Drug Specialist Investigator; Medical Device Specialist Investigator;
Team Biologics Compliance Officer; Food Investigator

AREAS OF EXPERTISE

- **GMP audits of API, oral, and sterile drug dosage forms. Evaluation of quality systems, manufacturing systems, validation programs, and microbiological laboratories**
- **Developed complaint and failure investigation system for medical devices**
- **Preparation for FDA pre-approval inspections**
- **Development and remediation of quality systems (from GAP analysis to development of SOPs to implementation**
- **Assist clients in achieving successful follow up inspections after receipt of warning letters**
- **Due diligence GMP audits**
- **FDA 483 responses**

INTRODUCTION

Documented compliance expert with thirty-four years in the U.S. Food and Drug Administration expertise auditing active ingredients, all drug dosage forms including active ingredient, sterile biotech and oral solids. Remediation of Quality Systems following FDA 483's, Warning Letters and consent decrees resulting in acceptable follow up inspections. Proven regulatory compliance, and remediation for pharmaceutical manufacturers. Preparations for FDA and EMEA pre-approval inspections.

WORK EXPERIENCE

2006 – Present
GMP Compliance Consultant
Duties:

- Successful remediation of quality systems (from GAP analysis to development of SOPs to implementation)
- Remediation efforts following Warning Letters from FDA have always led to passing follow up inspections.
- Brought in by drug product manufacturer following receipt of 17 page FDA 483 and Warning Letter which raised fears of a consent decree. The FDA inspection following my long term remediation efforts resulted in a one page FDA 483 and no further action.
- Remediation following receipt of Warning Letter by Medical Device Manufacturer consisted of development of complaint investigation system which passed FDA scrutiny.
- Part of remediation team that resulted in a consent decree being vacated one year early for a vaccine manufacturer.
- GMP audits of API, oral solid and sterile dosage forms. Evaluation of quality systems, manufacturing systems including aseptic filling operations, facility and equipment systems, validation programs, microbiological laboratories, investigations, CAPAs, etc.
- Due diligence GMP audits

- Prepared a number of firms for FDA pre-approval inspections (PAI's) through mock FDA audits and/or by exposing employees to typical FDA interview questions. FDA inspections following these PAI preparations have never resulted in significant findings or delay of the application approval.
- Consent decree remediation and certification of corrections.
- FDA 483 responses
- Gap analyses of CMC Sections of NDA's and ANDA's
- Medical Device QSIT Audits
- Audits of pharmacy compounders and outsourcing facilities

01/2006 – 10/2006
Hyde Engineering and Consulting, Inc.
Senior Compliance Consultant
Duties:
- Preparation of biotech manufacturers for FDA pre-approval inspections.
- GMP audits of biotech manufacturers
- Execution of equipment cleaning validation studies

1997 – 2006
U.S. Food and Drug Administration, Office of Enforcement, Rockville, Maryland
Team Biologics Compliance Officer
Duties:
- Lead Compliance Officer on FDA's national biotechnology and vaccine inspection team
- Drafted about 25 Warning Letters to CBER licensed drug manufacturers
- Managed FDA's more critical biotechnology, vaccine and plasma fractionated GMP warning letter and consent decree cases
- Evaluated numerous responses from industry to FDA-483's and Warning Letters
- Speeches to pharmaceutical industry groups on: Application of GMPs to Biotechnology, CAPA, Cleaning Validation, FDA Inspections, Pharmaceutical Water Systems, Process Validation for Sterile Biotechnology Products.
- Trained FDA Investigators on sterile drug inspections.

1976 – 1984 & 1987 – 1997
U.S. Food and Drug Administration, San Juan, Puerto Rico
Drug Specialist Investigator
Duties:
- Conducted FDA drug inspections in Puerto Rico, Europe, Central American and Asia covering APIs and sterile and non-sterile drug product dosage forms.
- Nominated FDA National Investigator of the Year for 1991 and for 1992
- Pharmaceutical plant inspections resulted in:
- Corporate-wide injunction and consent decree of a "big pharma" company
- Shut down of multi-national company's sterile, antibiotic manufacturing facility.
- Injunction of a manufacturer of unapproved cancer drugs.
- Inspection of tablet and capsule manufacturer resulted in the placement of about 1000 lots on stability testing and the recall of over 200 lots

1984 – 1987
U.S. Food and Drug Administration, Dallas, Texas
Spanish Speaking Compliance Officer
Duties:
As Liaison between FDA and the Mexican Departments of Health and Agriculture, established lines of communication which resulted in the correction of problems with the application of pesticides on Mexican produce.

1981 – 1984
U.S. Food and Drug Administration, Houston, Texas
Medical Device Specialist Investigator

1972 – 1976
U.S. Food and Drug Administration, Berkeley, CA
Food Investigator

EDUCATION

California State University, San Bernardino
Bachelor of Arts: Biology