J. SETH OLSON

solson@kmclaw.com | 801.328.3600

ATTORNEY (UTAH BAR ADMISSION PENDING*)

Seth Olson is an FDA regulatory attorney in the firm's International section. He advises clients on regulatory, compliance, and transactional matters involving the U.S. Food and Drug Administration (FDA) and other federal health agencies, including the medical device, pharmaceutical, biotechnology, human cell and tissue product, food, dietary supplement, and cosmetic industries.

Mr. Olson leverages his experience as a former regulatory counsel at the FDA and his extensive experience advising large and small companies in the life science industry to provide strategic and pragmatic solutions for clients faced with complex regulatory, compliance, and enforcement challenges and to comply with FDA's ever-changing regulatory requirements.

Mr. Olson advises companies through all aspects of the FDA-regulated product life cycles, including:

- Product regulatory assessments
- Pre-market development and testing strategies
- FDA product premarket submissions
- Product labeling, advertising, and promotional reviews
- Facility registration and product listing
- Developing quality system policies and procedures
- Responding to FDA inspections, FDA 483s, Warning Letters and other compliance and enforcement actions by regulators
- Administrative appeals
- Negotiating clinical trial, manufacturing, distribution, supply, and quality agreements
- Assisting clients with FDA-regulated products detained at U.S. Customs

Mr. Olson advises on transactional matters requiring specialized regulatory expertise, including regulatory diligence and disclosure matters for public offerings, mergers and acquisitions, and private transactions.

Prior to joining Kirton McConkie, Mr. Olson was an FDA regulatory attorney in the Washington, DC, offices of Latham & Watkins LLP. Seth previously served as regulatory counsel in the Center for Devices and Radiological Health at the FDA.

** Licensed in District of Columbia. Utah State Bar licensure pending District of Columbia reciprocity.*

EDUCATION

The George Washington University Law School, JD, 2016
University of New Hampshire, MBA, 2014
Brigham Young University, BS, Biology, 2009

PRACTICE AREAS

CORPORATE
CYBERSECURITY AND DATA PRIVACY
INTERNATIONAL

INDUSTRIES

HEALTHCARE

J. SETH OLSON

EXPERIENCE

FDA Regulatory and Compliance

- Assisted medical device companies through the FDA premarket review processes (i.e., 510(k), De Novo, PMA, EUA, and Breakthrough Device Requests).
- Advised pharmaceutical, medical device, food, and supplement companies responding to FDA Form 483 inspectional observations, warning letters, untitled letters, and "It Has Come to Our Attention" letters.
- Negotiated with FDA's import officials to release shipments of detained FDA-regulated products.
- Advised clinical stage biopharmaceutical companies on regulatory compliance with ClinicalTrials.Gov reporting requirements.
- Advised pharmaceutical and medical device manufacturers and distributors on state licensing and permit requirements.
- Advised food and food packaging companies on the regulatory status of food additives and packaging materials.

Transactional and Capital Markets

- Assisted life science clients in negotiating clinical trial, manufacturing, supply, distribution, and quality agreements.
- Provided FDA regulatory diligence support on many transactions involving life science companies, including clinical stage biopharmaceutical companies, medical device manufactures, clinical and contract research organizations, clinical laboratories, food, and food packaging companies.
- Advised on the FDA regulatory review of public disclosures made by publicly traded life science companies before the Security and Exchange Commission (SEC).

Legislative Policy

- Advised medical device industry group on FDA legislative proposals and drafted comment letters to proposed regulations and guidance documents.
- Coordinated FDA regulatory policy strategies with Washington, DC-based policy experts on behalf of clients.

Pro Bono Work

Mr. Olson's pro bono practice has included representing individuals seeking asylum and T-visa immigration status from human trafficking, non-profit organizations advocating for victims of domestic violence and abuse, Medicaid disputes with DC's Department of Health Care Finance, and landlord/tenant disputes within the District of Columbia.

ADMISSIONS & AFFILIATIONS

Bar Admissions: District of Columbia

HONORS & AWARDS

Super Lawyers Washington, DC: Rising Star - Food & Drugs (2020-2025)