FDA REGULATORY COMPLIANCE ADVISORS, INC.™

About Us

FDA Regulatory Compliance Advisors, Inc.™ (FDA-RCA™) provides world-wide regulatory services to the Pharmaceutical, Active Pharmaceutical Ingredient (API), Biotechnology and Medical Device industries.

All services are conducted by **Rebeca Rodríguez**, Industry Advisor/President, FDA-RCA™ and **Former FDA National Expert Investigator** with 27 years of FDA experience.

FDA-RCA™ offers excellency addressing client needs, task execution, problem solving and timely completion of studies, analysis, projects and presentations. Recommendations are performed on an individual basis and developed specifically for the practical solution of each client's situation.

"Combining science with regulatory knowledge for optimized systemic solutions." ™

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AREAS OF EXPERTISE

- Response to FDA-483s
- Response to FDA Warning Letters
- Failure Investigations, Root-Cause-Analysis (RCA) and Problem-Solving Techniques
- Evaluation of Corrective and Preventive Action Plans (CAPA)
- Laboratory and Manufacturing cGMP Controls
- Process Validation
- Vendor audits
- Gap assessment of manufacturing/laboratory validation and execution of protocols
- Assessment of Technical Transfer and Analytical/Bioanalytical Test Methods
- FDA Audits of Microbiological Laboratories
- NDA/ANDA Pre-Approval drug manufacturer inspections for all dosage forms including combination products
- Biotechnology Manufacturing and Laboratory Operations
- GMP and FDA Inspection techniques geared towards Drug, Biotech and Medical Device manufacturers
- Data Integrity in Laboratory and Manufacturing Operations
- Computer System Validation (CSV)
- Electronic Records; Electronic Signatures (21 CFR Part 11)
- Process Analytical Technology (PAT)
- Cleaning Validation Program
- Stability Program
- Regulatory Submissions, NDAs and ANDAs
- Pre-Operational Reviews of Facilities

- ★ BIOTECH
- ★ PARENTERALS
- ★ STERILITY
- ★ PROCESS VALIDATION
- ★ CLEANING VALIDATION
- ★ STABILITY

- ★ DATA INTEGRITY
- ★ CSV/PART 11
- ★ FDA AUDITS
- ★ FDA WARNING LETTERS

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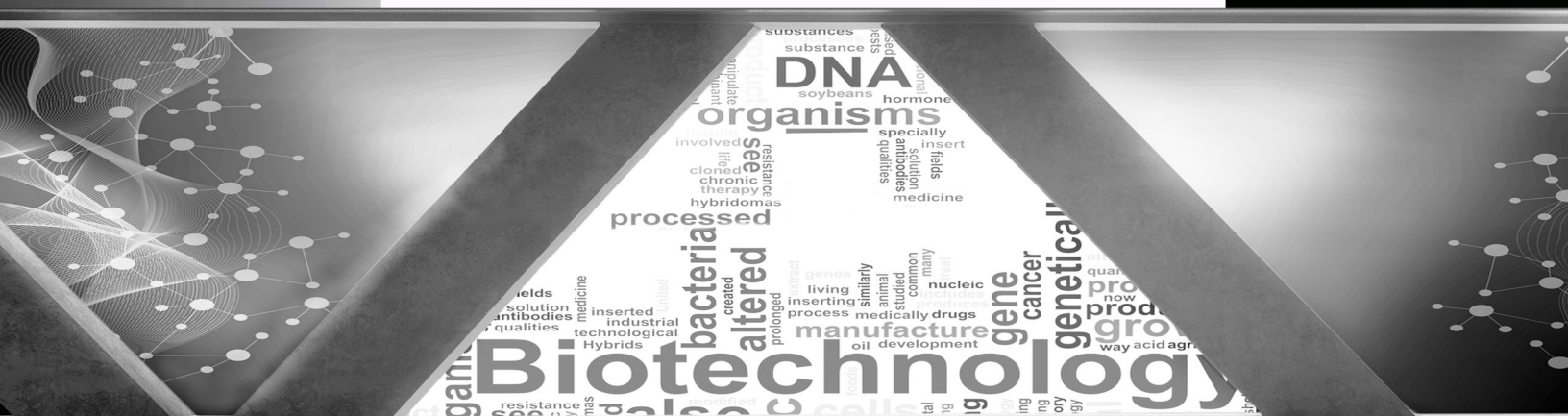

