Joshua Sharlin, Ph.D.

Washington, D.C. ♦ C: 410-231-8900 ♦ josh.sharlin@fda-expert.net

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 regulatory strategy, clinical trial planning and execution, to submission preparation and review at FDA. Authority in the collection, analysis, interpretation, and presentation of information to FDA. Expert in understanding FDA reviewer's actions and reactions.

Based on experience training over 40,000 staff at FDA-regulated companies on technical and regulatory topics, skilled in explaining FDA related topics to juries.

Worked as an FDA regulatory expert witness in over 50 cases, deposed 16 times and testified 5 times. Specialist in analyzing FDA compliance information to answer three questions: 1) What did the company know and when did they know it? 2) What should the company have known and when should they have known it? 3) What should the company have done and when should they have done it?

Provide FDA related regulatory support to attorneys in cases involving; (i) death or injury caused by drugs, biologics, or medical devices, (ii) patent infringement, (iii) insurance claims, (iv) wrongful termination, (v) trade secrets, (vi) merger and acquisitions, (vii) stock fraud, (viii) software development, (ix) data integrity.

FDA Related Skills, Experience & Qualifications

- Former FDA reviewer
- Improve regulatory strategy
- Audit companies, CROs, vendors and clinical sites for FDA compliance
- Instructor on FDA topics
- Prepare clinical sites and companies for an audit by FDA
- Answer written FDA questions
- Write and improve clinical study protocols and clinical study reports
- Write drug and medical device submissions
- Secret clearance (Dept of Defense)
- Identify and fix data integrity problems
- Audit and improve Trial Master Files
- Evaluate adverse event reporting compliance for drugs and medical devices
- Perform software validation
- Expert witness in lawsuits with an FDA regulatory component
- Speaker at meetings at FDA as a representative of drug and medical device companies
- Expert in analysis and interpretation of FDA safety databases; MAUDE (medical devices), FAERS (drugs)
- Conduct statistical analysis
- Identify, prevent and solve compliance problems

Work History

Consultant & Principal, 06/1994 to Current

Sharlin Consulting, LLC – Washington, D.C.

- In August 2019 completed a 3-year contract as a Drug Development Leadership Advisor. 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 as medical countermeasures. Write white papers for all programs identifying regulatory strengths, weaknesses and risks affecting progress toward FDA approval. Make and implement recommendations for improvement.
- 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.
- 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 40,000 people at hundreds of FDA-regulated companies. All were paid presentations.
- 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 and present information to FDA at meetings with companies.
- Expert witness in lawsuits regarding matters related to FDA's regulatory process. Deposed in cases involving injuries caused by drugs and medical devices, also trade secrets, wrongful termination, insurance claims, patents, and mergers.

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. - Zoology, **University of Iowa** – Iowa City, IA

Dr. Sharlin's Knowledge and Experience Relevant to Expert Witness Work

Table of Contents

	Table 1 of 4. Eighteen Class Topics About FDA Regulations Developed & Taught by Dr. Sharlin to Staff in FDA Regulated Companies		
Row	**Class Topic (Dr. Sharlin developed 45 class titles covering these 18 topics.)**	**Number of Companies Paying to Attend the Class**	**Total Number of People Attending**
1	What Needs to be in a Product Submission: An FDA Reviewer's Perspective	731	6,074
2	Avoiding Statistical Errors in Clinical Trials	385	2,873
3	Electronic Records (21 CFR 11) Compliance	512	3,777
4	SAS Software: Programming & Compliance (SAS software is used by FDA and over 90% of FDA-regulated companies for statistical analysis, data management and reporting.)	615	3,331
5	Drug Safety Reporting & Compliance	421	3,346
6	Electronic Submissions – Creation & Compliance	352	2,061
7	How to Write FDA Compliant Standard Operating Procedures (SOPs)	753	5,579
8	Drug Labels and Labeling	151	1,113
9	FDA Reviewer Training	368	3,316
10	Annual Reports: Compliance Requirements for Content	168	1,095
11	Medical Device Safety Reporting & Compliance	284	1,671
12	Planning & Executing Clinical Trials Outside the U.S. - Compliance Requirements	175	1,112
13	Implementation of Adaptive Design for Clinical Trials	187	1,165
14	ClinicalTrials.gov - Requirements for Entering Information into the Clinical Trials Registration Website	732	3,977
15	510(k) Medical Device Submissions	77	404
16	Computer System / Software Compliance	269	1,687
17	Integrated Summary of Efficacy Requirements	84	809
18	FDA Requirements for Websites & Social Media	33	221
	Column Total =	6,297	43,611

