Marisol Cooke

Senior Manager, Life Sciences Operational Transformation Advisory Services

Experience

Marisol is a Senior Manager in Grant Thornton's Advisory Operational Transformation practice, with a focus on Life Sciences regulatory and compliance. Marisol has 14 years of demonstrated experience and leadership within the Life Sciences and Health Care industry.

Highly accomplished and trusted compliance advisor with over 14 years of direct experience developing and implementing regulatory and privacy programs for high-profile organizations. Maximizes resources to manage complex, and often ambiguous, circumstances resulting in cost-effective solutions to compliance challenges. Able to interface with all management levels, including C-level, and lead, guide and motivate others to meet organization objectives.

Marisol has led compliance assessments and implementations by creating compliance and privacy core policies, third party hotline and acting as interim compliance officer/privacy officer. Marisol has also performed gap analysis on the compliance program and other high-risk functional areas against leading practice and industry standards for organizations undergoing significant organization change. In addition, Marisol has a full range of program and project management skillsets. Lastly, Marisol has directed and project managed registration management assessments and change management in regulatory operating models for medical device companies.

Sector experience

Prior to joining Grant Thornton, Marisol spent several years as a Chief Compliance Officer of two different healthcare organizations and worked at Deloitte for six years, where she focused on leading projects for Pharmaceutical/Healthcare companies within the Regulatory & Compliance space.

Industry Experience

Below is an example of projects that Marisol has led for Life Sciences clients:

- Conducted a current process review for a Pharmaceutical Company using current process review of people, process and technology, identified gaps and developed recommendations
- Designed and implemented the Regulatory Operating Model for a Medical Device Company using the Registration Information Management platform to support the International Regulatory executive leadership.
- Captured, validated and analyzed data for a Medical Device Company to prepare for upcoming EU UDI requirements to submit required product data to the EU. As part of the process, we reviewed data against the EU UDI standard to understand gaps with Class I-III devices and determine gaps between available data and required set.
- Supported a Medical Device Company in their Regulatory Operations transformation, including strategy workshops, process maps, roles and responsibilities, SOPs and provided updates to the project sponsors and executive leadership. In addition, worked with different workstreams to define governance structure, operating models, and re-design processes.
- Conducted an ecosystem mapping and roadmap development for a BioMedical Company. As part of the process, we analyzed previous studies of the region's life sciences and manufacturing ecosystem, participated in targeted meetings, interviews, researched, analyzed and developed a fund strategy to accelerate the start-up and growth of high impact potential companies.
- Supported a Pharmaceutical Company conduct a functional assessment to determine the effectiveness of the company's global compliance program. As part of the process, we aligned with the requirements and expectations set forth in key guidance documents such as the Office of Inspector General, Department of Justice and HCCA-OIG Measuring Compliance Program Effectiveness.

Education

- **Juris Doctor** – Thomas M. Cooley Law School
- **Bachelor of Science in Politics, Laws and Court** – Suffolk University

Professional Qualifications / Other Involvement

- Certified in Health Care Compliance, Health Care Compliance Association