SPECIALIZED SERVICES

- Provide support for FDA GMP and Pre-Approval inspection readiness
- How to audit like an **FDA Auditor**: A combination of consulting, auditing and training program, including ***"Train-the-Trainer"***
- Annual GMP training for Drug, Biotech and Medical Device manufacturers
- Data Integrity in Manufacturing and Laboratory Operations
- Evaluation, response and commitments to FDA Warning Letters
- Evaluation of regulatory risk and criticality of non-conformances, deviations, complaints, manufacturing investigations, and OOS reports from an FDA perspective
- Development of Quality Policies for Manufacturing and Laboratory Operations
- Support management with formal communication with FDA Field and Headquarter Offices
- Gap assessments of Environmental Monitoring and Cleaning Validation programs for aseptic and non-sterile manufacturing facilities
- Evaluation and recommendations for emerging technologies
- Provide support for Quality by Design (QbD), Process Analytical Technology (PAT) and Continuous Manufacturing projects

- **QUALITY POLICIES**
- **COMPLAINTS**
- **OOS**
- **LIAISON WITH FDA OFFICES**

- **ANNUAL GMP TRAINING**
- **QbD**
- **PAT**
- **EMERGING TECHNOLOGY**

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TRAINING SERVICES

- GMP training for Pharmaceutical Dosage Form, Active Pharmaceutical Ingredient (API) and Biotechnology Industries
- Representative Sampling Techniques
- Sterility and Media Fills
- FDA Auditing techniques:
  - o Parenterals
  - o Biotech, API, and Dosage Form Manufacturing Processes
  - o Aseptic Manufacturing Processes
- Critical Thinking: An FDA Regulatory Perspective for Investigative Writing
- Do's and Don'ts:
  - o Root Cause Analysis
  - o Corrective and Preventive Action Plans (CAPA)
- GMPs from an ICH Q8, Q9 and Q10 perspective
- FDA Readiness for Pharmaceutical and Biotechnology Industries
- An FDA Perspective of Cleaning Validation
- FDA Approach to Good Outsourcing Management (GOM)
- FDA Auditing techniques of Data Integrity, Computer System Validation (CSV) and Part 11
- Developing an effective Failure Investigation and CAPA system

- ★ SAMPLING
- ★ MEDIA FILLS
- ★ ASEPTIC API BIOTECH
- ★ ROOT CAUSE ANALYSIS
- ★ CAPA
- ★ PROCESS VALIDATION
- ★ FDA READINESS
- ★ DATA INTEGRITY
- ★ CSV/PART 11
- ★ FDA AUDITING TECHNIQUES

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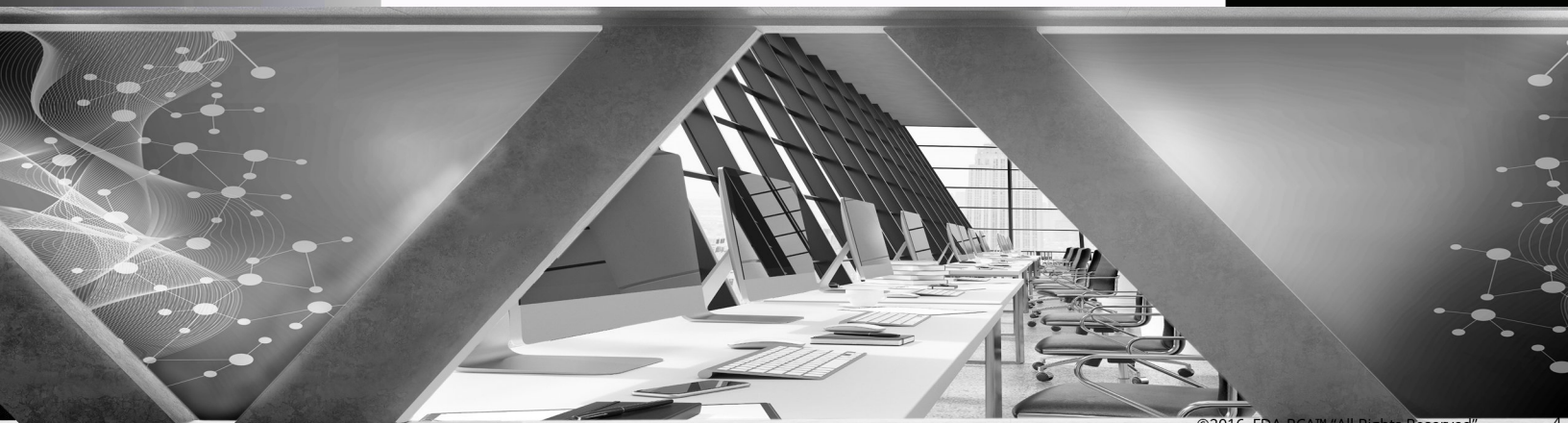

CONSULTANT QUALIFICATIONS

Rebeca Rodríguez, ASQ CQE
Industry Advisor/President
Former FDA National Expert Investigator

Rebeca Rodríguez is an Industry Advisor and President of FDA Regulatory Compliance Advisors, Inc.™ She worked for 27 years at the Food and Drug Administration (FDA) as Investigator. For the last 13 years of her career Rebeca worked as a National Expert Drug Investigator reporting to FDA ORA Headquarters in Rockville, MD.

