

Jaime De Jesus

Summary:

Jaime De Jesus has a 20 plus year career in the Pharmaceutical (sterile and non-sterile products), Medical Device (catheters, stents, automated devices), and Consumer industry (nutritional and other consumables). He obtained his B.S. from the University of PR. He began his career in Bristol Alpha Labs in Barceloneta, Puerto Rico, as a Chemical Laboratory technician. He held positions of increasing responsibility, in QC/QA, and Sterile and Liquids Manufacturing. He has occupied positions as Operations Head at Alcon Labs (Start up of Medical Device Plant), Smith Kline and French (New Sterile facility start-up), Schering Plough (Key Pharmaceuticals Solid Dosage R&D/Technical Services), Schering Plough (Solid Dosage Manufacturing and Technical Services Manager), and Johnson and Johnson (R&D, NDA Submissions, CM&C) and Quality and Compliance Services (Corporate Quality & Compliance WW).

Languages (spoken and written): English, Spanish and Portuguese

Summary of Career Experiences:

- Extensive hands-on and managerial validation experience
 - Sterilization (Steam, Dry Heat, ETO, Radiation)
 - Sterile filling Suites (Environmental, Media Fills)
 - Analytical Methods
 - Computer System Validation
 - Medical Devices
 - Sutures
 - Automated wheel chairs
 - biomaterial-based medical devices (closures, cyanoacrylate technology)
- Start up- new product/process line and facilities
- Start up- new business/service/function (Medical Device Mfg. Plant, class 3 device)
- Turn around- poor performing business/service/function (corrected product failure to meet Japanese specifications)
- Leadership of cross-functional/cross-company team (Leader of worldwide virtual teams)
- International Ex-patriate assignments
- Identified/implemented major process improvement
- Technical writing, preparation of regulatory documents
- Trainer in Validation, Compliance, and Complaint Vigilance

Experience

Alimera Sciences

(1/07 to Present)

QA and Technical Consultant, (R&D, Ophthalmic)

- Main areas of work: Validation reviews, developing a Quality System, Quality Assurance, external and internal audits

Johnson and Johnson

(1993 to 2006)

Director, Corporate Quality and Compliance WW (2001-2007)

- Compliance oversight of consumer, pharmaceutical and medical device companies within J&J family of companies.
- Supported major product launches. Participated in Cordis compliance teams as an expert in the area of combo drug/device products quality systems.
- **Earned J&J Standards of Leadership Award, May 2004.**
- Worldwide Corporate Administrator of Total Risk Assessment and Control software system used to conduct assessments and elevate issues of high compliance risk to Management Action Plans. Provided support for MD&D Complaint Vigilance and Drug Surveillance programs.

QCS Director, Latin American Region (1996 – 2001)

- Corporate Quality representative that partnered with the Pharmaceutical, OTC, MD&D and Consumers regional operating companies.
- Developed programs to enable Latin American consumer and medical device business to meet regulatory requirements to supply US market.
- Provided technical assistance, coordinated and managed regional training programs on Corporate Quality Program, Process and Computer System Validation, and International Quality Compliance and Manufacturing improvement.
- Promoted innovation and provided compliance support to ensure corporate and business goals and objectives. These included TRG/QCS processes and tools such as TRAC, MAARS, Process Excellence (6 sigma), Cost of Non-Conformance, IRPP, etc. Helped engineered compliance initiatives to prepare Latin American regional businesses to enter the EU and US market.

R&D RWJ PRI, Manager Pre-Clinical Development, Raritan, NJ (1993-96)

- Led group of Scientists that prepared CM&C submissions for small molecule products. Obtained approval for 5 aseptically filled and terminally sterilized product lines.
- Achievements included leading team of experts in preparation of J&J Worldwide Policy on Aseptic Products in 1995.

Schering – Plough Corporation
(1985 – 1993)

Technical Services Manager, Las Piedras, PR (1985-1993)

- Made major contributions to addressing contractual quality demands from the Japanese Market. Initiated and implemented process improvements that corrected product failures. The product line, a sustained release drug product, represented 35 % of site business/earnings.

Manufacturing Manager, Las Piedras (1988 – 1991)

- Led introduction of sustained release coated particles products with Glatt Wurster column technology and obtained regulatory approval (No FDA 483 in PAI).

Key Pharmaceuticals, Miami, Florida (1985-1988)

Senior Scientist, Solid Dosage R&D

- Refined process for manufacturing K-Dur product (sustained release potassium supplement tablets). Developed the use of new particle coating technology, (Glatt particle coating equipment); and new automated compression equipment (Hata Press).

Smith, Kline and French, Carolina-Cidra
(1982 – 1985)

Process Development Analyst (1984-1985)

- Construction, led start-up and validation of sterile operations facility. Facility was finished on time and on budget and passed FDA PAI (No FDA 483).

Production Technical Coordinator (1982-83)

- Production liaison to Engineering group for new facility construction and validation.

Other pharmaceutical experiences: Will provide upon request

Education:

BS, General Science, Magna cum Laude, University of Puerto Rico
Pre-Med Program, Major in Ecology/Biology

Professional Associations:

Regulatory Affairs Professionals Society (RAPS)
Institute of Validation Technology
International Society for Pharmaceutical Engineering