FDA Investigator

AREAS OF EXPERTISE:

- **US FDA Investigator (1972-1996)**
- **Pre-Approval Inspections**
- **cGMP Compliance/Audits**
- **ISO 9001 Quality Systems Auditor**
- **cGMP and Documentation Training**
- **Pharmaceutical and Medical Device Inspections**
- **Quality System Development & Implementation**
- **21 CFR Part 11 Electronic Records; Electronic Signatures**

INTRODUCTION

This resource has more than 24 years of experience as a US Food & Drug Administration Investigator with more than 15 years of industry experience. He was the resident in charge at a large US port of entry, handling import operations regarding control and sampling/interdiction for the enormous amount of food crossing the US border. His FDA experience includes pre-approval inspections of pharmaceutical manufacturers, non-clinical and clinical trials, and medical devices assessments with areas of expertise in sterile operations and computer controlled processes. His experience includes significant domestic and international pre-approval inspections, including some of the largest antibiotics manufacturers in the world, biotech drug/device research and API/finished dose facilities, and a major Metered Dose Inhaler manufacturer.

EXPERIENCE SUMMARY:

- **The FDA Group, Worcester, MA**
  Assist large- and medium size pharmaceutical and biological manufacturing facilities in preparation for FDA pre-approval inspection, using a "mock FDA inspection" style. Critical evaluation of computer assisted manufacturing operations and computer assisted operations of non-clinical laboratories and computerized clinical trial operations. Assessments include manufacturing process controls, analytical chemistry and microbiology laboratories' controls, procedure and policy controls, training.

- **NNE Pharmaplan--formerly Valicor, West Chester, PA**
  More than 4 years as senior compliance consultant performing Quality Assurance assessments of pharmaceutical manufacturing plants for compliance to cGMP regulations. Regularly presented a two-day course nationwide to FDA regulated industry representatives, titled "Conducting Internal Audits and Pre-Approval Inspections".

- **Aventis/Rhone Poulenc-Rorer, Collegeville, PA**
  Conducted International QA Audits of manufacturers of Finished Pharmaceuticals and Bulk Pharmaceutical Chemicals. Managed the PAI audit program for successful FDA approval of RPR's two large NDA projects. Prepared sites for Pre-Approval Inspections and received successful approval of two major New Drug Applications (Synercid and Taxotere). Coached key site managers and production staff on Pre-Approval Inspections and on critical current Good Manufacturing

Practice philosophies and skills by an integrated approach, using in-depth knowledge of regulatory practices. Developed corporate written procedures and assisted in development of corporate policies. Conducted supplier audits to assist domestic supplier audit staff.

- **US Food & Drug Administration Investigator (1972-1996).**
  Promoted safety and efficacy of FDA regulated products through domestic and international inspections of FDA regulated industry. Responsible for six (6) successful prosecutions of food establishments during long FDA carrier. Responsible for numerous FDA warning letters and numerous food seizure operations, including federal seizure of entire warehouses. Areas of specialty include sterile operations and computer controlled processes. Broad inspection expertise in the following:
  - Foreign commodity importation reviews
  - Low-Acid thermally processed products and HACCP inspections
  - Resident in charge
  - Animal tissue residue investigations (FDA Program Manager)
  - Pre-approval medical device and pharmaceutical inspections
  - Non-clinical and clinical trials
  - Institutional review boards
  - Biological Products: Plasmapheresis & Blood bank operations

  Inhalant Manufacturing Inspections: Experience includes pre-approval inspections for aerosols/pressurized Metered Dose Inhalers (MDI)--potent steroid drugs--using "sterile"/containment manufacturing operations. These operations are handled in containment/isolators for the protection of the employees. These MDI inspections lead to meaningful changes in complicated operations as the result of inspection observations.

  MDI coverage typically includes drug substances that are micronized usually via computer controlled equipment to control particle size distribution at manufacturing and during stability testing. Micronization of Drug Substance and measurement of total canister pressure and reworking of weight cans (fill, propellant leakage rates, etc.) are issues; in that, leakage rate is directly related to the total pressure of the canister and the composition leads to higher API content per actuation.

CONTINUED PROFESSSIONAL DEVELOPMENT

Quality Systems Lead Auditor RAB	C Programming Language
Validation of Biologics	Autocad 13
Process Validation	Computer Software Validation

EDUCATION: Cal. State Fresno
Graduate study - Biology

TRAINING: 21 CFR Part 11 Electronic Records; Electronic Signatures: auditing system development and system maintenance, application to legacy systems and the systems' development life cycle. Training by FDA--as FDA investigator and later during service as an official for a large validation firm.

AFFILIATIONS: Parental Drug Association
International Society for Pharmaceutical Engineering
American Society Quality Control
Regulatory Affairs Professionals Society

CERTIFICATION: ISO 9001 Quality System Auditor

The following is a list of professional development courses completed:

Drugs:
Pharmaceutical and Experimental Therapeutics
Nonclinical Bioresearch Monitoring
Preapproval Drug Inspection
Clinical Supplies Packaging
Industrial Sterilization of Drugs/Devices
Drug Manufacturing Quality Control
Drug GMP Updates (annual)
DIA Conference
Compressed Medical Gas GMP

Biologics/Biotech:
Blood Bank & Plasmapheresis
Biotechnology Intro.
Validation of Biologics

Medical Device:
Medical Device Training
Quality Auditing ASQC
Medical Device Process Validation

Computer Systems:
Advanced Regional PC Training
Computer Use in FDA Investigations
Computers in Process Control
Train the Trainer –Investigating Computer Application
Computer Software Validation
C Language programming Level 1
DBase IV, Quattro Pro, Autocad 13

Foods:
Food Micro. & Sanitation Control
Control of Foodborne Disease
Current Concepts Food Protection
FDA/NCA Better Process Control
Basic Food Technology

FDA Law:
Acting Compliance Officer
Basic Food & Drug Law
Legal Aspects of Enforcement

International:
Orientation to International Inspections

Management:
Pre-Supervisory Workshop
Acting Supervisor Investigator
Working Together for managers
EEO Awareness
Intro to Supervision
Ethics & Bribery Awareness
Communicating with the FDA
Report Writing

Veterinary:
Animal tissue residue investigations (FDA Program Manager)
Medicated Feed Inspection