ArentFox Schiff LLP
Attorneys

# Abha Kundi

COUNSEL AND LONGEVITY & HEALTHSPAN INDUSTRY GROUP CO-LEADER

Abha advises life sciences companies, including longevity and healthspan, consumer wellness, and digital health companies, across innovation, development, commercialization, and compliance.



## Industries

Life Sciences
Longevity & Healthspan

## Practices

Food, Drug, Medical Device & Cosmetic
— Drugs & Biologics

## Education

Boston University School of Public Health, MPH, 2009

Boston University School of Law, JD, 2008

Kalamazoo College, BA, magna cum laude, 2004


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Abha's approach anticipates how FDA applies established authorities to pharmaceutical innovation. She brings a practical understanding of agency priorities and institutional decision-making to her work helping companies integrate pathways, evidence, claims, commercialization, and compliance across product lifecycles. Drawing on nearly 15 years at FDA, including more than a decade developing and leading the agency's Drug Supply Chain Security Act (DSCSA) program, Abha translates legal complexity into business options that increase efficiency, strengthen resilience, and withstand scrutiny across intersecting, evolving, and emerging federal and state regulatory regimes. She uses this firsthand perspective to help teams prepare for change, make sound strategic choices, and respond effectively when faced with scrutiny, enforcement, or supply chain challenges.

## Client Work

### FDA Regulatory Counseling: Drugs, Biologics, Medical Devices, and Digital Health Technologies

Abha's FDA regulatory counseling covers drugs and biologics, medical devices including software as a medical device (SaMD), and digital health technologies, as well as the evolving ecosystem of longevity and healthspan products such as peptides and biomarker tests. She helps companies transform scientific advances, new technologies, and commercial objectives into practical and sustainable operating models that exceed business objectives and remain defensible under agency review.

Her work includes:

- Clarifying the identity, classification, and risk profile of innovative offerings and operating models;
- Assessing how emerging technologies and delivery models fit within existing regulatory frameworks;
- Selecting and adapting pathways as evidence, design, intended use, and business objectives

evolve;

- Aligning claims, labeling, promotion, and commercialization plans with supporting evidence and risk tolerance;
- Navigating intersecting federal and state regimes affecting development, market entry, and ongoing compliance;
- Building scalable governance programs that support growth, operational readiness, and accountability;
- Supporting clinical development, launches, acquisitions, and strategic pivots;
- Conducting regulatory diligence to evaluate enforcement exposure and allocate risk across commercial relationships and distribution networks;
- Advising on regulatory engagement and disputes and providing strategic advocacy when scientific, legal, or policy questions are contested or novel regulatory questions emerge; and
- Translating FDA priorities into practical choices that preserve flexibility while strengthening compliance.

### DSCSA Compliance & Supply Chain Resilience

Abha's distinctive perspective comes from her direct experience developing and directing FDA's DSCSA program for more than a decade. She helps companies across the pharmaceutical supply chain and their technology partners comply with the Act's requirements, applying disciplined governance, visibility, operational readiness, and coordinated disruption response to operating models amidst volatile and dynamic global supply chain risk landscapes. Her guidance aligns policy, data, contracts, and operations to establish resilient and compliant operating models, including:

- Building resilience through governance, visibility, and preparedness programs;
- Strengthening authorized trading-partner oversight through disciplined qualification and monitoring;
- Connecting data, interoperability, verification, tracing, and product-identifier controls to day-to-day operations;
- Clarifying contractual responsibility, data governance, and incident-response roles; and
- Preparing for inspections, recalls, shortages, and other disruptions through coordinated response and continuity planning.

### FDA Investigation & Enforcement Support

Abha helps clients respond to scrutiny and enforcement, providing critical insight into the agency's concerns, available options, and likely next steps. She handles inquiries and enforcement matters involving regulated offerings, coordinating clients' legal, scientific, and operational responses from immediate mitigation through remediation.

Abha's investigation and enforcement counsel includes:

- Assessing the significance of remote regulatory assessments, inspections, Form FDA 483s, warning letters, and other communications, and developing a coordinated response;
- Designing proportionate mitigation, remediation, disclosure, and continuity plans; and
- Managing incidents, recalls, shortages, and related stakeholder communications with FDA and relevant partners.

## Publications, Presentations & Recognitions

Abha writes and presents on FDA developments, policy initiatives, enforcement trends, and emerging questions affecting the life sciences sector, including longevity innovation and the intersection of medicine, technology, and consumer engagement. Her work focuses on how these developments shape design, claims, commercialization, and post-market strategy. Abha's thought leadership is routinely sought by external publications, including *Law360* and *NPR.*

Abha was recognized as a Key Lawyer in the Healthcare – Service Providers practice area by *The Legal 500 United States 2026.*

## Bar Admissions

District of Columbia

New York