	Table 2 of 4. Forty Standard Operating Procedures (SOPs) Written by Dr. Sharlin
1	Risk Assessment: Overview and Approach
2	Risk Assessment: Part 11 Applicability
3	Risk Assessment Checklist
4	SOP on SOPs
5	Device Annual Reports Required of Sponsors and Investigators Before Product Approval
6	Device Annual Reports Required of A PMA Sponsor, Manufacturer or User Facility
7	PMA Safety Reporting
8	Medical Device Reporting (MDR) Requirements for Device User Facilities
9	Medical Device Reporting Requirements for Device Importers
10	Medical Device Reporting Requirements for Device Manufacturers
11	Medical Device Complaint Records
12	IND (Drug) Safety Reporting
13	IND (Drug) Annual Reports
14	Biologics Annual Reporting
15	Post-Marketing Safety Reporting for Drugs and Biologics: Responsibilities
16	Post-Marketing Safety Reporting for Drugs and Biologics: Content
17	Validation of Electronic Adverse Event Data Capture Systems
18	Data Monitoring Committee – Creation and Activities
19	Statistical Analysis of Adverse Event Data
20	MedDRA Coding of Adverse Event Data
21	Drug Post Approval Annual Reports
22	Format and Organization Requirements For a Drug Label
23	Blinding Activities During a Clinical Trial
24	Initial SAS Software Installation
25	SAS Software Validation
26	SAS Software Requirements Specifications
27	SAS Software Coding Conventions
28	Debugging SAS Software Logic Errors
29	SAS Software Log Review
30	SAS Software Testing
31	SAS Software Change Control
32	Archiving and Restoration of Electronic Data
33	Audit Trails for Electronic Data

	Table 2 of 4. Forty Standard Operating Procedures (SOPs) Written by Dr. Sharlin
34	Computer Systems Disaster Recovery
35	System Access Security
36	Preparing for an FDA Inspection
37	Computer and Software Compliance
38	Technical Review of Submission Documents
39	Vendor Selection
40	Transfer of Study Obligations

	Table 3 of 4. Sixteen Depositions by Dr. Sharlin
1	Circuit court of Baltimore City. Deposed on FDA medical device regulatory and submission issues associated with a failed hip implant.
2	United States District Court, Middle District of Florida, Orlando Division. Deposed on FDA medical device regulatory and submission issues associated with a failed hip implant.
3	Circuit Court of the 17th Judicial Circuit, In and For Broward County, Florida. Deposed on the role of an Institutional Review Board (IRB) and the responsibilities of IRB members regarding conduct of a clinical trial and the safety of clinical trial subjects.
4	US District Court, Eastern District of Pennsylvania. Deposed on the regulatory responsibilities of drug manufacturers to provide Medication Guides to patients when they receive a prescription.
5	US District Court for the District of Oregon. Deposed on the regulatory issues involving patent infringement of a medical device.
6	Court of the Chancery of the State of Delaware. Deposed on regulatory issues regarding meeting drug development milestones in a merger agreement between a small biotech company and a large pharmaceutical company.
7	US District Court, Northern District of Illinois Eastern Division. Deposed on regulatory issues regarding the failure of a drug company to properly investigate the relationship between the use of their drug and the likelihood of heart attacks and stroke.
8	U.S. District Court, Minnesota. Deposed on the failure of a device company to accurately inform FDA about the frequency and cause of their medical device catching fire and the company's failure to fix the problem.
9	Circuit Court of the Sixth Judicial Circuit, Champaign County, Illinois. Deposed on the regulatory issues associated with the detection and analysis of brain catheter failures.
10	United States District Court Middle District of Louisiana, Deposed on a large pharmaceutical company's lack of regulatory compliance and actions regarding the association between Nexium and gastric cancer.
11	State of New Mexico County of Santa Fe, First Judicial District Court. Deposed on the non-compliant off-label promotion of AndroGel by the Defendants.
12	Court of the Third Judicial Circuit Madison County, Illinois. Deposed on Defendant's lack of regulatory compliance and actions regarding Zantac and its breakdown into and contamination with NDMA, a carcinogen.
13	Superior Court of the State of Washington, Snohomish County. Implantation of an unapproved version of an artificial ankle.
14	US District Court for the Western District of Texas, San Antonio Division, Deposed on off-label use of a sealant applied to a bone repair matrix medical device.
15	US District Court, Central District of California, Southern Division. A patent infringement case involving a neuromodulation medical device.
16	Missouri Circuit Court, 22nd Judicial Circuit, City of St Louis. Deaths of preterm infants from necrotizing enterocolitis (NEC) after fed formula.

	Table 4 of 4. Dr. Sharlin has Testified Five Times
1	State of New York Supreme Court. Damages case for a birth defect. Testified about the FDA drug approval process.
2	Superior Court of the State of California, County of San Diego. A trade secret case.
3	US District Court, Northern District of Illinois, Eastern Division. Testified in a failure to warn case regarding injury from a cardiac event caused by Androderm, a testosterone replacement therapy drug.
4	US District Court, Southern District of Mississippi. Testified in a failure to warn case regarding injury caused by a gastric balloon medical device.
5	International Trade Commission. Trade secret case. Testified about predicting the likelihood of a drug being approved by FDA.