Douglas A. Campbell
Senior Consultant

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InterProQRA
QUALITY & REGULATORY AFFAIRS

Summary

- 14 years of FDA inspection and enforcement experience
- Skilled practitioner of pharmaceutical GMP
- Lead Investigator – compliance with CGMP and pre-approval/licensing of NDA/ANDA/BLA
- Expertise with myriad dosage forms with a focus on parenterals manufacturing
- International and domestic experience
- Primary CDER Office of Compliance source for inspection and enforcement strategy and parenterals manufacturing
- Primary CDER source regarding Application Integrity Policy (AIP)
- Lead inspector negotiating the Consent Decree for Permanent Injunction of a major international drug manufacturer
- Represented FDA at executive meetings with industry representatives, regulatory counsel, and international FDA counterparts
- Designed and delivered training programs to international and domestic audiences
  - Concepts and principles of inspection/enforcement
  - Technical aspects of parenteral drug manufacturing operations

Experience

2012 - Current

Senior Consultant
Interpro-QRA

GMP Auditor

Conducted vendor and client audits

Performed mock FDA inspections for international companies

Assisted with Warning Letter and FDA-483 responses

2011 - 2012

Senior Policy Advisor
International Compliance Branch
Office of Manufacturing and Product Quality (OMPQ)
CDER/Office of Compliance (OC)
U.S. Food and Drug Administration

Conducted regulatory enforcement actions and actively conducted inspections, with a focus on parenteral drug manufacturing operations

Provided resolutions and problem solving related to inspection, enforcement, and emergency issues in the OMPQ

- Domestic and international CGMP enforcement cases
- Drug Shortage issues
- Field Alert and Adverse Event Reports

2011 - 2012 cont. Conducted a 4-week trip (June 2011) as part of a "Capacity Building" project with the FDA China Offices to provide training, communication, and planning for the SFDA and Provincial FDA as they prepare for a new era in drug regulation and enforcement.

- Delivered presentations to students and industry personnel at Peking University and the Chinese Pharmaceutical University (Nanjing)

Served as lead for the Office of Compliance

- Culminated in January 2012 with a high-profile and precedent-setting Consent Decree for Permanent Injunction

2006 - 2011 **Compliance Officer**
International Compliance Branch
Division of Manufacturing and Product Quality (DMPQ)
CDER/Office of Compliance
U.S. Food and Drug Administration

Reviewed and evaluated inspectional data from international drug inspections

Initiated and coordinated regulatory enforcement actions for operations where GMP deficiencies were observed and responses from that firm were deemed inadequate

Member of the International Inspection Cadre (since 2001)

- Conducted inspections as the Lead Investigator, with a focus on parenteral drug manufacturing operations

Subject matter expert for the DMPQ

- Responded to external inquiries related to water systems, facilities and equipment, aseptic processing, and cross-contamination issues, among other topics

CGMP expert within the DMPQ and OC

- Provided expert advice related to conducting inspections, evaluating compliance, and enforcement philosophy

2005 - 2006 **Drug Specialist**
Baltimore District Office
U.S. Food and Drug Administration

Coordinated the Drug Program for Baltimore District and served as the Assistant Pre-Approval Manager

Conducted comprehensive inspections of complex drug manufacturing operations, with a focus on parenteral drug manufacturing operations

1998 - 2005 **Consumer Safety Officer**
Roanoke Resident Post (Virginia)
Baltimore District Office
U.S. Food and Drug Administration

Conducted complex inspections in many different program areas

- Infant formula
- Acidified/low-acid canned foods
- In-vitro diagnostic devices
- Solid oral dosage drugs
- Medicated animal feed/BSE

1998 **Laboratory Scientist**
SRA Life Sciences
Rockville, MD

Conducted laboratory operations to extract and collect white blood cells from blood that had been collected from patients/subjects who were involved in studies related to drug treatments for HIV and hepatitis-C Infection

Professional Affiliations

- Parenteral Drug Association (PDA)
- International Society of Pharmaceutical Engineers (ISPE)

Invited Presentations

- Peking University, Beijing, China, June 2011; *Process Validation: A Lifecycle Approach*
- Chinese Pharmaceutical University, Nanjing, China, June 2011; Process Validation: *A Lifecycle Approach*
- PDA Workshop on Aseptic Processing, November 2009; Issues and Approaches, Washington, DC; *Regulatory Trends in Aseptic Processing*

Education

1998 **B.S. - Science of Food, Nutrition, and Exercise (Pre-Med)**
Virginia Polytechnic Institute & State University