Ms. Rodríguez received her degree in Chemistry from the University of Puerto Rico, Río Piedras Campus. Ms. Rodríguez is certified by the ASQ (American Society for Quality) as a Quality Engineer (CQE) since 1991; as such, she has specialized knowledge in the principles and tools that have been used to support Quality by Design (QbD) and Statistical Process Control (SPC) in the regulated industry.

During her FDA career Ms. Rodríguez has accumulated expertise in areas such as complex biotechnology, drug and medical device inspections, both domestically and internationally. Her professional experience includes planning, conducting and directing highly technical, complex and multi-faceted inspections and in-depth investigations, including regulatory inspections and criminal investigations of data integrity cases.

Ms. Rodríguez was one of the first four ORA Investigators that were certified as members of the PAT (Process Analytical Technologies) Review and Inspection Team, and more recently was the Senior ORA representative to the ETT (Emerging Technologies Team).

Ms. Rodríguez was the leader of the team that conducted two of the first PAT pre-operational visits that resulted in the approval of the first PAT Comparability Protocol that proposed changes in the manufacture and control of both the active pharmaceutical ingredient (manufactured in Germany) and the drug product (manufactured in the US).

Ms. Rodríguez also led an FDA/EMA team on a foreign pre-approval inspection of a QbD NDA that identified and established a process control strategy using PAT, multivariate modeling, SPC and risk management tools. In addition, she led several FDA/EMA teams on CM (Continuous Manufacturing) pre-operational visits and pre-approval inspections. These team inspections used FDA's integrated approach that includes Reviewers and Compliance Officers on inspections. Ms. Rodríguez has also demonstrated her specialized knowledge and support of FDA's QbD and PAT initiatives by providing numerous presentations and frequent technical assistance to FDA personnel, Academia and Industry.

In July of 2004, Ms. Rodríguez was among the first to become certified as Level II Drug Investigator and as Level II Drug Investigator Certification Performance Auditor under the newly implemented Drug Certification program. She was also among the first five Investigators certified at Level III (Pharmaceutical Inspectorate). Ms. Rodríguez was an Instructor in FDA training courses such as Pharmaceutical Inspectorate, Process Validation, Basic Drug School, API (Active Pharmaceutical Ingredients) Manufacturing, International Inspections, Pre-Approval Inspections, Industrial Sterilization, and Computer-Aided Inspections. Since 2013, she was the Lead Instructor in one of the two main Drug Investigator Training Courses, DG 230. This 2-week course comprised Systematic Drug Inspection elements of drug manufacturing principles, Process Validation and inspectional/auditing techniques.

Ms. Rodríguez was also responsible for providing on-the-job training to ORA Investigators and Analysts. CDER personnel also received on-the-job training from Ms. Rodríguez. In addition to training FDA staff, Ms. Rodríguez has regularly provided drug GMP training to Industry and regulatory bodies from foreign countries. Ms. Rodríguez has extensive experience providing advice and serving as liaison to international organizations such as WHO, regulated industries, other Federal agencies and executive managers within FDA.

Ms. Rodríguez work in the international arena included activities that supported FDA's leveraging efforts. For instance, Ms. Rodríguez was ORA's field expert working towards FDA's acceptance in PIC/S (Pharmaceutical Inspection Convention Scheme). Ms. Rodríguez also worked for three years with representatives of regulatory bodies from US, Canada and Latin American countries in drug GMP harmonization activities promoted by PAHO/WHO.

In June of 2004, Ms. Rodríguez was the only ORA representative in outreach meetings held in South Africa and India under PEPFAR (the President's Emergency Plan for AIDS Relief). This high-profile mission was assigned by the Department of Health and Human Services, and was led by the Assistant to the HHS Secretary. The US Embassies in both countries hosted the US HHS Team and participated in the meetings with local government authorities and drug manufacturers. Ms. Rodríguez' role in these meetings was to explain FDA's inspectional process to firm's interested in getting FDA's expedited approval for Anti-Retroviral drugs intended for the treatment of AIDS in the countries listed under PEPFAR.

During her FDA career Ms. Rodríguez regularly wrote and/or evaluated regulatory and policy documents, such as Compliance Programs, CDER's Q&A documents, and Guidances to Industry on OOS Investigations, PAT (Process Analytical Technologies), Process Validation, Contract Manufacturing, etc. In addition, she prepared and delivered briefings, technical and scientific papers, specialized and complex training, and official reports and decision memos.

Ms. Rodríguez is the recipient of numerous prestigious awards for outstanding performance.

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CONTACT US

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