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City : Beijing, Shanghai

Practices : Life Sciences & Healthcare, Anti-Corruption & Compliance, Intellectual Property

Basic Information

Ms. Wu is the leading partner of Haiwen's life science and healthcare practices. She has 15-year experience in advising multinational pharmaceutical, biotechnology, medical device and healthcare clients on a wide variety of legal matters arising from the entire product life cycle, including day-to-day consulting matters as well as commercial transactions such as licensing deals, investment, joint venture and M&A.

Professional History

Before joining Haiwen, she worked at Sidley Austin LLP, Clifford Chance and Ropes & Gray as the core member of their China life science teams for over ten years.

Experience Highlights

IP Licensing and Other Complex Commercial Deals

- Assisted multiple innovative biopharmaceutical and medical device companies with the transactions in connection with collaboration development, licensing and product localization arrangements, China entry and commercialization strategies, supply chain restructure, and provided legal advice on relevant regulatory matters.
- Assisted a digital therapeutics company in its strategic collaboration with a leading global pharma company in co-developing digital therapeutics treating non-small cell lung cancer.
- Advised a public biotech company on numerous licensing-in deals in relation to antibody drugs as well as co-development collaboration on combination therapy.
- Assisted a public pharmaceutical company in its strategic collaboration with Wuxi AppTec and its acquisition of the global rights of numerous innovative biologics.

- Assisted a clinical-stage biotech company in acquiring an exclusive license from a European pharma company to develop and commercialize an innovative antibody drug in Asian market.
- Assisted a rare disease therapeutics company in acquiring the global rights of three innovative orphan drugs.
- Advised a prestigious PE fund in investing in an innovative biotech company for developing COVID-19 vaccine.
- Assisted a prestigious investment management firm in acquiring R&D assets and mature brand assets from a global researched-based biopharmaceutical company.
- Assisted a renowned institutional investor in establishing a JV platform with a European medical device company.
- Assisted a renowned institutional investor in investing an innovative biotech company and conducting regulatory due diligence.
- Advised a leading US pharmaceutical company on its drug development collaboration with a China-based CAR-T Biotech Company.
- Assisted a prestigious PE fund in investing in a global leading beauty device company.

Regulatory Compliance

- Advised multinational pharmaceutical, biotech, medical device, cosmetics and consumer health companies in various pre-market and post-market regulatory matters, including matters related to clinical studies, product registration, GLP, GCP, GMP, GSP, GUP and GVP compliance.
- Advised multinational pharmaceutical, biotech, medical device and cosmetics companies on commercialization and market access issues, including online and offline advertising and promotional activities, patient education and management programs, patient benefit and assistance programs, direct-to-patient communications, interactions with HCPs.
- Assisted multinational pharmaceutical and medical device companies in evaluating and handling internal review and investigations on clinical and non-clinical studies involving the use of Chinese human genetic resources.
- Assisted multinational pharmaceutical and medical device companies with their responses to inspections conducted by local Chinese Administration of Market Regulation and Chinese National Medical Products Administration.
- Advised a US medical device company on the product registration strategies in China.
- Assisted a US medical device company in handling its disputes with its Chinese legal agent and exclusive distributor.
- Advised an MNC pharma company on HGR compliance assessment on its R&D activities in China.
- Advised a publicly listed biotech company on its general corporate matters.
- Assisted a Japanese pharma company in the termination of the relationship with its exclusive local distributor.

- Advised a leading medical payment service provider on potential compliance risks associated with its innovative payment solutions, including insurance programs.

Digital Health

- Advised several pharmaceutical and medtech companies on regulatory matters in relation to cross-border transmission and processing of medical big data and patient data.
- Advised a leading oncology real world big data company on its data compliance and mitigation program and the legal opinions concerning its HK IPO.
- Advised a leading TMT company on registration and marketing strategies for its AI-powered software medical device.
- Advised a leading medical device company on regulatory matters in relation to its cloud-based medical mobile App.
- Assisted a leading medical device company in developing privacy notice and do's and don'ts for its digitalized business.
- Assisted a leading online medical service provider in developing a compliance guidebook for its online hospital business model and evaluating potential commercial bribery, advertising and anti-competition risks associated with the business model.
- Assisted a multinational consumer health company in developing its data privacy policies and documents.
- Assisted a leading biotech company in developing its data protection policy, data processing policy and consent documents.

Education

Ms. Wu graduated from China Pharmaceutical University, Peking University and Columbia University. She is qualified to practice in PRC and New York.

Language

Ms. Wu is a native Mandarin speaker and is fluent in English.