



Who we are:

Annual Product Quality Review & Complaint Operations:

The Global APQR program provides a holistic evaluation of products and processes to maintain compliance, drive continuous improvement, and reinforce Roche's reputation as a leader in the industry.

Objective

Reviews [...], should be conducted with the objective of **verifying the consistency of the existing process**, the **appropriateness of current specifications** for both starting materials and finished product, to **highlight any trends and to identify product and process improvements**.

Vision:

APQR Process Vision:

Real time product and process evaluations to maintain compliance, drive valuable continuous improvement and reinforce Roche's reputation as a leader in the industry.

Global APQR & Complaint Operations Team Vision:

An empowered, self-managed team of experts that exemplify open, dynamic collaboration driven by the values of trust, feedback, accountability, helpfulness and proactive continuous learning.

Notably, the successful incumbent:

- Conducts annual single-site, cross-site, and E2E reviews to deliver site and E2E APQR reports per requirements in GSP037.
- Supports the compilation of APQR reports via the acquisition and visualization of data from sites across the Roche network.
- Contributes to the performance metrics and overall Quality assessment and reporting as part of the APQR business process.
- Work with APQR stakeholders to identify, escalate, and resolve product quality issues.
- Proposes APQR actions items, as needed.
- Provides training and guidance as needed regarding the Global APQR process, including planning and implementation of procedures.
- Supports the development, maintenance, and execution of Global APQR systems, projects, and administrative activities.
- Perform any other tasks as assigned to support APQR and Quality oversight activities (e.g., process governance, systems/tools, operations maintenance, training matrices and materials, document and records management, procurement, etc.).
- Work independently to actively contribute to the success of the Global APQR team objectives and OKRs. Ensure cross-functional team deliverables are completed in a compliant, accurate, high quality and timely manner.

Our goal is to build a flexible pool of Quality resources. Part of this role might therefore be other quality work to match business needs with employee interest.



Annual Product Quality Review & Complaint Operations

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Who You Are:



Global APQR & Complaint Operations:

End-to-End Product Quality's goal is to enable faster launches and the delivery of compliant products to patients. End-to-End Product Quality will incorporate quality into the process through early collaboration with partners to support make-assess-release activities and to proactively mitigate errors from product development to divestment. Global APQR & Complaint Operations is accountable for ownership and execution of the APQR process and its performance. This Chapter is also accountable for the Quality management of Global Complaints for PDS Devices.

The successful incumbent supports and executes the APQR process per GSP037 "Annual Product Quality Review (APQR)" for Roche commercial products to identify trends and issues that affect the overall state of control of products and their manufacturing process throughout their life cycle, and, if necessary, appropriate actions for product quality issues.

Live these behaviours. We succeed and fail as a team



COACHING PROGRAM:

YOUR COACH WILL:

- HELP YOU BUILD THE SKILLS AND MINDSETS YOU NEED TO SUCCEED.
- ASK POWERFUL QUESTIONS WITH OPENNESS AND GRACE
- FOCUS ON YOUR PERSONAL GROWTH AND IS COMMITTED TO CREATING AN AMAZING EXPERIENCE
- PROVIDE A SAFE SPACE FOR OPEN DIALOG WITH THOSE BEING COACHED

PUT PATIENTS FIRST, FOLLOW THE SCIENCE, ACT AS ONE TEAM, EMBRACE DIFFERENCES, ACCELERATE LEARNING, SIMPLIFY RADICALLY, MAKE IMPACT NOW, THINK LONG TERM

Qualifications:

Education and Experience

- B.A., B.S. or Higher degree (preferably in Life Science).
- Experience collaborating in a global setting to support product teams and global quality initiatives is a plus.
- Technical expertise in small and large molecule drug substance and drug product manufacturing processes and associated control and documentation systems. Knowledge of medical devices and device combination products is desirable.
- Experience with enterprise database, collaboration platform tools, and analytics (IT platforms) is preferred.
- Experience in routine (business and/or compliance) metrics reporting processes is desirable.
- Experience with technical writing is a plus.

Knowledge / Skills / Competencies:

- Demonstrates strong knowledge of Global pharmaceutical/biotechnology industry regulations, and GMPs as well as Roche standards and guidance documents. This includes the ability to interpret standards for implementation and review.
- Demonstrates experience in Quality and pharmaceutical or biopharmaceutical manufacturing.
- Demonstrates strong knowledge of analytical data, critical thinking skills, proficiency in the application of statistics and technology platforms.
- Demonstrates excellence in communication. Must communicate clearly and professionally both in writing and verbally, including effective facilitation skills. Fluent in English.
- Ability to lead cross-functional teams to resolve complex technical, quality, and business process-related issues; extract optimized business results through skillful collaboration and application of principles for influencing without formal authority.
- Proactive in building relationships and working with global interdisciplinary teams in collaborative cross-functional settings.
- Drives continuous improvement and operates with a Lean and Agile mindset.
- Demonstrates resourcefulness, proactive dynamic learning potential, matrix leadership, and accountability.
- Mentors network stakeholders and Global APQR stakeholders on process governance, executions and business operations systems.
- An additional language proficiency to support Roche network regional collaboration preferred (especially German).



APQR Governance

Own and Manage the APQR Business Process in line with the Community of Practice Model.



APQR Authoring

Author End-to-End and Site APQR reports
End-to-End APQR reports are cross-site product evaluations



Performance

Monitor and report performance against metrics to support continuous improvement of our Business Process.

