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FDA EXPERT WITNESS PROFESSIONAL SUMMARY

Skilled at writing expert reports that describe and explain regulatory and compliance-related issues involving FDA-regulated companies. Talented in depositions and testimony. Specialist in analyzing drug/medical device-related safety data and 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? (See page 3 for a description of expert witness projects.)

KEY SKILLS, EXPERIENCE & QUALIFICATIONS

• Former FDA reviewer	• Skilled in depositions
• Develop and present more than 40 FDA-related technical, regulatory and compliance topics to over 50,000 people	• Support attorneys in cases involving sulindac, fentanyl, Actos, breast cancer drugs and ADHD drugs
• Critique adverse event reporting	• Perform statistical analysis
• In-depth understanding of the FDA approval process for drugs, and medical devices	• Identify, prevent & solve FDA compliance problems for drug and medical device companies
• Expert in data integrity and software development	• Write expert reports on safety and FDA compliance of hip implants
• Vast experience auditing companies for FDA compliance	• Write FDA submissions, standard operating procedures (SOPs), and study reports
• Speaker at FDA meetings with drug and medical device companies	• Testify as an FDA expert witness in drug, biologic, and medical device cases

WORK HISTORY

Drug Development Leadership Advisor: Regulatory, 04/2016 to Current
Gap Solutions – Herndon, VA

Advise senior Department of Defense leadership on changes to tactical and strategic regulatory actions that improve 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 FDA. Write white papers for all programs identifying regulatory strengths, weaknesses and risks affecting progress toward FDA approval. Develop and implement recommendations for improving regulatory strategy.

WORK HISTORY (continued)

Consultant & Principal, 06/1994 to Current

Sharlin Consulting – Washington, D.C.

- Expert witness in court regarding matters related to FDA's regulatory process for drugs, biologics, and medical devices.
- Audit drug companies, contract research organizations (CROs), clinical sites, labs and software vendors for good clinical practice (GCP) compliance. Identified and closed compliance gaps in anticipation of an audit by FDA.
- Write, review and improve INDs, NDAs, IDEs, PMAs, 510(k)s, SAPs, 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 50,000 people
- Assist drug companies 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-related activities
- Prepare information for, and present information at FDA meetings with drug, biologic, and medical device companies

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. 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

FDA EXPERT WITNESS EXPERIENCE

1. For a hip implant, identify pre- and post-approval actions and inactions by the manufacturer that were noncompliant with FDA submission and adverse event reporting requirements. Deposed by defendant's attorneys.
2. For a hip implant, write an expert report describing the manufacturer's lack of FDA compliance in their efforts to obtain a 510(k) approval. Deposed by defendant's attorneys.
3. Conduct an FDA regulatory review of medical device company's actions after the installation of their implantable pulse generator (intended to relieve pain) caused harm.
4. For a hip implant, write an expert report describing the company's non-compliance with FDA labeling requirements and reporting of adverse event information.
5. Write a report explaining why the Warning Section of the label for a generic version of sulindac was deficient.
6. Write a report describing why the processes establishing the stability of a drug product met FDA compliance requirements for marketing.
7. Review the design of a trial requested by foreign regulatory authorities to compare the effectiveness of two drugs. Determine if the study design was manipulated to mask the weakness of one drug over the other.
8. Review and find weaknesses in a defense expert's report on the adverse event reporting of fentanyl. Write a report of findings.
9. Evaluate FDA compliance in reporting adverse event information about Actos. Review all annual reports. Write a report of findings.
10. Deposed about the roles and responsibilities of an Institutional Review Board in a wrongful firing case.
11. Testify for the defendant in a fertility clinic damages case. Explain the process and predictability of FDA approval of a drug under development.
12. Analyze the content of a drug IND submission to identify any trade secret content.
13. Identify FDA regulatory deficiencies in the adverse event reporting of a breast cancer drug and the describe the resulting deficiencies in the drug's label.
14. Determine if the adverse event reporting for a drug that treats Attention Deficit Hyperactivity Disorder (ADHD) is complete and correct and determine if the drug's label meets FDA regulatory requirements.
15. For a schizophrenia drug, analyze the scientific literature to determine if the drug's label and the company's updating the label's safety information was FDA compliant.