

JunHe boasts a dedicated healthcare team acting for key clients in the pharmaceutical, medical devices and financial services sectors.

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Medical Devices

The regulation of the medical device industry in China has two layers: the product regulatory system and the enterprise regulatory system. These regulations relate to the research and development of medical devices as well as their registration, manufacturing, operation, advertising, usage, monitoring, product recall and the evaluation of adverse events. Since the first amendment of the Regulations on the Supervision and Administration of Medical Devices, (basic regulations that oversee the medical device industry), rules and normative documents have now been successively promulgated. The state is currently upgrading regulations for the medical device industry by introducing reforms and improving standards systems. Notably, the introduction of the medical device registrant system in 2021 has driven significant evolution and transformation within the industry.

The state regulates medical devices into three different types, based on their risk level. The food and drug administration at each level will take regulatory measures on the research and development, manufacture, sale and application of medical devices, depending on their category.

With many years of legal experience in the medical device industry, JunHe is equipped with sensitive insight and unique views on market movements, legislative developments and regulatory tendencies. The firm has a deep understanding of the industry, abundant experience accumulated over many years, a broad client base and a good working relationship with the regulatory authorities. We provide clients with a full range of legal services covering the entire life cycle of medical devices including research and development, registration, manufacturing, commercialization and usage. Our legal service team is composed of lawyers with abundant experience in the industry, and they come from a range of offices and specialty areas. We provide clients with a range of one-stop legal services, such as advising on laws and regulations, mergers and acquisitions, capital markets, private equity/venture capital, intellectual property, labor, compliance and dispute resolution.

We provide legal services regarding the medical device industry to multinational companies, private equity/venture capital firms, medical institutions, listed companies, large and middle-scaled enterprises, and innovative and growth companies in the following areas:

- Legal services with respect to the preclinical research and development of medical devices, clinical trials, product registration, manufacturing, commercialization, product use and product recall, and the monitoring and re-assessment of adverse events;
- Cooperation in the development, research, manufacturing and commercialization of medical devices;
- Intellectual property protection and services for intellectual property transactions related to product development and licensing;
- Private equity/venture capital, merger and acquisitions and capital markets;
- Legal services for day-to-day operations, including services related to product promotion and marketing activities, product supply and distribution arrangements, compliance, labor laws, taxation laws, dispute resolution, patient disputes and risk management; and

JunHe, founded in Beijing in 1989, is one of the first private partnership law firms in China. Since its establishment, JunHe has grown to be a large and recognized Chinese law firm. The firm has fourteen offices around the world and a team comprised of more than a thousand professionals.



JunHe approaches issues from the client's perspective and has lawyers with extensive experience in the medical devices field, who actively share new trends and legal developments with us.

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- Legal services including compliance with laws and regulations for medical devices, compliance with anti-competition laws, compliance with anti-commercial bribery laws, compliance with privacy protection and data security and compliance with China's human genetic resources regulations.

Selected Deals

SSI Diagnostica A/S Acquisition of BGB's Vitro Diagnostic Reagent Business

As the PRC legal advisor to SSI, we conducted legal due diligence on BGB, participated in the design of the transaction structure and reviewed, revised and negotiated the full set of transaction documents. JunHe's team provided legal advice on major issues of concern to the acquirer, assisted the client to complete the signing of the full set of transaction documents, simultaneous domestic and overseas closing and post-closing arrangements, and provided professional legal advice on various government approvals/recordings. JunHe also provided advice on the settlement of the registered capital for the payment of the equity transfer price.

Integra's acquisition of the assets of Johnson & Johnson

While preparing the transaction documents for the Chinese party, JunHe's deal team worked closely with Johnson & Johnson's global team to balance the global terms and conditions with the local regulations and practice in China. JunHe has abundant experience in the healthcare industry and assisted the client in reviewing and finalizing the transitional service agreement. The transfer of the employment relations was a challenge in this transaction and JunHe provided practical and effective suggestions on how Johnson & Johnson could control its legal risks under Chinese labor laws.

Lepu Medical's Issuance of GDR and listing on the Swiss Exchange

JunHe as the domestic legal counsel to the underwriter participated in the entire process of the issuance of global depository receipts (GDR) and listing on the Swiss Exchange by Lepu Medical on September 21, 2022. Lepu is the first A-share listed company in the pharmaceutical manufacturing industry to issue GDR and raised a total amount of USD 224 million.

MedBot was listed on the Main Board of the Hong Kong Stock Exchange and became the first surgical robot stock in the Hong Kong capital market

JunHe was the PRC legal advisor to the joint sponsor of the project and was involved in the listing of MedBot on the Main Board of the Hong Kong Stock Exchange on November 2, 2021, which raised approximately HK\$ 1457 million.

China's first early cancer screening stock: New Horizon Health's listing on the Hong Kong Stock Exchange

JunHe was the PRC legal advisor to the joint sponsors and underwriters of the project and was involved in the listing of New Horizon Health Limited ("New Horizon Health") on the Main Board of the Hong Kong Stock Exchange on 18 February 2021, which raised over HK\$ 2 billion.

Johnson & Johnson Medical (Shanghai) signed a joint marketing, promotion and distribution agreement and a research and development cooperation agreement with Beijing Tinavi

JunHe was counsel to Johnson & Johnson Medical (Shanghai) and provided a full range of legal services for the drafting, negotiation and signing of agreements for the commercial and R&D

**Law Firms of the Year -
Healthcare, Pharma & Life Sciences**
2024, 2023, 2022
China Business Law Awards

Healthcare Law Firm of the Year
2021
ALB China Law Awards

**PRC Firm of the Year -
Healthcare and Life Sciences**
2017
China Law & Practice Awards

With the deepening of global economic integration, a considerable number of the international financial institutions and multinational corporations entering China have sought innovative and strategic legal services from JunHe. Additionally, JunHe has worked with many Chinese and foreign-funded financial institutions to assist them in becoming more compatible with internationally accepted practice, while staying compliant with current PRC laws. JunHe takes advantage of the international background and local practice experience of its professionals to continue to innovate within the framework of the existing PRC laws and to meet the various business needs of their clients.