JENNIFER DiMARCO, MBA, MS-QA/RA

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PROFILE

Successful senior leader specializing in compliance and quality management, including and not limited to health authority inspections, GxP audits, and operational excellence utilizing six sigma (Black Belt Certified). High-caliber leadership experience with merger and acquisitions (M&A) transitions, multi-project management, stakeholder relations, and organizational design. Create or lead teams through compliance, quality management and improvement projects within pharmaceutical, biologics and device areas.

AREAS OF EXPERTISE

Team Leadership	Regulatory Requirements (GxPs: GVP, GPV, GCP)	Compliance Programs	Strategic Operations
Executive Presentations	Inspection Readiness and Hosting	Corporate Integrity Agreements (CIA)	Lean/Six Sigma: Black Belt
Organizational Design	Quality Assurance	Quality Management Systems (QMS)	Integration from Mergers and Acquisitions (M&A)
Strategic Planning	Root Cause Analysis (RCA)	Healthcare Professional (HCP) Engagement	Project Management
Stakeholder Management	Corrective and Preventative Actions (CAPA) Management	Sunshine Act/ Transparency Reporting	Continuous Improvements
Change Management	Risk Management	Sponsorships and Grants	Performance Metrics: KPIs/KQIs

PROFESSIONAL ACCOMPLISHMENTS

DiMarco Consulting, Boston, MA 2019-present

I help R&D Organizations within the Pharmaceutical Industry to simply and successfully integrate compliance through mergers and organizational change. I support my clients by creating robust inspection readiness programs so that they are prepared for any health authority, worldwide. My expertise includes and is not limited to: Regulatory Requirements (GxPs), Compliance Programs, Strategic Planning, Quality Systems and Assurance, Root Cause Analysis, Change Management, Project Management, Continuous Improvements, Performance Metrics

Takeda Pharmaceuticals 2017-2019

Head (Senior Director) Global Patient Safety Evaluation Quality Assurance (GPSE QA), i.e. PVQA

- Led and optimized quality management related activities for Patient Safety, Regulatory Affairs and Medical Affairs stakeholders, including over 100 Local Operating Companies
- Takeda-Shire merger: designed and implemented organizational structure for future state, expanding department by 15% post integration
- Hosted FDA inspection where a **483 was not issued** for the first time in company history
- Implemented risk based approach for audit program **yielding a savings of $300K**, annually, while maintaining regulatory requirements
- Pioneered utilization of audit data to support informed decision making

Alexion Pharmaceuticals and Alkermes Inc 2015-2017

Pharmacovigilance Quality Assurance

- **Introduced PVQA competency** to the organizations which covered the entire pharmacovigilance system, including case processing, label changes, related commercial activities and vendor oversight

Shire Pharmaceuticals 2006 – 2015

Quality Standards and Training

- Responsible for achieving and maintaining full compliance with industry regulations in research and development, patient safety, regulatory affairs and commercial activities globally.
- Address all procedural aspects of Corporate Integrity Agreement (CIA) ensuring minimal timeline was needed demonstrate compliance with CIA, i.e. company was **released from CIA** after initial 5 years.
- Lead project to consolidate 5 systems into one harmonized way of working globally; saved over 1000 work hours, **$3.2MM annual cost savings and payback was <18 months**. Earned Six Sigma Black Belt.
- Led global project to implement Good Vigilance Practices (GVP) per European Medicines Agency (EMA); designed company's Pharmacovigilance System Master File which was the **first accepted** by the EMA
- Lead various merger and acquisition activities for department
- Developed and monitored quality management system implemented in R&D functions which harmonized the departments, including associated standard operating procedures (SOPs) and training programs

Other career leadership highlights:

- Budget responsibilities as much as $12MM, annually
- Resource and team management varying from 1-8 direct reports and total team of 21
- Sales and marketing: Responsible for all aspects of new business and product development overseeing sales and volume targets and expected profit margins
- GCP and GMP quality management

EDUCATION

Six Sigma Certification: **Black Belt**

Temple University, Fort Washington, PA
M.S. Degree in Quality Assurance and Regulatory Affairs

Saint Joseph's University, Philadelphia, PA
M.B.A. Degree in International Marketing

Bloomsburg University, Bloomsburg, PA
B.S. Degree in Chemistry
B.A. Degree in Philosophy

PROFESSIONAL & COMMUNITY ACTIVITIES

- Member of AFSP/SOS, 1995-2011; Board Member (Philadelphia), 2009-2011
- Volunteer interests: AIDS Fund and Habitat for Humanity