**Former Consumer Safety Officer/Investigator**

**AREAS OF EXPERTISE**

- **Human Subject Protection / ICF process & document review through mock FDA inspections**
- **Bioequivalence Clinical & Laboratory, GMP, cGMP, GLP non-clinical & clinical, GCP, eTMF, and ICH**
- **FDA bioresearch monitoring (BIMO) review NDA, IND, BLA, and fast Trak**
- **PAI cGMP Readiness and eTMF GAP**
- **Mock FDA Inspections with a CGMP Systems Approach**
- **Computer system validation & 21 CFR part 11 compliance / LIMS / Data Management System compliance**
- **IRB & QA audit Training through continuing education presentations on FDA Regulatory Strategy**
- **Protocol data-validation Auditing / Quality Management / SOP auditing**
- **Drug Component and Supplier Qualification Audits**
- **QC/QA & Microbiology Laboratories Audit**

## INTRODUCTION

Consultant is an experienced Documented Regulatory Affairs 21 CFR compliance professional and advocate for human subject protection. Twelve years of U. S. Food and Drug Administration experience auditing Sponsors, CROs, API & sterile drug manufacturers, cell & gene therapies, IRBs, Principal Investigator pre-approval (CBER, CDER, & CDRH), Bioequivalence / Bioanalytical Clinical & Laboratory, computer systems and 21 CFR part 11, GLP laboratories clinical & non-clinical, and test article bio-test sampling. Specialize in gene therapy and IRB 21 CFR compliance. Regulatory review experience with oncology therapies for most human body systems (vulnerable patient populations included), cardiovascular disease, HIV (President's emergency plan for AIDS relief / PEPFAR), vaccine studies including Department of Defense test articles, pain management for multiple indications, in-vivo & in-vitro devices, and API & sterile drug cGMP manufacturers of biochemical and biological therapeutics. FDA bioresearch monitoring (BIMO) review experience including phase I, II, III clinical trials, Sponsor, CRO, GLP clinical & pre-clinical trials and for-cause compliance audits. FDA Inspectional history includes eTMF regulatory and legal FDA actions including warning letters, NDA revocations, and disqualifications.

## WORK EXPERIENCE

**04/2011 – Present**
Industry Consultant
**Duties:**

- Provide mock regulatory BIMO audits, BIMO Quality Assurance recommendations, regulatory consulting for CROs, IRBs, device, and drug companies conducting IND, NDA, 510K, IDE, PMA clinical trials.
- Aseptic pharmaceutical (API) manufacturing mock FDA Inspections and pre-approvals (PAI).
- Conduct GCP clinical site audits, vendor qualification, data management systems audits & qualifications, 21 CFR Part 11 compliance, and validation review.

- API & sterile Drug Product pharmaceutical cGMP audit conduct including deliverables, such as preparing detailed report of audit findings and remediation follow-up.
- Provide technical support for FDA-required compliance strategies including employee training, protocol adherence, ICF process, and research operation SOP's for regulated industry, professional societies, and academia.
- Patient safety compliance and surveillance for IRB's.
- Informed consent form process review and maintenance for IRBs, Sponsors, & Study sites.
- Recall audit checks for any regulated product, post market surveillance Medwatch adverse event reporting, & medical device reporting (MDR).
- Marketing strategies for all FDA regulated products including social media campaign compliance.

**08/1998 – 03/2011**
U.S. Food and Drug Administration
Consumer Safety Officer/Investigator
**Duties:**

- Conducting over 300 BIMO phase I, II, & III GCP investigations for pharmaceutical small molecule and biotechnology-derived human drugs and devices.
- Performed GCP audits of human subject protection / IRB/EC, Sponsors, Principal Investigators and Bioequivalence clinics & laboratories, IRBs/ECs in accordance with U.S. GCP regulations and ICH guidelines; Performed GMP audits of API, OTC, sterile dosage form human drug manufacturing facilities and GLP audits of clinical and non-clinical testing facilities.
- Responsible for collecting biotest samples of human pharmaceuticals during bioequivalence / bio-analytical investigations.
- Independently conducted domestic and international high priority / for-cause 21 CFR regulatory compliance audits and prepared establishment inspection reports (EIRs) for every audit which are available through Freedom of Information (FOI).
- Experience performing 21 CFR part 11 compliant data management systems / LIMS / validation review, electronic patient source records, and electronic CRF regulatory review.
- Regulatory review classifications include FDA legal and voluntary action such as clinical hold, NDA revocation, regulatory meetings, requests for additional information, warning letters, and disqualifications.
- Provided training to FDA and Texas Department of Health new hires in BIMO and human drug investigational techniques from 2004-2011. Provided technical support and FDA field operation initiatives to international counterpart organizations including the Canada Health Ministry, Argentina (ANMAT), and the Brazilian Ministry of Health.
- Responsible for biohazard pathogen trace-back using biosafety level II containment for bioterrorism and pandemic teams in the Dallas District (Texas, Oklahoma, and Arkansas).
- Conducted continuing education seminars for industry and academia including Baylor College of Medicine, M.D. Anderson Cancer Center, UTMB, and SoCRA.
- Served as Hispanic Employee Program Representative (HEPR) for Dallas District from 2001 to 2009; responsibilities included recruiting & maintaining Hispanic workforce in the Dallas District (Texas, Oklahoma, and Arkansas), provided mentorship for high school & college student in the greater Houston area, and planned educational events for National Hispanic Heritage month.

## EDUCATION

**1996 – 1998**
University of Texas at San Antonio (UTSA)
Master of Science: Biotechnology

**1990 – 1995**
University of Texas at San Antonio (UTSA)
Bachelor of Science: Biology

## PROFESSIONAL ORGANIZATIONS

- Society of Clinical Research Associates, Inc. (SoCRA)
- Society of Quality Assurance (SQA)

## LANGUAGES

- Proficient in reading, writing, and speaking Castilian Spanish
- Read Brazilian Portuguese and conducted BIMO audits without interpreter

## RECOGNITION

- 2001 FDA National EEO Achievement Award (HEPR mentorships)
- 2006 FDA National Outstanding Service Award Compounding Pharmacy Inspection Team
- 2006 Group Recognition Award Rapid HIV Test Inspections Group
- 2006 Commissioners Special Citation FDA Hurricanes Katrina / Rita Response Team
- 2001-2009 Dal-DO Group Award for BIMO Team Efforts
- 2011 Candidate BIMO National Expert for FDA