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# Example of Director, Quality Systems Job Description

Our growing company is looking to fill the role of director, quality systems. Please review the list of responsibilities and qualifications. While this is our ideal list, we will consider candidates that do not necessarily have all of the qualifications, but have sufficient experience and talent.

## Responsibilities for director, quality systems

* Establish and oversee an independent escalation method to support global GxP CAPA governance
* Appropriately escalate individual CAPAs at risk and/or negative trends in Key Performance Indicators to the appropriate forums and management
* Interact with key senior leaders to maintain executive awareness of GxP CAPA performance
* Oversee the planning, execution and delivery of CAPA strategies/plans for the remediation, correction and prevention of recurrence of those significant quality events with broader impact across the Janssen R&D QMS
* Drive investigation of large scale significant quality events, including the identification of issues, impact assessment, root cause analysis, oversight of appropriate communication and escalation to senior leadership, as appropriate
* Establish defined thresholds enabling the tracking/trending of escalated issues across the QMS holistically inclusive of CAPA escalations to leadership councils or forums
* Develop CAPA trending capabilities, enabling the identification of systemic root causes leading to the implementation of solutions to eliminate root causes
* Establish and drive the use of accurate and actionable metrics for clearly identifying areas of risk, performance to commitments, effectiveness and timeliness of GxP CAPAs
* Ensure the effective functioning of CAPA system/process to eliminate the causes of detected discrepancies (reactive), and preventive actions are in place to eliminate the causes of potential discrepancies of other undesirable situations (proactive)
* Lead a team and contribute to the effective and accurate implementation and delivery of global Good Clinical Practice (GCP) CAPA management in Janssen R&D

## Qualifications for director, quality systems

* Demonstrated success leading cross-functional development, implementation, application, and maintenance of Quality Systems
* Well versed with regulatory compliance (GxP, 21CFR Part 11, EU Annex 11 )
* Experience with conducting risk assessment and knowledge of current industry good practice for risk assessment methodologies and tools, , GAMP-5, NIST, ICH
* A minimum of 10 years of experience in a medium to large scale matrix organization is required
* Experience managing staff, developing future quality leaders and building an organizational culture is required
* Ability to effectively operate in a matrix environment and influence and interact with senior enterprise leaders and functional leaders on a regular basis is required