SETON HALL | **LAW**

Healthcare Compliance
Certificate Program

Geneviève Michaux
Partner
King & Spalding LLP (Brussels/ Paros)
gmichaux@kslaw.com

Geneviève Michaux is a Belgian- and French-qualified lawyer in the FDA and Life Sciences practice.

Recognized as one of the most highly regarded European Union (EU) life sciences regulatory specialists, Ms. Michaux assists companies on a wide variety of issues under EU and national (French and Belgian) food and drug laws and regulations, with an emphasis on regulatory matters involving drugs, biologics, medical devices, cosmetics, and food. She also advises life sciences clients on significant policy developments in the EU and assists with broader European and global projects.

Ms. Michaux's work spans matters ranging from regulatory status of borderline products, authorization procedures, life cycle management, clinical trials and investigations, labeling, advertising and promotions for all categories of products, and issues raised by specific categories of medicinal products, such as pediatric, orphan, or advance therapy medicinal products. She has advised on various issues arising out of the EU Pediatric Regulation, EU Orphan Regulation, SPC and SPC extension, and ATMPs at the European and national level. She also counsels startups on establishing themselves in the EU as well as complying with advertising and scientific information rules, regulatory and legal guidance.

Ms. Michaux assists life sciences companies in forming patient/compassionate use programs in Europe, negotiating and drafting consortia related agreements, reviewing clinical trial and clinical investigation agreements, interacting with health care professionals in connection with advertising and promotion efforts, and product classification matters such as borderlines between drug, medical device, cosmetic and food supplement, and assistance with local authorities.

Ms. Michaux has extensive litigation experience in life science matters, including product liability and advertising and promotional activities. She is recognized as one of the "Most Highly Regarded Individuals" in the regulatory field (Who's Who Legal, Life Sciences 2016). In the same publication, her clients reported that she has an "unsurpassed knowledge of legal areas," as well as being "extremely dedicated to the case and the client." She has published numerous articles on food

and drug law and speaks at legal and regulatory conferences on pharmaceuticals and medical devices.

Ms. Michaux obtained a ULB, *magna cum laude*, from the Université Libre de Bruxelles, and her LL.M. from Harvard.