Joshua Sharlin, Ph.D.

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FDA RELATED PROFESSIONAL SUMMARY

Broad and deep skills in drug, biologic and medical device development. Hands-on experience in the entire lifecycle of product development from initial strategy to review at FDA. Authority in the collection, analysis, interpretation and presentation of information to FDA. Expert in predicting FDA reviewer's actions and reactions.

KEY SKILLS, EXPERIENCE & QUALIFICATIONS

- Former FDA reviewer
- Improve regulatory strategy
- Audit for FDA compliance
- Instructor on FDA topics
- Prepare site/sponsor for an audit by FDA
- Answer written FDA questions
- Write submissions, SOPs
- Secret Clearance (DoD)
- Identify and fix data integrity problems
- Audit and/or improve Trial Master Files
- Evaluate adverse event reporting
- Perform software validation
- Expert witness in lawsuits with an FDA regulatory component
- Speaker at FDA meetings with sponsors
- Conduct statistical analysis
- Identify, prevent and solve compliance problems

WORK HISTORY

Drug Development Leadership Advisor: Regulatory, 04/2016 to Current

Gap Solutions – Herndon, VA

Advise senior Department of Defense leadership on tactical and strategic regulatory actions affecting the path to FDA approval of 19 products (drugs, vaccines and medical devices) under development intended as defense against biological weapons.

- Attend all meetings with CDER, CBER and OCET (Office of Counterterrorism and Emerging Threats) and program contractors
- Write white papers for all programs identifying regulatory strengths, weaknesses and risks affecting progress toward FDA approval. Make and implement recommendations for improvement.

WORK HISTORY (continued)

Consultant & Principal, 06/1994 to Current

Sharlin Consulting – Washington, D.C.

- Audit sponsors, Contract Research Organizations (CROs), clinical sites, labs and software vendors for Good Clinical Practice (GCP) compliance. Identify and close compliance gaps in anticipation of an audit by FDA.
- Write, review and improve INDs, NDAs, PMAs, 510(k)s, protocols and SOPs.
- Expert witness in lawsuits regarding matters related to FDA's regulatory process for drugs and medical devices
- Solve compliance problems identified by FDA auditors and answer questions posed by FDA reviewers
- Develop and present more than 40 FDA-related technical, regulatory and compliance topics to over 50,000 people
- Assist sponsors and CROs in FDA compliance of electronic records, software products, databases and software development
- Investigate, analyze and improve data quality and data integrity in FDA regulated tasks and activities
- Prepare information for, and present information at FDA meetings with sponsors

Drug Reviewer, 05/1992 to 06/1994

Food and Drug Administration (FDA) – Rockville, MD

Manage the drug review process. Instruct firms on how to proceed with drug approval. Summarize outstanding problems and issues with protocols and studies and determine if deficiencies were adequately addressed. Review statistical methodology of studies. Author all written communication to the sponsoring firm and integrate comments from other reviewers.

EDUCATION

Ph.D. - Physiology, **University of Georgia** – Athens, GA

M.S. - Physiology **University of Maryland** – College Park, MD

B.A. - Biology, **University of Iowa** – Iowa City, IA