Gisela Rodriguez Rosado
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PROFESSIONAL PROFILE

- **Senior Chemist and MBA** with more than 20+ years of experience in biopharmaceutical processes of active ingredients, pharmaceutical drugs and drug-medical combination products.
- **Certified Quality Auditor** and ISO 31000 **Risk Manager** with expertise in technical writing, compliance review, technology transfer, root-cause analysis, and data science applications**.**
- **Facilitator** of technology transfer, validations, process knowledge, commercial manufacturing and continuous Improvement projects to meet customer expectations | company strategic goals.

COMPETENCIES

- Cross-functional teamwork | leader
- Strategic Planning | Operations
- Bilingual (English | Spanish)
- Interpersonal oral | written communication
- Technical | scientific writing
- Knowledge | experience with inspections (FDA, DEA, EMA, TGA, COFEPRIS, ANVISA, PMDA, KFDA) and standards (ICH, GAMP5, ISO, PIC/S)
- Supplier management (raw material qualification, supplier audits | risk control)
- Root cause analysis | Problem solving
- Basic knowledge in process improvement | projects (PDCA, Lean, Six-sigma, SDLC, visual management)
- Problem solving | risk analysis (PHA, FMEA, HAZOP, 5Why's)
- Specialized QC testing (HPLC, GC, IR, KF, LOD, particle size, LIMS)
- EHS standards | regulations (RECRA, SPCC, OSHA, PSM | Lab Safety, JHA)
- Basic knowledge in equipment controls (PLC, HMI, Databases, etc)
- Standard IT applications (Excel, Word, Power Point, Word, Project, Acrobat)
- Change Management (DCA, Track Wise, SAP, Documentum, Cognos, Maximo, MODA).
- Basic knowledge and experience with data analytics | visualization tools (Minitab, Power BI, Weka).
- Learning content design | facilitation | reporting technologies (Moddle, Blackboard, SAP-Success Factors, Plateau, Isotrain).
- IT technologies for Agile teams (Webex, MS Teams, Skype, Zoom, Share Point)

EXPERIENCE

Technical Writer-Change Specialist (*Agile-Weil Group Contractor*)**,** Enterprise Resilience Modernization and Data Integrity (ERMD), IT | Automation Engineering, **Merck,** *Las Piedras, PR* | Jun 2018 - May 2020

- Technical writing | Implementer of business cases, change controls and data integrity processes in conjunction with system development life cycle (SDLC) for automated | computerized systems.
- Technical writing | Implementer of document change controls and revisions for SOPs and trainings of granulation (HSG, FBD), blenders, extruder, InfinityQS, MES, USP Water SCADA, and compression.
- Designed | facilitated training materials (plan, presentations, exams) for individual | group sessions.
- Follow up completion of CSV deliverables through cross-functional team meetings and data science.
- Creation of templates for change proposal of modernization and data integrity improvements.

New Product Technology Transfer | Validation Specialist *(RCM Technologies Contracted)*, ***Thermo Fisher Scientific Patheon-PR,*** *Manati, PR | Oct 2016 – Feb 2018.*

- Technical writing of new product transfer plans, experimental | clinical protocols, specifications, boundary limits | sampling plan rationale, investigations, risk analysis (pFMEA) for oral drug products.
- Support the characterization of new or existing assets, identifying boundary limits, critical parameters, developing the testing strategy and statistical sampling plans
- Interfacing with functional groups (EHS, Client, QA, Engineering) on product transfer issues.

Compliance Specialist, *Bristol Myers Squibb Company,* *Manati, PR | Oct 2010 – Jan 2016.*

- Site Stewart for internal audits and risk management including design and provide trainings.
- Review-approval of SOP, master batch records, risk assessments, critical investigations, technical reviews, and CAPA effectiveness checks) to assure are aligned with policies and relevant regulations.
- Developed annual schedule, lead, and follow CAPA for internal audits and risk assessments for new or changes to laboratories, computer systems, products, processes, utilities, assets and facilities.
- Supported supplier management program as supplier audit, qualification, and periodic reviews.
- Developed | facilitated presentations for metrics review and OJT (risk management / quality audits).
- Applied lean six-sigma and operational excellence tools for quality assurance support and special projects (quality metrics trending, annual product quality reviews, risk management, product-transfer).
- Member of inspection readiness team in over 25 full-GMP regulatory audits (FDA, EMA, PMDA, TGA, COFEPRIS, ANVISA, KFDA) resulting in minor or zero observations.

