MARLÈNE GARCÍA SWIDER, PhD

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PROFILE

Organizational Manager with PhD and 30+ years' experience and increasing responsibilities in regulatory affairs and quality management at FDA. Proven leadership in budget allocation ($1.1B) and technical team management (200+). Leverages expertise in project management and process improvement to drive drug approval process (7+ biotech drugs, combined value $9.013B) and quality audits. Published/presented at 8+ industry conferences and publications.

Six Sigma Black Belt (ASQ). Certified Project Manager (PMI). Bilingual: English/Spanish

Areas of Expertise

Organizational Management. • Quality Assurance • Process Improvement • Project Management • Regulatory Process (BLAs, NDAs, INDs and clinical trials)

PROFESSIONAL EXPERIENCE

CONSULTANT (Self-employed)

- CEO, Principal and Instructor of biotech courses for Biotech Online at www.biotechonlineschool.com
- Lead Biotech firms audits in US and other countries for SQA, Palo Verdes, CA since 2019 – keep going
- Re-engineering of CNS Quality and Regulatory Department, Garden Grove, 2019
- Directed Employer Engagement for Biotech Programs at OC Community Colleges and Industry, 2019
- Professional Speaker and trainer for biotech Academic events and professional associations' conferences

AZUSA PACIFIC UNIVERSITY (APU)

Biotech Graduate Program

Adjunct Professor (Fall 2019 - Present)

Teach face-to-face and online graduate students regulatory affairs and Good Clinical Practices (GCP).

- Responsible for planning, developing, implementing, revising, managing, and standardizing curriculum to meet Department goals on a timely manner.
- 5 years prior experience reviewing Industry clinical trials.
- Coach and mentor graduate students conducting bioresearch research as requirement for graduation.

CALIFORNIA STATE UNIVERSITY (CSU)

School of Business and Economics

Adjunct Professor (2017 – Present)

Teach face-to-face and online management, leadership, quality and statistics

- Responsible for planning, developing, implementing, revising, managing, and standardizing policies and procedures, and standards crossing departmental lines of management to meet goals on a timely manner.
- Seven years of experience in teaching professionals.
- Work with students from diverse backgrounds in East LA and Pomona, CA areas.
- Certified to design online courses and Effective Teaching by CSULA and ACUE

FOOD AND DRUG ADMINISTRATION (FDA) Quality Manager, Irvine, CA (2010 – 2019)

Developed, implemented, and manage FDA Quality Program for So CA. Advised senior management on quality initiatives to improve organizational performance in support of FDA mission for 250+ employees.

- Direct professional experience with drug and/or high-tech product regulation, manufacturing auditing, and approval in United States.
- Created a Quality Leadership Network among Academia and Industry leaders to collaborate with FDA and successfully promote Agency's mission, programs and services.
- Trained personnel (250+) in Quality tools and practices.

- Developed reports based on research, data collection and statistical analysis for Senior Management decision making.at a many times fast work pace to meet tight deadlines.
- Maintained compliance with internal and external standards; in addition, collaborates with the all key leaders within FDA to ensure compliance with applicable standards.
- Represented FDA's mission, information and goals at Congress, Academia and professional associations.
- Initiated quality issue escalation process as required.
- Participated in Office of Inspector General audits and lead internal FDA audits as the FDA Quality Expert Representative.
- Wrote response communications to inquiries from regulators and other FDA units.
- Remained knowledgeable of all pertinent regulations and/or guidelines and assesses impact on company Quality and Risk Management processes.
- Established and maintained effective working relationships across Agency collaborating closely with other departments to maintain compliance with standards and regulations.
- Managed multi-disciplinary multi-cultural teams to develop strategy of process and product compliance with all relevant standards and regulations.
- Responsible for integrating HQ FDA directives and policies into local policies and SOPs.
- Used of Six Sigma Black Belt tools and Project Management skills creatively and strategically bringing innovative continual improvement solutions to daily operations.
- Communicated business related issues or opportunities to next management level using negotiation skills to influence others internally and externally to FDA.

Regulatory Project Manager, Center for Drug Evaluation and Research | Silver Spring, MD (2005 – 2010)
Led scientific multidisciplinary review team of 12 (MDs, statisticians, pharmacists, attorneys, scientific/administrative assistants) in approval process for 7+ biotech drugs (Humira (a.k.a. Adalimumab – first US approved drug for pediatric Crohn's disease), Tysabri, Botox, Cimzia, Adalimumab, Remicade, Palifermin and Rifaximin). Produced more than 20 BLAs, NDAs and INDs and associated supplements.

