Implement, maintain, and communicate relevant QRM metrics.
- Actively engage in external interactions (including regulatory agencies) to influence the development of industry best practices for QRM in a manner that provides a competitive and strategic advantage to Roche. Support staff development through targeted participating in

industry activities. Monitor environment for regulatory changes and emerging issues.

- Directly responsible for organization design and implementation to include staffing, talent management, performance management, budgeting and resource allocation
- Accountable for PQS-related budget and financial performance of function

Who You Are

B.S. or B.A degree (prefer ably in Life Science, Statistics or Risk Management) with Graduate or Ph.D preferred and fifteen plus years relevant experience in the pharmaceutical or biopharmaceutical industry (manufacturing, supply chain, engineering, etc).

- Demonstrated experience and highly competent in Quality Risk Management (QRM) including tools; demonstrated Knowledge Management experience
- Eight to ten years' previous people management experience, preferably leading Quality Risk Management and/or Knowledge Management programs. Experience managing cross function operations and staff.
- Highly competent in EU, US, Japan, and ICH GMPs with a good understanding of current trends and expectations of Quality Risk Management and Knowledge Management
- Active membership in Quality Risk Management and Knowledge Management industry-related organizations preferred. Ability to identify and share best practices in the scientific quality field.
- Demonstrated experience and with Quality Systems including demonstrated successful development and practical deployment
- Demonstrated track record of consistently appropriate business judgment and decisions
- International business experience
- Has successfully led processes and other continuous improvements.
- Previous experience successfully interacting with management at all levels across an organization
- Clear and concise communicator
- Ability to travel domestically and internationally approximately 25%

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