

JOSÉ RODRÍGUEZ-PÉREZ, *PHD*

PO Box 8326, Bayamón, PR 00960

Phone 787.525.3014 ✦ fax 787.730.0851

pepe@calidadpr.com ✦ www.calidadpr.com

Founder and Owner of Business Excellence Consulting (BEC), a leading Puerto Rican training and consulting organization focused on the FDA regulated industry.

Profile

- Twenty years of experience as quality and technical professional.
 - Recognized Quality and Regulatory Expert.
 - Professor of the Polytechnic University of PR (Industrial Engineering Graduated Program)
 - Leader of the Puerto Rico Section of the American Society for Quality (past chair 2003-05)
 - Lean Six Sigma pioneer in Puerto Rico
 - Certified by American Society for Quality [ASQ] as *Six Sigma Black Belt, Quality Manager, Quality Engineer, Quality Auditor, Quality HACCP Auditor, Biomedical Auditor, and Pharmaceutical GMP Professional.*
 - Speaker for the American Society for Quality, Colegio de Químicos de Puerto Rico, Colegio de Tecnólogos Médicos de PR, Asociación Española de Hematología.
 - Science Advisor, FDA-San Juan District Office Laboratory
-

Professional Associations

- Senior member of the American Society for Quality (ASQ)
 - Regulatory Affairs Professional Society (RAPS)
 - Parenteral Drug Association (PDA)
-

Education

Post-Doctoral training (1989-1991), Univ. of Puerto Rico, Medical Science Campus, School of Medicine

Ph.D. Degree in Immunology (1989), Univ. of Granada, Faculty of Sciences, Granada, Spain

Bachelor Degree in Biology (1984), Univ. of Granada, Faculty of Sciences, Granada, Spain

Areas of Expertise

Training

- Incident Investigation and Documentation
- Technical Writing – Effective Documentation
- Root Cause Analysis
- Effective CA-PA
- Human Error Investigation and Prevention
- Lean Six Sigma Green Belt and Black Belt
- Applied Sampling
- Statistical Process Control
- Basic Applied Statistics
- GMP Interpretation
- Medical Devices QSR Interpretation and comparison with ISO 13485
- Quality Risk Management (Q9)
- FMEA workshop for the Regulated Industries
- Internal Audit Best Practices using the QSIT Model
- Supplier Certification Best Practices

Coaching and Consulting

- CAPA Systems
- Investigation and documentation systems
- Internal and External Audits
- Implementation of HACCP systems including ISO 22000:2005
- Lean Six Sigma implementation

Employment

Continuous Improvement Coach and Trainer *Business Excellence Consulting, Puerto Rico* 2005-present

- Created in May 2005, Business Excellence Consulting provides quality and regulatory training to most of the FDA regulated industries established in Puerto Rico. Leading food and beverage, electronic and insurance companies are also clients.

Professor Graduated Program *Polytechnic University of PR, Industrial Engineering Dept.* 2003-present

- Currently he is a par-time professor, responsible for the following courses: “*Measuring Customer Satisfaction and Loyalty*”, “*Quality Foundations*”, “*Quality Audit Program*” and, “*Assessment Tools to Improve Business Performance*”.

Technical Service Manager, Abbott Diagnostic Division, Barceloneta PR 1993-2005

- Advanced thorough increasingly responsible positions within this 900+ employees medical device manufacturing plant, demonstrating a track record of success and promotions. Positions held were:
 - Scientist
 - Senior Scientist
 - Principal Scientist
 - Validation Coordinator
 - Production Section Manager
 - Technical Support Section Manager
 - Technical Operations Manager
 - Technical Support Manager

- Lead a team of 100+ people, including four managers, 31 scientists (PhD and MS), three administrative assistants and over sixty laboratory technician.

Assistant Professor and Chairperson Microbiology and Immunology Dept, San Juan Bautista Medical School, Caguas 1991-1993

- Responsible for Department research, budget and grants in addition to teach medical courses. Established a R&D laboratory for Molecular Immunology.

Research (post-Doctoral) Associate, University of Puerto Rico, Medical Science Campus, School of Medicine 1989-1991

- Applied molecular biology research to development of diagnostic tests. Postdoctoral training included rotations at Massachusetts Institute of Technology (MIT), Duke University and University of Wisconsin at Madison.