Team Lead - Quality Operations

Job ID
REQ-10020782
Sep 12, 2024
Brazil

Summary

Manage all operations and activities supported by QOP to ensure it complies with business partner´s requirements, cGMP regulatory requirements and the Novartis Quality Manual & Policies.

About the Role

Major accountabilities:

- Direct, oversee and coordinate all processes supported by QOP Mexico.
- Select, recruit, develop, manage, coach, coordinate and appraise the performance of direct reporting associates and ensure high quality performance management across the team. Additionally, support the professional growth and talent development of team members through mentorship and training initiatives, fostering a culture of learning, collaboration, and career advancement.
- Ensure efficient and transparent allocation of resources to each process and assignment of activities to ensure on time and right first-time deliverables.
- Author, review and approve GxP documents and reports like trends, performance, qualification, validation, quality events and technical investigations.
- Hold and manage key accounts in workflow applications (like AQWA, AGILE, 1QEM, SAP etc.) to ensure appropriate execution of deliverables.
- Generate and analyze predefined and ad-hoc reports in various quality systems and perform follow-up actions if required.
- Ensure compliance of the responsible QOP team to the Novartis internal quality standards, relevant regulatory requirements, filed product quality standards and service level agreements.
- Support, monitors and reports on process, data and system integrity & performance in order to proactively drive adherence to the defined process, within the organization, as well as to achieve excellence in the process and system.
- Lead new developments or expansion projects and transitions. Monitor and report progress and deviations, as appropriate.
- Ensure business partner´s and QOP management is regularly informed of issues related to the support provided and elaborate risk mitigation plans, as appropriate.
- Act as escalation contact point for business partners and team members for any GxP or non-GxP issues and lead related investigations to ensure compliance with local and global operating procedures.
- Ensure all time readiness for business partners and internal audits and follow up on implementation of agreed CAPAs in the responsible areas.
- Support process harmonization and continuous improvement efforts, ensure quality standards and turnaround times are met.
- Assume proactive role in receiving and providing feedback to all our business partners.

- Collect and communicate the appropriate KPIs and metrics used to monitor team performance and project progress for management and customer review.
- Ensure the SOPs; working procedures, process maps, dashboards, are kept updated for all QOP processes.
- Provide technical guidance, mentoring and support to the onboarding associates in the team.
- Develop technical training content, establish training programs and impart training to the associates in the responsible area.
- Proactively collaborate with various teams to drive efficiency, productivity, operational excellence and innovation.

Key performance indicators:

- Assigned deliverables provided meet targets for quality, time and productivity in adherence with business standard operation procedures and in accordance with agreed performance indicators.
- Positive customer feedback
- People development
- Ability to find creative ways to improve and innovate
- No critical audit findings
- Maintain high standard in respect GxP practices within the teams

Minimum Requirements:
Work Experience:

- Overall 6-10 years of experience in GxP, Quality Assurance or related Pharma Domain. Past work reflects a track record of operational excellence.

Skills:

- Continuous Learning.
- Dealing With Ambiguity.
- Strong people management and development skills.
- GMP Procedures.
- QA (Quality Assurance).
- Quality Standards.
- Self Awareness.

Languages :

- PortuguesEnglish.

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Division
Operations
Business Unit
Innovative Medicines
Location
Brazil
Site
Santo Amaro
Company / Legal Entity
BR03 (FCRS = BR003) NOVARTIS BIOCIENCIAS S.A
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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