Curriculum Vitae

Douglas A. Campbell

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Summary of Special Skills/Qualifications

Within my fourteen years working at the USFDA, I had the opportunity to develop a working knowledge of inspection and enforcement policy and procedures. As a skilled practitioner of the pharmaceutical CGMP, I served as the Lead Investigator on numerous USFDA inspections for evaluation of compliance with CGMP and for pre-approval/license of NDA/ANDA/BLA. These inspections were conducted at locations in the U.S. and abroad, and covered a myriad of dosage forms, with a focus in parenteral drug manufacturing operations.

During the last six years at CDER Office of Compliance, I established myself as the primary source for consultation regarding inspection and enforcement strategy and parenteral drug manufacturing. I had the opportunity to provide innovative approaches to regulation within a dynamic industry. In addition, I established myself as the primary source for consultation regarding the Application Integrity Policy (AIP) and served as the lead for CDER Office of Compliance regarding the negotiation of the Consent Decree for Permanent Injunction of Ranbaxy Laboratories Limited, Inc.

My skills as a public speaker/instructor have proven to be a complement to my technical expertise. I have represented the USFDA during many high-profile meetings with industry representatives, regulatory counsel, and international counterparts of the USFDA. In addition, I developed and presented training ranging in topics from the concepts and principles of inspection/enforcement to training designed to discuss technical aspects of parenteral drug manufacturing operations and Quality Risk Management.

It has been nearly fifteen years since I left my position in the USFDA, and I have had the opportunity to develop my technical expertise and make the transition from regulator to consultant. This work continually presents situations that require critical thinking and effective solutions. I continue to enhance my reputation as a professional that is dedicated to the public health mission.

Work Experience

2026 Owner and Principal, Campbell CGMP Services

Guidance for Effective QRM
Consulting Services for the Global Pharmaceutical Industry

2012 – 2026 Senior Consultant, InterPro QRA

Managed and executed the Supplier/CMO Audit Program at WorldGen Critical Care and HQ Specialty Pharma

Developed and presented the Semi-annual and Quarterly CGMP Training Program at WorldGen Critical Care and HQ Specialty Pharma

Provided guidance and support with consulting services to clients in the global pharmaceutical industry, ranging from non-sterile API to sterile finished dosage forms, ATMP, etc.

Conducted audits, mock inspections, and inspection readiness assessments for compliance with US and EU regulations, and conducted visits with a broad range of goals and specific missions, with focus on data integrity, QRM, and quality assurance accountability

Demonstrated success with remediation operations in response to enforcement actions by FDA and other regulatory entities

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

Coordinated regulatory enforcement actions and actively conducts inspections, with a focus in parenteral drug manufacturing operations

Served as a resource to provide resolutions and problem solving related to inspection, enforcement, and emergency issues in the OMPQ -
This includes domestic and international CGMP enforcement cases, Drug Shortage issues, and Field Alert and Adverse Event Reports.

Conducted a four-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 - This included presentations to students and industry at Peking University and the Chinese Pharmaceutical University (Nanjing).

Served as the Lead for the Office of Compliance during several years that 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 to be inadequate

Served as a member of the International Inspection Cadre (since 2001) and actively conduct inspections as the Lead Investigator, with a focus in parenteral drug manufacturing operations

Served as a subject matter expert for the DMPQ and responded to external inquiries related to water systems, facilities and equipment, aseptic processing, and cross-contamination issues, among other topics

Served as a CGMP Expert within the DMPQ and OC on and 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 in 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
These inspections included: Infant Formula, Acidified / Low-Acid Canned Foods, In-vitro Diagnostic Devices, Solid Oral Dosage Drugs, and Medicated Animal Feed/BSE.

1998 **Laboratory Scientist**
SRA Lifesciences
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)
Planning Committee – PDA/FDA Joint Regulatory Conference

International Society of Pharmaceutical Engineers (ISPE)

Invited Presentations

February 2025 – Clean Lab 2025, Milan Italy, "Work Smarter Not Harder with Your QRM"

September 2024 – PDA/FDA Joint Regulatory Conference, Washington D.C., "Applying QRM Principles to Better Navigate Outcomes and Partnerships with Your CMO"

September 2022 – PDA/FDA Joint Regulatory Conference, Washington D.C., "Haste Makes Waste – Lessons Learned for How to Avoid a Crisis"

April 2016 – Pharmaceutical Technical Exchange Association (PTEA), Kansas City, MO – "Five Years with the FDA Process Validation Guidance: Has the Industry Embraced the Concepts and Expectations?"

April 2014 – PDA Annual Conference, San Antonio, TX – Data Integrity Session "Ranbaxy: Lessons Learned – 'Don't let this happen to you!'"

June 2011 – Peking University, Beijing, China – "Process Validation: A Lifecycle Approach"

June 2011 – Chinese Pharmaceutical University, Nanjing, China – "Process Validation: A Lifecycle Approach

November 2009 – PDA Workshop on Aseptic Processing: Issues and Approaches, Washington, DC – "Regulatory Trends in Aseptic Processing"

Publications

"Points to Consider When Applying QRM: Principles to Better Manage the Partnership/Relationship with Contract Operations," Parenteral Drug Association – PDA Letter, December 2024

Education

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