AREAS OF EXPERTISE:

- **FDA's QSR/GMPs – 21 CFR Parts 820, 210 & 211, 600, 806, 58, 7, and 11, 803, 806,**
- **QSIT Mock Inspections**
- **Root Cause Analysis and CAPA**
- **Post-Market Surveillance and Vigilance**
- **ISO 13885, 9001:2015, 14971**
- **MDD/IMDD requirements**
- **MHLW Ministerial Ordinance no. 169**
- **Health Canada Medical Device Regulations**
- **Quality Engineering**
- **Design Control**
- **Design Dossier Reviews**
- **Technical Files Compilation**
- **ERES and Documentation Systems**
- **Complaint Handling**
- **HIPAA requirements**
- **Process Validation**
- **CE-Marking**
- **Post Market surveillance and Vigilance programs**
-
- **Quality Systems and Systems-based Implementation & Auditing**
- **Process Validation**
- **Supplier Quality Agreements**
- **Quality Engineering**
- **Mock FDA inspections**
- **Risk Management / hazard analysis**
- **Process Improvement**
- **Lean Manufacturing and Six-sigma**
- **Compliance Master Plan remediation**
- **Facilitating responses to address FDA-483s and Warning Letters**
- **Product Registrations**
- **Pre-Approval and Readiness Assessments**
- **CAPA remediation**
- **Complaint Handling and MDR remediation**
- **Pharmaceutical, and Biologics Industries**
- **Facilitating responses to address FDA-483s and Warning Letters**
- **ERES and Documentation Systems**
- **Quality Assurance and Audits**
- **Quality Systems and Systems-based Implementation & Auditing**
- **OTC Cosmetics**
- **Aseptic audits & Aseptic operations**
- **Cleaning Validation**
- **Regulatory Compliance**
- **Failure Investigation and OOS**
- **Deviation Handling**
- **Equipment qualification**
- **Documentation Systems**
- **cGMPs, GCP, GLP Training**
- **Supplier Quality Assurance**
- **Analytical method validation**
- **Change control programs**
- **sterility assurance**
- **Pharmacy Compounding Audits**
- **USP 797**
- **GLP Laboratory**

- Certified Member - Board of Examiners for the California Quality Award.
- Certified Member - Board of Examiners for the President's National Quality Award.
- Certified Member - Board of Examiners for the Malcolm Baldrige National Quality Award. (4 years)
- Served on the Editorial Advisory Boards for Software Quality Professional and the Institute of Validation Technology (IVT)
- ASQC Certified Quality Auditor, CQA Certification No. 17390
- Certified RAB ISO Lead Assessor
- Six-Sigma Champion since 2003
- Author: CAPA in the Pharmaceutical and Biotech Industries, Publisher: Woodhead Publishing Series in Biomedicine, Oxford, UK, 2015

Ms. Rodriguez is the president of Monarch Quality Systems Solutions and has over 34 years of extensive experience working in the Medical Device, Pharmaceutical, Biologics, Compound Pharmacy, OTC, and OTC Cosmetics industries. She has worked both within the industry and as a Principal Consultant to the industry. For over 20 years she held multiple positions as Director of Quality and Regulatory Compliance, and Senior Manager of Quality and Regulatory Affairs. In addition, she has more than 13 years as an independent consultant advising to industry leaders.

Ms. Rodriguez's primary focus is to effectively and efficiently assist Medical Device, Pharmaceutical, Biologics, Compound Pharmacy, OTC, and OTC cosmetics companies in identifying compliance gaps within their respective quality systems and then remediating those issues into meeting all aspects of US and Global regulatory compliance. She develops solutions that include; process mapping, interim controls, corrective actions, coaching, and training for ultimately obtaining clearance from regulatory bodies.

Ms. Rodriguez also has extensive knowledge of Compliance- Mock Inspections, Facilitating responses to address FDA-483s and Warning Letters, and she has helped many companies (worldwide) to prepare for FDA inspections and participated/facilitated responses during the inspection (in front room) and managed back room as well.

She develops As-Is and To-Be process mapping to determine future-state improvements and training. She shares her extensive quality knowledge with companies using training exercises to transfer fundamental quality expertise to those organizations, so that they may become more effective in developing their own quality tools, procedures, and work instructions. She places focus on all aspects of Regulatory Compliance, Corporate Quality Policies and Procedures, Change Management Systems, and Batch Record Process Reviews. In one example, she developed a compliant Master Drug Batch Record Dossier for the worlds largest OTC Cosmetic Manufacturer. In addition, she created Global ECR and Change Management Systems.

She acts as a key contributor to Global Leadership Teams and helps to develop organizational strategies and structures. She creates and implements compliant: Deviation Management Systems, Failure Investigation Processes, CAPA Systems, Immediate Corrections, Interim Controls, Retrospective Reviews, Root Cause Analysis, Document Management, Production and Process Controls with Validation, Out of Specification (O.O.S.) Procedures, R&D Support Tools, Pilot Batch Testing, Stability Testing, Analytical Test Methods, Document Control, Supplier Quality Assurance, Quality Engineering, Risk Management/hazard analysis, Electronic Records/Electronic Signatures and Documentation Systems, as well as HIPAA requirements, as well as Lean Manufacturing and Six-sigma.

Ms. Rodriguez has implemented several Audit programs, and has performed internal and external GMP/ISO and clinical audits *of ongoing clinical trials in progress across the organization* (for both US and EU trials). As well as, completed an objective assessment of where the client's documentation was in with respect to processes and systems and compliance to US FDA (medical device, Pharmaceutical, Biologics and Combination products), EU MDD/IMDD, and EMEA, ISO13485, ISO14971, JPAL, MDD/IMDD, ISO14155 (2011) requirements in order to provide and address any gaps in order to provide recommendations and improvement plans.