- Collaborated with all members of the drug review team to effectively manage time for resolution of regulatory conflicts with agencies in US/four countries to less than 60 days.
- Executed regulatory strategies/plans. Provide ongoing support to product development teams for regulatory issues/questions.
- Provided support to new and currently marketed products as necessary. This includes reviewing labeling, promotional material, and other post-market activities.
- Provided support to Product and Manufacturing changes as necessary. This requires development of regulatory strategies, creating and submitting change notifications to regulatory agencies, updating technical files and design dossiers.
- Ensured regulatory affairs files are maintained to support compliance with regulatory requirements.
- Provided regulatory guidance to project managers, attorneys and scientists to secure US drugs' labeling approval based on knowledge of clinical trials, medical terminology, and/or research.
- Developed technical library, procedures and educational presentation for Project Management staff comparing biologics versus drugs' regulations in US.
- Advised industry officials on rules and regulations to recommend changes based on working knowledge of FDA policies including ICH guidelines and Good Clinical Practices (GCP).
- Reviewed, evaluated and prepared recommendations to ensure compliance with FDA policy, legal and regulatory adequacy or evidence.
- Lead prepare for and conduct Advisory Committee preparatory meetings to seek scientific and legal data.

Reviewer/Auditor for Biotech Drugs, Center for Biologics Evaluation and Research | Silver Spring, MD (2001 – 2005)

- Led team of ~5 in FDA audits for five US biotech companies, expediting approval of European satellite offices, from 12 months to six months.
- Reviewed FDA and international submissions of new products and product changes on a timely manner from approval for market release. Communicated directly with international affiliates and regulatory agency personnel.

- Monitored compliance initiatives and served as lead Agency representative in US and Europe inspections.
- Supervised and trained three new investigators for drug inspections of 12 US biotech manufacturers.
- Reviewed Manufacturing Process Documentation for 10+ companies to verify GMP compliance.

Management Analyst, Budget Analyst, Public Affairs Specialist | Rockville, MD (1988 – 2001)

- Helped manage changes to legislation & policies, and implementation of regulations and procedures base on studies' findings and Congressional requests.
- Planned resources and allocated three-year budget for two national programs ($1.1B). Executed budget analysis formulation and execution projects and reports per US Congressional requests.
- Facilitated face-to-face FDA Senior Management meetings with 60 Congressmen on 100+ FDA regulated products.
- Provided English-Spanish translation for emergency room MDs, taught medical Spanish to 30 healthcare professionals and translated media resources.
- Developed/delivered Spanish broadcast on breast cancer awareness for the Department of Health and Human Services, reaching audience of 2,000+ Hispanics in Washington DC area.

VA Health Care Administration Resident and Nursing Administrative Assistant | San Juan, PR (1985 – 1987)

- VA Healthcare Administration Internship studying and presenting quantitative research on health insurance and Medicare financial codes.
- Designed studies on administrative functions, and conducted other special management, resources and financial projects for the Nursing Unit (437 nurses) within one of the largest VA Medical Center (963 beds).
- Analyzed of data, advised Senior Management, and supported Administrative functions for Nursing staff.

Other Experience:

Consultant for Healthcare, Quality and Regulatory Professional Associations
Research Mentor, USC and CSU biotech graduate students/interns (2014 – 2015)
Acting Special Assistant to the Associated Commissioner for Regulatory Affairs, Ron Chesemore (1990)
Acting Deputy Director for Division or Management, ORA, Jim Strachan (1991)
Various Acting Chief Division positions and Senior Budget Analyst for Office of Commissioner
Multiple Agency Awards including the 2015 FDA Collaboration and Leveraging Award

EDUCATION

CAPELLA UNIVERSITY
Doctorate in Organizational Management
Thesis: ISO 26000 and Employee Engagement

UNIVERSITY OF PUERTO RICO
Masters, Health Service Administration
Bachelor's in biology

Professional Certifications/Memberships

Distinguished Toastmasters, Toastmasters International, 2018
Continual Improvement Social Responsibility Practitioner, Sherpa Sustainability Institute, since July 2017
Certified Project Manager, PMI, since May 2016, Certification No. 1932693
Certified Six Sigma Black Belt, ASQ Chapter 701, Orange County, CA, since October 2015, Certification No. 17412
Certified Baldrige Examiner, 2014
Certified Quality Manager, ASQ Chapter 701, Orange County, CA, since October 2011, Certification No. 14953
FDA Project Manager certified by CDER, 2008 and FDA Level III Inspector, 2005
CSULA – CETL online class designer
ACUE Effective Teaching certification

Professional Societies

Past or current member of the Management Academy, the American Management Association, the American Society for Quality, Toastmasters International, Association of Colleges and University Educators, Sherpa Sustainability Institute, and the OC Regulatory Affairs Association.

