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| Xin TaoBaker McKenzie US LLP | Xin TaoWashington DCPartner Baker McKenzie US LLP+1 (202) 835-1890xin.tao@bakermckenzie.com https://www.bakermckenzie.com/en/people/t/tao-xin |
| **ㅡ**CREDENTIALS | Georgetown University Law Center (JD) (2012)Texas A&M University (MS) (2009)Bar Admission: Washington DC  |
| **ㅡ**CAREERS / WORK EXPERIENCE | Baker McKenzie US LLP/ PartnerJan 2023 - PRESENT, Washington DCXin Tao is a member of Baker McKenzie's North America Steering Committee for Healthcare & Life Sciences, and heads our US Food and Drug Law Practice. Clients describe Xin as "His dedication to his clients stands out; he goes above and beyond to do whatever we need. He's really pragmatic with his advice too." (Chambers USA Client Interview - 2024).A former research scientist, Xin brings a deep understanding of the complex scientific issues that relate to the US legal compliance and government enforcement issues, enabling him to help clients with all phases of product development, manufacturing, and marketing. As the science and technology continues to evolve, Xin supports our clients to constantly innovate and push the boundaries of what's possible in the world of science.Xin is a frequent speaker and writer on US life science legal developments, and he was selected to serve on the 2023 Law360 Life Sciences Editorial Advisory Board, and also nominated as a Thomson Reuters Stand-out Lawyer based on its 2024 client survey, and ranked in Chambers USA 2024.Hogan Lovells / Counse/AssociateSep 2013 - Jan 2023, Washignton DCUS FDA Regulatory/Food, Cosmetics, Device, PharmaKeller and Heckman / Associate/ScientistDec 2011 - Sep 2013, Washington DCUS FDA Regulatory/Food, Cosmetics, Device, Pharma |
| **ㅡ**AREAS OF FOCUS | **Xin's practice focuses on advising high-growth companies and investors in life science, healthcare, cosmetics, E-commerce, and technology industries globally. As part of the firm's US Government Enforcement Practice, he has represented many global companies during high-stake US government investigations (including actions initiated by the US Congress, U.S. Department of Justice (DOJ), and U.S. Food and Drug Administration (FDA)) around the world. Xin also has a strong track record in US consumer product recall matters, and with a deep understanding of the intricacies involved in navigating the complex and interrelated legal and scientific issues, Xin can creatively and effectively represent companies in these bet-the-company cases.**As a seasoned US government regulatory and enforcement counsel, Xin works closely with global companies with novel pharmaceutical, medical device, food, and cosmetic applications that require US government's pre-market approval or clearance and FDA Current Good Manufacturing Practices (cGMP) compliance. Xin has extensive experience advising both emerging and established companies on the strategy with launching and promoting innovative products such as cell-cultured meat, cellular and gene therapy products and AI/ML-enabled medical devices. Xin also draws on his scientific expertise and experience to provide clients with practical regulatory advice regarding compliance with federal and state health care fraud and abuse law, particularly under the federal Anti-Kickback Statute (AKS).Representative Legal MattersXin handled the following mattersSuccessfully helped a global technology company in conducting internal investigation for legal compliance and engaging FDA for concurrence of voluntary corrective actions to address potential violations.Advised Vandemoortele, a leading European family-owned food group, in a strategic partnership with Banneton, a high-quality manufacturer of premium freezer-to-oven croissants, Danishes and pastries in North AmericaAdvised Takeda in connection with its worldwide license and collaboration agreement with Protagonist Therapeutics, Inc., for the development and commercialization of rusfertide.Advised a global medical device company on its strategy of establishing compliance with the US healthcare fraud and abuse laws for selecting advisory board members.Advised a leading global E-commerce company on its strategy with global regulatory risk compliance and mitigation for consumer products.Successfully helped a global pharmaceutical company in resolving FDA Warning Letter for drug cGMP violations and delisting from Import Alert.Successfully helped a global food and beverage company in obtaining FDA's concurrence for conducting a voluntary market withdrawal instead of a nationwide product recall.Advised a dietary supplement company during a voluntary nationwide product recall and helped implement corrective actions.Successfully obtained FDA's favorable review of intended uses of novel food additives, generally recognized as safe substances (GRAS), and food contact substances (FCS) in foods and beverages.Developed legal strategies in helping consumer products companies and trade associations establish compliance with California's Proposition 65 warning and federal and state laws and regulations involving heavy metals and PFAS.Successfully helped global life sciences companies in developing response to NMPA (China) enforcement actions to narrow the scope of follow-up actions; developed premarket strategy of new drug products and advised on one of the first drug recalls in China conducted by a global pharmaceutical company. |