



Joshua Sharlin, Ph.D.

Washington, D.C. ♦ C: 410-231-8900 ♦ jsharlin@pipeline.com
www.SharlinConsulting.com

Provide Food and Drug Administration (FDA)-related regulatory support to attorneys in cases involving; (i) death or injury caused by drugs, biologics or medical devices, (ii) patents, (iii) insurance claims, (iv) wrongful termination, (v) trade secrets, (vi) merger and acquisitions. Expert in data integrity and software development. Talented in testimony and depositions.

Hands-on experience in the entire lifecycle of FDA-regulated product development, from creating an initial regulatory strategy, thru data collection and analysis, to review and approval at FDA. Skilled at writing expert reports that describe and explain regulatory and compliance-related issues involving FDA-regulated companies.

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?

Key Skills, Experience & Qualifications	
• Former FDA reviewer	• Skilled in depositions and testimony
• Develop and present more than 40 FDA-related technical, regulatory and compliance topics to over 50,000 people	• Create lawsuit-specific information from FDA databases of safety information about medical devices and drugs
• Critique adverse event reporting	• Perform statistical analysis
• In-depth understanding of the FDA approval process for drugs, biologics & medical devices	• Identify, prevent & solve FDA compliance problems for drug, biologic, and medical device companies
• Expert in data integrity and software development	• Speaker at FDA meetings with drug, biologic and medical device companies

Work History

Consultant & Principal, 06/1994 to Current, **Sharlin Consulting** – Washington, D.C.

Drug Reviewer, 05/1992 to 06/1994, **Food and Drug Administration (FDA)** – Rockville, MD

Education

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