- ➢ Developed and managed the implementation of the risk-based strategic plan for deployment of quality risk management program (including risk evaluation rationale, templates, training materials | plan).
- ➢ Recognized Site SME and Trainer-Facilitator for OJT quality auditing techniques and risk assessment.
- ➢ Awarded as Key Contributor in OPDIVO Launch (March-2015) and PVA-PAI Readiness (Aug-2012).

Technical Investigative Writer, *APP Pharmaceuticals,* *Barceloneta, PR* | *Oct 2008 – Jul 2010.*

- ➢ Authored risk-impact assessments, investigations (OOS, OOT, deviations, events, complaints), CAPA, effectiveness checks, APQR's (trend analysis, summary reports) for parenteral operations.

Senior Associate Scientist, *Amgen,* *Juncos, PR* | *Oct 2006 – Oct 2007.*

- ➢ Investigate, and document investigations (OOS, OOT, deviations) of formulation | visual inspection.
- ➢ Monitoring of process data for product defect solving and performing Product Quality Reviews.
- ➢ Developed | executed experimental protocols | reports for characterization of protein particle defects.
- ➢ Performed periodic reviews of key | critical parameters and EHS department metrics.
- ➢ Supported as Department Coordinator the implementation of 2007 EHS Site plan.

Bulk Process Scientist, *Bristol-Myers Squibb Company (BMS),* *Humacao, PR* | *Apr 2001 – Oct 2006.*

- ➢ Investigate and document investigations, change requests, process reviews, and process trainings.
- ➢ Gather-analyze process data to detect and prevent product loss and/or negative quality impact.
- ➢ Planned | technical writing | execution of experimental | validation documents for process changes.
- ➢ Served as GMP trainer-coach for new hired personnel and summer interns from 2001 to 2006.
- ➢ Designed experimental studies and technical solutions to improve Aztreonam | TACA processes.
- ➢ Provided technical support to investigations, characterizations, experimental studies (pilot plant, lab-scale) using statistics, root cause analysis and testing (HPLC, KF, GC, particle size, LOD, IR).

Manufacturing Cell Leader-Technical Support, *BMS* *Humacao, PR* | *Sep 1997 – Apr 2001.*

- ➢ Supervised chemical manufacturing of sterile API and USP / WFI water generation and distribution.
- ➢ Performed self-inspections, regulatory audits and manufacturing 3rd party (Wyeth) audits.
- ➢ Supervised execution and document control for commissioning and qualifications (URS, IQ, OQ, PQ, CIP, SIP, media fill, sterilization) of new or existing processes, assets, GMP utilities and facilities.
- ➢ Author and implementer of SOPs, MBRs, change controls, investigations (calibration alerts, deviations, excursions CAPAs, special projects | tasks and periodic reviews,
- ➢ Developed and facilitated process-specific / OJT training sessions to new hire peer / operators.
- ➢ Coordinated and performed recruiting, shift schedule, payroll monitoring, OJT, performance review.
- ➢ Awarded for Contributions as Implementer of Continuous Improvement Tools in cleaning validations | process improvements for sterile APIs (Aztreonam, TACA family) and OJT training program.

EDUCATION

MBA – *Business Administration & General Management* | **University of Phoenix**, Guaynabo, PR

BS - *Chemistry Major* | **Universidad de Puerto Rico**, San Juan, PR

PROFESSIONAL CERTIFICATIONS AND LICENSES

- Certified Quality Auditor (ASQ, since Dec 2011)
- Certified ISO 31000 Risk Manager (PECB, since Apr 2017 until May 2023)
- Certified QRM Expert (BEC, since 2014)
- Certified Food Safety Manager (NRFSP, Apr 2016 - Apr 2021)
- Data Science Certification (UPR Health Professions School, Feb 2020)
- Virtual Course Design and Facilitation Certification (UPR DECEP, Mar-Apr 2020)
- Lean Six-Sigma Yellow Belt (BMS, Oct 2014)
- Basic trainings in PMI Methodology (2008, 2014)
- ASQ Training Certificates in BoK for CBA | CMQOE 2009-2010).
- Aseptic Processing Certification (BMS, Jul 2012)
- Licensed Chemist 4097

VOLUNTARY EXPERIENCE

- **Member** of *American Society of Quality, ASQ* (since Dec 2011)
- **Member** of *Colegio de Químicos de PR*
- **Lecturer** (since ASQ PR 2019 Conference)
- **Chorus Singer** of *Coro Nacional de PR*
- Yoga Practitioner at Centro Cultural Devanand