Our North American Life Sciences Regulatory Team has extensive experience in the complex world of products regulated by the FDA, including drugs, medical devices, food, cosmetics, and dietary supplements. The team serves as key strategic and legal advisors for innovative start-ups to global companies on matters that cover the full range of a product's life cycle.

We work with the Firm’s Global Regulatory practices to assist in providing worldwide coverage of regulatory and biopharmaceutical compliance issues for a wide range of life sciences.
The complexity of the FDA-regulated products landscape requires a knowledgeable team with extensive experience navigating the regulatory ecosystem. We stay abreast of applicable laws and regulations to provide clients current and forward-thinking advice and counsel across a broad range of issues. Our deep substantive understanding of the life sciences industry and our comprehensive regulatory experience allows us to serve as strategic legal advisors. We provide critical legal advice and counsel that is aligned with the company’s goals and regulatory requirements.

We advise clients on all regulatory aspects affecting the industry at a global, regional and jurisdictional level. Our industry knowledge is enhanced by our attorneys who have gained a wealth of hands-on experience from their roles served within the regulatory agencies and as senior in-house counsel for biopharmaceutical companies.

### Helping Clients Navigate The Maze

#### Product Development
- Requirements for IND & IDEs
- Clinical holds
- Meetings with FDA
- Product Approval Strategies for prescription products, over-the-counter (OTC) products and consumer products
- Product reclassification
- Packaging and Labeling

#### Transactional Due Diligence
- Mergers and acquisitions
- Investments
- Divestitures
- Licensing, joint ventures and collaborations
- Cross-border transactions
- Post-acquisition integration

#### Compliance, Investigations & Audits
- FDA inspection preparation
- Internal audits
- Internal training
- Federal and state law compliance including Sunshine Act
- Monitoring
- Assist with development of policies and procedures

#### FDA Government Enforcement
- Formal Dispute Resolution
- Assistance with responding to 483 Observations, Warning Letter, Untitled Letters and other Agency correspondence
- Product recalls
- Import/export alerts

#### Pre-Launch Planning and Commercialization
- Advertising and promotion
- Promotional review
- Product labeling review
- Medical legal regulatory review
- Preparation for preapproval meetings with FDA including Advisory Committee Meeting, labeling and REMS discussions
- Assistance with development and training of medical science liaisons, sales team and managed care professionals

#### Litigation Support
- Assistance with Fraud and Abuse, Anti-kickback and False Claims matters related to FDA regulated products
- Assistance with product liability claims related to FDA regulated products

#### Manufacturing and Supply
- Manufacturing and supply agreements
- Quality agreements
- CMO audits and inspections
- Drug Quality and Security Act (DQSA) including Drug Supply Chain Security Act (DSCSA)
- Compounding

#### Research and Clinical Trials
- Clinical research regulation
- Clinical trial agreements
- Data coordinating center agreements
- Informed consent
- CRO agreements
- Assist with CRO engagement and management
- Steering Committee
- Part 11 Compliance
- Pharmacovigilance
Biopharmaceutical

- Assisted a global biopharmaceutical client with product recall, field alerts and other related communications with the FDA.
- Provided advice and counsel to a global biopharmaceutical company on alliance management programs that involve licensing arrangements with other companies to develop and commercialize products internationally.
- Provided corporate regulatory advice and guidelines to a German pharmaceutical company relating to a project in the US that would involve the cultivation and growing of a particular type of plant that is required in the manufacture of certain pharmaceutical products.
- Advised an investment company on its CHF 20,000,000 equity-linked debt financing for a Swiss pharmaceutical company via issuance of senior secured exchangeable notes. This work involved guiding the team in negotiating and drafting the payment milestones tied to FDA regulatory filings and approvals.
- Serve on the Medical Legal Review (MLR) Team as the legal representative for a pharmaceutical company and provide advice and counsel regarding key promotional initiatives for commercializing current products and launching new campaigns.
- Assisted global companies with the development and implementation of corporate compliance programs, including various policies and procedures to support the development and commercialization of drugs and combination products.
- Provided advice and counsel to global biopharmaceutical companies on cGMP, FDA inspection preparation and response, and implementation and execution of corrective and preventative action plans.
- Assisted global pharmaceutical companies with all pre-launch planning, including the development of a compliance program, clinical trial matters and medical, legal and regulatory review of all company materials.

Medical Device

- Regulatory lead counsel to multinational device and healthcare company on a number of transactions and advisory projects, including:
  - Investment with option for total acquisition of clinical stage biotech company focused on development of neurology focused medical devices
  - Supply and distribution agreement for COVID-19 test
  - Global assessment of mobile medical application classification
- Assisted a private equity company in the acquisition of major US product line.
- Lead regulatory counsel for multinational biotech company in transaction involving acquisition of digital health algorithm.
- Advise and assist with preparation of Service Agreement Template for global medical device company specializing in precision healthcare solutions.
- Assist in preparation of APA regulatory terms for purchase of technology used to develop medical device equipment for a global pharmaceutical company.
- Review development and manufacturing agreement and revise to include regulatory terms for a medical device company in the dermatologic space.
- Advise medical device company on creation of R&D program to ensure compliance with FDCA, state and federal transparency and disclosure reporting requirements.
- Provide counsel on telemedicine agreement and customer terms of use for website.

Shipping clinical trial products to patient homes.

Advised Thermo Fisher Scientific on the regulatory and privacy issues that would apply in 18 jurisdictions related to shipping clinical trial products and materials from clinical trial sites directly to patient homes to avoid disruptions resulting from COVID-19. In addition, advice and counsel on legal and regulatory implications of employer initiated surveillance programs involving COVID-19 screening tests and contact tracing mechanisms.
The nature of the FDA regulated industry requires engagement with regulatory agencies including FDA, FTC, DOJ, HHS and regulatory authorities around the world. Our lawyers know when a matter requires such engagement. With Veleka Peeples-Dyer’s in house experience and Khelin Aiken’s and Tiffany Humphries’ prior career at the FDA, this team understands the importance of providing practical and strategic legal advice and counsel.

Khelin Aiken leads the firm’s US Food and Drug Administration group.

Khelin practices in the area of US Food and Drug Administration regulatory and compliance law. She leverages her deep understanding of the US Food Drug & Cosmetic Act, US Public Health Service Act and their implementing regulations along with her prior experience at the US Food and Drug Administration (FDA) to help clients develop and achieve their strategic business objectives. Khelin previously served as regulatory counsel at the FDA in the Center for Drug Evaluation and Research, in both the Office of Regulatory Policy and in the Office of New Drugs with the Therapeutic Biologics and Biosimilars Staff.

Khelin focuses her practice on leading and counseling life sciences companies from product development through the product life cycle. Khelin also advises clients on strategies for addressing critical regulatory matters, including inspection observations, untitled letters, warning letters, dispute resolution issues and advisory committee comments.

Clients seek Khelin’s counsel on developing innovative strategies for FDA regulatory approval, compliance with FD&C Act regulatory requirements for investigational and marketed products including current good manufacturing practices (cGMPs), promotion and marketing, supply chain and quality issues. Khelin regularly advises large, mid-size and emerging life sciences clients on a variety of transactional issues including acquisitions, divestitures, collaborations, clinical trials and related agreements. She also counsels pharmaceutical and consumer product companies on cannabis and cannabis-derived product development and marketing plans.

Professional accolades include:

• LMG Life Sciences 2020 Regulatory Firm to Watch, Winner
• LMG Life Sciences 2020 Regulatory US Rising Star, Finalist
• Hampton University Forty Under 40 Alumni Recognition Society