Volunteer Work:
National Association for Mental Illness (NAMI) certified Trainer and Facilitator (2019)
Lead Mental Health Ministry at Mariners Church, Irvine, CA (2018 – 2019)
Lead Life Group at Mariners Church, Irvine, CA (2018 – on going)
Community Leader on Health issues since 1990
PTA Board member since 1993
Catechist and Confirmation teacher since 2012
Basketball and Soccer mom and assistant coach in 2015 and 2016
Toastmasters Area D4 Director and ASQ FD&C Division Regional Councilor – 2017

PUBLICATIONS + PRESENTATIONS

Expert Speeches and Panel Presentations

"Data Integrity and Quality Tools," Personal Care Council, American Society for Quality, Omni Hotel, Los Angeles, CA, June 2018 (Panelist, Quality Tool Designer)
"Continual Improvement Social Responsibility Tools," American Society for Quality, Orange County Section 701, DoubleTree Hotel, Santa Ana, CA, April 2018 (Keynote Speaker)
"Regulatory Science Careers at FDA," Life Beyond the PhD Event, Graduate & Doctoral Programs at University of California, Irvine, March 23, 2018 (Keynote Speaker)
"Quality and Program Alignment and current FDA Trends," American Society for Quality, Section 702, October 18, 2017 (Keynote Speaker)
"Regulations at FDA," American Society for Quality, Section 703, San Diego, October 10, 2017 (Keynote Speaker) – 2 hours
"Data Integrity," BioCom, La Jolla Hotel, San Diego, CA, August 2017 (Panelist)
"Regulatory Affairs for FDA," American Society for Quality, Section 701, Wyndham Irvine Hotel, Irvine, CA, August 8, 2017 (Keynote Speaker)
"Outsourcing," American Association Pharmaceutical Scientists, Hilton Hotel, Irvine, CA, June 2017 (Keynote Speaker)
"FDA 483 Inspectional Issues and Solutions," Parental Drug Association (PDA), Chapter 6 Annual Industry Summit Expo, Hilton Hotel, Irvine, CA, October 6, 2016 (Keynote Speaker)
"FDA Quality Metrics Guidance," American Society for Quality, Orange County Section 701, Double Tree Hotel, Santa Ana, CA, August 2016 (Keynote Speaker)
"FDA Quality Metrics Guidance," Quality Metric Conference, Institute for Validation & Technology, Loews Coronado Island Hotel, San Diego, CA, February 22, 2016 (Guest Speaker)
"Quality Leadership Network," American Society for Quality, Orange County Section 701, Double Tree Hotel, Santa Ana, CA, August 2015 (Keynote Speaker)
"FDA, Global Expectations, and Validation Statistics," Doubletree Hotel, Santa Ana, CA, September 8, 2015 (Keynote Speaker)
"Quality Leadership Network," Orange County Regulatory Affairs (OCRA), Irvine, CA, June 4, 2015 (Guest Speaker and Panelist)
"Global Validation," Institute for Validation & Technology, Omni Hotel, Philadelphia, PA, February 2015 (Guest Speaker)

Publications –
Stewart, A.; Yeik, G.D.; Casey, L.; Swider, M.G.; Heckman, N.; and Clemens, R. "*Scorecard Tool Assists with FSMA Compliance"* – Food Technology Journal, Vol.70 (4), April 2016, pg. 52 -55

ISO 26000 – Social Responsibility and Employee Engagement – Doctoral Thesis, Capella University, 2014

Swider, M. "*FDA Outsourcing and Globalization"* - BioPharm Journal, Philadelphia, PA, July 2012

What is FDA and How Can It Serve You – Coalition of Hispanic Associations, Washington D.C., May 1996 (newspaper article in Spanish)

Hispanic Health in America (Power Point presentation) – Commission Corps Annual Conference, New Mexico, 1991

Scholarship –

Continual Improvement Social Responsibility 2017 Scholarship granted by Sherpa Sustainability Institute, Durango, CO, to be certified as a Social Responsibility Continual Improvement Practitioner.