She applies GMPs and Quality System standards to IVDs, Medical Devices, Biologics and Sterile Packaging. She has specific experience in controlled aseptic environments, sterilization validation, cleaning validation, microbiological quality issues. She also managed programs for internal and supplier audits and served as a Lead Auditor for all critical and technical areas and Suppliers. She implemented Lean/6 Sigma improvement methods yielding significant savings, for several companies worldwide.

She has trained thousands of Pharmaceutical, Biologics and Medical Device Professionals as a Educational Course Director for over 11 years. The courses included:

1. How to Implement an effective Root Cause Analysis and CAPA Program
2. Effective Quality Assurance Auditing for FDA Regulated Industries
3. Process Validation for Medical Devices and IVDs

4. Design Control for Medical Devices
5. Field Actions and Their Management – Recalls, Product Recovery and Safety Alerts
6. Implementing Risk Management Principles and Activities within a Quality Management System
7. Overview of FDA Regulatory Compliance for Medical Devices and Combination Products
8. How to Effectively Prepare for FDA Inspections
9. Computer Systems Validation & Part 11 compliance
10. How to Develop an Effective Complaint Handling and Post Market Surveillance and MDR Program for Devices
11. How to prepare for a Systems-based Inspection
12. Comprehensive Overview of FDA Regulatory Compliance for Drugs and Biotech Products
13. Reporting Failure Investigations and Process Deviations
14. How to Develop an Effective Complaint Handling and Post Market Surveillance and MDR Program for Devices
15. Field Actions and Their Management – Recalls, Product Recovery
16. Supplier Qualification and monitoring programs

Performed full on-site assessment/audit of an API and Aseptic filling manufacturers covering all areas of the Quality Assurance, Quality Control , Manufacturing, Equipment Qualification and Software and Process Validation, Chemistry, and microbiology laboratories in relation to the site's GMP Compliance. Resulting in the Reports of "readiness" or gaps in compliance and provided recommendations for any remediation requirements

Her wide-ranged experience and recognized expertise in these areas have acquired her guest speaker positions worldwide, which include several FDA validation workshops (for FDA investigators), and has teached hundreds of public and onsite CAPA and Process Validation courses for Pharmaceutical, Biologics, and Medical Device manufacturers. She has worked closely with CDRH's FDA HACCP team for both promotion of Risk Management and training of over 1000 individuals (industry and FDA).

Ms. Rodriguez holds a BS in Business Management and is a certified member of the Board of Examiners for the Malcolm Baldrige National Quality Award program. Ms. Rodriguez is an ASQ Certified Quality Auditor and an RAB Lead Assessor. She has published numerous validation and compliance-related articles and has been a global industry speaker and presenter on several compliance topics.

EMPLOYMENT HISTORY:
10/04 to Present, Industry Consultant, Marlton, NJ

Ms. Rodriguez is currently an industry consultant and she is currently serving in a technical and regulatory compliance consultation capacity for several Pharmaceutical, Biologics compounding Pharmacies and Medical Device companies. Her consulting activities place emphasis on all aspects of FDA Mock Inspections, Implementation of Risk Based programs, delivered public and onsite training thousands of attendees, quality site assessments, regulatory affairs, compliance, regulatory submissions, and various FDA-related activities.

Mrs. Rodriguez has been a Director of Quality Assurance, Regulatory Affairs, Regulatory and Compliance for several Medical Device, Pharma, and Combination products Manufacturers' including (startup, medium and Multi-billion dollar Corporations such as Medtronic)

Accomplishments:

- Assisted the Food and Drug Administration HACCP Cadre in teaching (over 1000 people) both industry and FDA officials the principles of HACCP and Quality System Regulations. From April 1999 through June 2001, worked with the FDA in their pilot study created to introduce the new Hazardous Analysis & Critical Control Points (HACCP) Inspection technique.
- Participated/instructed at the National FDA Medical Device Process Validation Training Course, 06/01(for FDA investigators only).
- Directed the implementation of several cost-saving programs and quality initiatives' to enhance efficiency, such as, the implementation of lean manufacturing projects, which resulted in a 70% cycle time reduction for the manufacturing and inspection processes.
- Revamp several processes such as, Compliance training, internal and external Audits, Process Validation and Risk Management.
- Create procedures and systems for several processes such as, Change Control, Process FMEA, Process Validation Document Control and Process Validation
- Completely revamped and enhanced the operational effectiveness of the Quality Documentation System for a Billion Dollar Corporation in under 9 months.
- Directed all software validation activities related to the implementation of a new ERP Software Program/system for over 1600 users.
- Managed the validation of the multimillion dollar ERP System, including, IQ, OQ, and PQ. in under 7 months
- Spearheading the 21 CFR Part 11 Compliance Program, which included support of site activities pertaining to the 21CFR11 (Electronic Records/Electronic Signatures) Compliance Program.
- Revamp several processes such as, Training programs, Internal Audit Program, Process Validation, Risk Management, CAPA, complaint handling and Quality Systems Software Validation and COTS systems.
- Created the following comprehensive processes: Facility and Equipment Validation, Sterilization, Environmental Monitoring, Shipping, Purchasing, Document Control, Supplier/Subcontractor Assessment, Vendor Audits, as well as all procedures needed to achieve 503A and 503B compliance.

EDUCATION:

- B.S. Degree Business Management.