

## Melissa Garcia

Senior Consultant

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## Summary

- 16 years of front-line FDA inspection and enforcement experience
- Helped launch and streamline the drug pre-approval program in response to a generic drug scandal
- Expertise in food, device, and cosmetic inspections
- Lead investigator on numerous foreign and domestic drug inspections
- Participated in all types of complex drug inspections, including mass seizures and drug search and seizure
- Conducted numerous food, device, and cosmetic inspections
- Designed and developed inspection and enforcement training programs for FDA personnel
- Drug Pre-Approval manager for the Baltimore District
  - Trained and organized a group of 6 investigators to perform drug inspections in 3 states and District of Columbia
- Strong working knowledge of pharma sales and marketing issues, regulatory affairs, and facility design

## Experience

2011 - Current

### **GMP Auditor**

*ACS Dobfar/Interchem Corporation*

Conducted vendor and client audits

Performed mock FDA inspections for international companies

Assisted with Warning Letter and FDA-483 responses

2007 - 2011

### **President**

*MG Consulting*

Conducted vendor and client audits

Prepared drug manufacturers for a first-time FDA inspection

Created responses to Warning Letters and FDA-483 documents

2002 - 2007

### **Drug Pre-Approval Manager**

*U.S. Food and Drug Administration*

Conducted pre-approval inspections of all drug manufacturers with Maryland, Virginia, West Virginia, and the District of Columbia

Responsible for all drug applications associated with the Baltimore District

Trained FDA investigators on the concepts and strategies to execute every type of drug inspection

2002 - 2007 cont. Performed foreign drug inspections twice per year for the Office of Regulatory Affairs

Certified Level I and Level II Drug Investigator

**Awards**

- Outstanding Professional, Excellence in Federal Career
- Sustained Superior Performance Award
- Exemplary Performance in the Contribution to Public Health

1994 - 2002

**Consumer Safety Officer/Project Manager**

*Office of Compliance, Foreign Inspection Team*

*U.S. Food and Drug Administration Center for Drug Evaluation and Research*

Lead investigator for many foreign drug inspections

Managed all pre-approval inspection processes

- Issued inspection requests for domestic and foreign inspections
- Reviewed foreign inspection reports
- Worked with all drug review divisions to aid in the approval of new and generic drugs

Helped develop the current CDER inspection tracking program

Liaison between CDER reviewers and field operations for all drug inspections

Helped write guidance for the Drug Industry regarding Part 11 and Sterile Drug Products

Lead investigator for many foreign drug inspections

**Awards**

- FDA Commendable Service Award
- Award of Merit
- Team Excellence Award
- Hammer Award
- Outstanding Achievement Award
- Group Recognition Awards

1992-1994

**Consumer Safety Officer**

*U.S. Food and Drug Administration*

*Los Angeles District Office*

Conducted drug, device, and food inspections

Participated in search and seizure

Assisted in criminal investigations

Conducted undercover investigations and participated in mass seizures

1991 - 1992

**Consumer Safety Officer/Project Manager**

*CDER, Office of Compliance  
Division of Manufacturing and Product Quality  
U.S. Food and Drug Administration*

Responsible for issuing inspection requests for domestic and foreign inspections

- Oversaw the pre-approval inspection process
- Reviewed inspection reports
- Worked with all drug-review divisions to aid in the approval of new and generic drugs
- Liaison between CDER reviewers and field operations for all drug inspections

1986-1989

**Bench Chemist, Microbiologist**

*Barre National Pharmaceuticals (AL Laboratories)*

Performed USP microbiological testing on liquid pharmaceuticals and antibiotics

**Education**

1986

**B.S. - Natural Sciences and Math (Pre-Med)**

*University of Alabama Birmingham*