**Steven David Silverman**
**9224 Woodland Drive**
**Silver Spring, MD 20910**
**301-213-5780**
**stevesilverman@silverman-group.com**

## Experience

**The Silverman Group** **2021-present**
**Silver Spring, MD**
**President**

- Guide clients on medical product regulatory, legal, and policy issues
- Represent medical device firms in the Case for Quality Collaborative Community, which joins FDA and stakeholders to promote medical device quality and improve patient outcomes
- Promote client-regulator engagement on medical product matters including medical device premarket approval, medical device advertising and promotion, and medical product quality and compliance
- Develop and implement strategies to satisfy regulators and engage customers, patients, and stakeholders on medical product quality, compliance, and post-market oversight
- Articles and other publications available at www.silverman-group.com/publications

**Advanced Medical Technology Association (AdvaMed)** **2017-2021**
**Washington, DC**
**Vice President, Technology and Regulatory Affairs**

- Represented member companies before federal agencies on medical device legislative and regulatory matters
- Engaged federal regulators and member firms to develop and implement medical device quality strategies
- Provided expert insight to Congress and state legislators on the development and content of medical device oversight
- Led policy development on regulatory and legislative issues, including medical device quality, combination product regulation, and product approval

**McKinsey & Co.** **2015-2017**
**Washington, DC**
**Senior Expert, Pharmaceutical and Medical Products Practice**

- Advised pharmaceutical, medical device, health technology, and biologics clients on regulatory strategies, compliance and quality initiatives, and stakeholder communication
- Counseled clients on regulatory requirements for the design, manufacture, and distribution of medical products. Helped clients bridge compliance gaps and leverage quality gains to strengthen regulator relationships. Counseled clients on the effects of, and opportunities to shape, regulatory policies. Directed an industry cost analysis identifying annual medical device recoverable quality costs of $6-11 billion
- Advised clients on good manufacturing practice requirements for drugs and biologics. Assisted companies in resolving violations and demonstrating remediation to regulators. Counseled clients on quality-related regulatory policies, including implications for product review and post-market oversight
- Co-author, "Capturing the value of good quality in medical devices," www.mckinsey.com/industries/life-sciences/our-insights/capturing-the-value-of-good-quality-in-medical-devices

**United States Food and Drug Administration** **2002-2015**
**White Oak, MD**

**Director, Office of Compliance**
**Center for Devices and Radiological Health, 2010-2015**

- Established and drove strategic and policy objectives, directing a staff of 180+ scientific and regulatory professionals in promoting medical device quality while assuring compliance with applicable federal laws

- Led Center and Agency interactions with Congress, the press, and industry on topics such as FDA-industry collaboration on quality, digital health oversight, and promoting innovation
- Led a post-market reporting enhancement initiative resulting in the first-ever guidance distinguishing recalls from device enhancements and a 50%+ reduction in recall classification time
- Planned and led the Office of Compliance reorganization, enhancing the scope of product and topic coverage by moving from a product-based to a function-based model deployed across 5 operating divisions
- Set CDRH regulatory and policy positions on issues including clinical data integrity, product labeling, promotion and advertising, global manufacturing practices, and proposed legislation

**Senior Advisor to the Center Director**
**Center for Devices and Radiological Health, 2009-2010**

- Led a Center-wide strategic initiative that enhanced compliance oversight through process alignment, identification and resolution of operational needs, and risk-based work planning
- Represented the Center in cross-Agency and external initiatives to safeguard imported medical devices

**Assistant Director**
**Center for Drug Evaluation & Research, Office of Compliance, 2006-2009**

- Developed and oversaw the implementation of drug regulations, policy, and public communications about prescription and over the counter drugs
- Led strategic initiatives focused on marketed, unapproved drugs, and pathways to bring new drugs to market
- Led enforcement actions focused on drug approval, drug labeling, adverse event reporting, and fraudulent drug promotion
- Developed and led FDA's enforcement policy targeting pharmacy compounding of unapproved new drugs

**Director, Division of New Drugs & Labeling Compliance**
**Center for Drug Evaluation & Research, Office of Compliance, 2003-2006**

- Directed development and implementation of strategic plans, policy statements, compliance actions, and litigation support for matters involving prescription and over the counter drugs
- Counseled FDA senior staff on legal and policy decisions, and communicated with Congress and state and federal agencies on drug enforcement matters
- Led initiatives to assure compliance with new-drug approval, labeling, and marketing requirements

**Associate Chief Counsel, Office of the Chief Counsel, 2002-2003**

- Led enforcement efforts targeting drug, medical device, and dietary supplement products for violations of the Food, Drug, and Cosmetic Act
- Served as senior litigation counsel in actions under the Administrative Procedures Act and the Freedom of Information Act

**United States Department of Justice** **1997-2002**
**Washington, DC**
**Trial Attorney, Tax Division, Civil Trial Section**

- Litigated tax matters including debt-equity swaps, summons enforcement actions, and bankruptcy proceedings

**United States Federal Trade Commission** **1995-1997**
**Washington, DC**
**Staff Attorney, Consumer Protection Bureau, Financial Practices Division**

- Investigated violations of federal laws governing truth in lending, fair credit, and debt collection

**Wiley, Rein & Fielding**
**Washington, DC**
**Associate** **1992-1995**

- Practiced civil litigation concerning health care fraud, insurance coverage, and labor and employment

## Education

**The University of Pennsylvania School of Law** — **Philadelphia, PA**
Juris Doctor, *cum laude* — **1992**
University of Pennsylvania Law Review, Comments Editor

**The University of Michigan** — **Ann Arbor, MI**
Bachelor of Arts, *cum laude* — **1989**
Phi Beta Kappa

## Memberships

State of Illinois and Washington, DC Bars