Director, Scientific and Regulatory Compliance

AREAS OF EXPERTISE

- **Training**
- **FDA and USP policies and procedures**
- **Analytical method validation / verification / transfer**
- **Dissolution / release rate testing / mechanical calibration**
- **Preparedness for inspection**
- **FDA enforcement policies and trends**
- **Laboratory GMP / Preapproval:**
- **Simulated FDA inspections / deficiency letter – 483 response / process improvement**
- **Laboratory quality system / SOP development per GMP / Q7A / ISO 17025**
- **Analytical method validation / verification / transfer**
- **Contract laboratory audits supplier audits**

INTRODUCTION

*36 years FDA experience * CDER Compliance experience * Pharmaceutical laboratory technical and management expertise * Pre-approval and GMP inspectional experience * Extensive government and industry teaching resume * Outstanding written and oral communications skills * Extensive network of Agency contacts

WORK EXPERIENCE

2010 – Present
Industry Consultant, Laboratory GMPs and related areas.

2010 – 2013
NSF International, Ann Arbor, MI
Director, Scientific and Regulatory Compliance, Reference Standards Program
Duties:
Development of analytical protocols for reference standard qualification, management of Technical Review Board for final approval of reference standards; liaison with industry and regulatory agencies

2009 – 2010
FDA, CDER, Office of Compliance, International Compliance Branch
Senior Policy Advisor
Duties:
Case management, regulatory actions, consultations in scientific and regulatory manners, international inspections.

2006 – 2009
FDA Division of Field Science in Rockville, MD
Senior Coordinator, Pharmaceutical Sciences
Duties:
Coordination of ORA drug laboratory programs, education and training of laboratory scientists, liaison with CDER and USP

2000 – 2006
FDA Division of Field Science in Rockville, MD
Deputy Director
Duties:
First-line supervisor of a staff of 19 professionals and program analysts, dealing with the full range of ORA science issues and laboratory activities

1990 – 2000
FDA Seattle District Laboratory / Pacific Regional Laboratory Northwest in Bothell, WA
Supervisory Chemist
Duties:
Supervised a team of as many as 14 chemists, providing service in pharmaceutical analysis to the entire Pacific Region

1987 – 1990
FDA Division of Field Science in Rockville, MD
Science Coordinator
Duties:
Coordination of ORA drug laboratory programs, including ANDA/NDA method evaluations, dissolution, drug surveillance, and research.

1974-1987:
FDA Los Angeles District Laboratory
Chemist
Duties:
Dissolution testing, automated analysis, HPLC, analyst inspections.

EDUCATION

1973
Michigan State University, East Lansing, MI
Bachelor of Science, Biochemistry

CAREER HIGHLIGHTS

- Developed the ORA Laboratory Manual Chapter on Drug Method Validation and Verification
- Developed the ORA-wide SOP on calibration and operation of dissolution equipment
- Structured the redesign of the New Hire training program for field analysts
- Trained numerous FDA analyst/investigators on GMPs, inspectional procedures, and FDA policies
- Developed and led the Pacific Regional drug analytical team, an agency leader in the response to many significant criminal and civil drug adulteration episodes, agency pioneer in analyst inspections
- Initiated and negotiated CRADA with USP to evaluate reference standard candidates; managed the program
- Coordinated the nationwide laboratory response to the 2007 Pet Food / Melamine emergency
- Numerous presentations: national training courses and scientific/regulatory conferences
- Foreign and domestic inspections, including India and China