LAÍS RAIANE PEREIRA GIL

QUALITY ASSURANCE | PHARMACEUTICAL OPERATIONS | VALIDATION
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PROFESSIONAL SUMMARY

Pharmacist with 8+ years of experience across pharmaceutical quality, validation, manufacturing documentation, and batch release, including progressive roles at Procter & Gamble. Experienced in leading teams, coordinating quality release activities, investigating deviations, driving CAPA, and improving quality systems. Led documentation digitalization initiatives with SAP integration and supported computerized system validation (CSV). Strong background in GMP compliance, equipment and process qualification, and cross-functional collaboration.

CORE COMPETENCIES

Quality Assurance & GMP Compliance | Pharmaceutical Batch Release | Team Leadership | Computerized System Validation (CSV) | Equipment & Process Qualification (IQ/OQ/PQ) | Deviation Investigation & CAPA | Change Control | Quality Documentation | APQR | Audit Readiness | Continuous Improvement | Document Digitalization | SAP Integration

PROFESSIONAL EXPERIENCE

PROCTER & GAMBLE | December 2021 – Present

Quality Release Team Lead | May 2025 – Present

- Lead pharmaceutical batch release operations, ensuring compliance with Good Manufacturing Practices (GMP) and applicable regulatory requirements.
- Coordinate batch record review and finished-product release activities.
- Lead the team, set priorities, and allocate work to support production schedules and release timelines.
- Lead quality documentation digitalization and process optimization initiatives, including system integration and interfaces with SAP.
- Monitor departmental performance indicators and implement continuous improvement actions.
- Oversee quality deviation reporting, investigations, root cause analysis, and Corrective and Preventive Actions (CAPA).
- Review and approve quality documentation related to pharmaceutical manufacturing and batch release.
- Participate in internal and external audits and regulatory inspections.

Senior Quality Release Analyst | August 2024 – April 2025

- Performed technical review of manufacturing and quality control documentation to support pharmaceutical batch release and regulatory compliance.
- Reviewed manufacturing records, packaging records, and analytical documentation.
- Evaluated quality deviations, change controls, and quality investigations.
- Supported improvements to documentation workflows and computerized systems.
- Worked cross-functionally with Manufacturing, Quality Control, Quality Assurance, and Supply Chain to resolve batch release issues.
- Contributed to process digitalization projects and document integration with SAP.

Senior Validation Analyst | December 2021 – July 2024

- Qualified manufacturing and laboratory equipment and critical utility systems, including HVAC, compressed air, and purified water.
- Executed cleaning and sanitization validation and prepared protocols, reports, and risk assessments.
- Supported process validation for liquid, solid, and semisolid pharmaceutical dosage forms.
- Performed supplier qualification and prepared Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) documentation.
- Conducted statistical analysis of results, maintained the validated state, assessed change controls, and prepared Annual Product Quality Reviews (APQR) for local and imported products.

LOGFAR LOGÍSTICA | Responsible Pharmacist | July 2020 – December 2021

- Supported product quality assurance and trained employees involved in operational processes.
- Developed standard operating procedures, work instructions, and employee training materials using Se Suite.
- Ensured facilities, processes, and documentation met applicable legal and quality requirements.
- Tracked operational events and branch performance indicators.
- Prepared and controlled transportation documents, including CT-e and MDF-e, shipping manifests, and payments to contracted carriers.

FARMED | Responsible Pharmacist | May 2019 – March 2020

- Provided pharmaceutical care and medication dispensing services.
- Managed procurement, inventory monitoring, receipt, storage, and handling of antibiotics and controlled medications.
- Maintained required medication records and supported health authority inspections.

SANOFI AVENTIS | Microbiology Intern | April 2017 – December 2018

- Prepared culture media and performed growth promotion testing.
- Identified microorganisms from factory environmental monitoring and water sampling points.
- Performed bioburden and bacterial endotoxin (LAL) testing and supported microbiological documentation and records management.
- Updated team training records.

EDUCATION & PROFESSIONAL DEVELOPMENT

Bachelor's Degree in Pharmacy | Universidade Braz Cubas | December 2018
Pharmaceutical Industry Qualification & Validation | Instituto Racine | July 2021
Technical Diploma in Pharmacy | Centro de Estudo de Saúde Lopes | June 2014
Technical Diploma in Information Technology | Server | June 2012

TECHNICAL SKILLS

SAP | Se Suite | Power BI | Microsoft Office | Chromeleon | Nexus (LIMS) | Veeva | GMP Documentation | CSV | IQ/OQ/PQ | CAPA | Change Control | APQR

LANGUAGES

Portuguese: Native
English: Intermediate (stronger reading comprehension; speaking proficiency to be further assessed)
Spanish: Intermediate (conversational)