



Pharma *(including Medical Devices & Health Care)*

The Pharma Practice of The Valid Points Law Office covers advisory to companies in pharmaceuticals, medical devices, health care, health tech or delivery of drugs/devices or services through online mode. We assist in understanding and preparing or safeguarding the entities for clinical trials, product approvals, setting up or running a manufacturing unit, distribution, licensing agreements, pricing issues, branding and promotion, product recall, data protection and disputes. Our team has extensive expertise and experience on commercial arrangements and transactions in the pharmaceuticals sector including M&A, collaborations and fund raising. The representative experiences include the following:

Advisory:

- Assisted an Indian e-commerce marketplace aggregator to understand the regulations related to online sale of medicines.
- Worked closely as in-house lawyer for a medical devices manufacturing company and counselled them on multiple issues related to regulatory licensing, finance, marketing, sales, PR, clinical trials, government liaison, IPR, HR and legal to both India and Asia team.
- Assisted in the review of the applicable laws and regulatory process involved in the approval of usage of drugs, insecticides or pesticides in sports clothing range or materials used for sports activities for almost 30 jurisdictions for one of the largest manufacturers of sports cloth manufacturers in the world.
- Assisting a leading American medical technology company that manufactures and sells medical devices, instrument systems and reagents in understanding the immunization & vaccination policy of India along with its implementation strategy.
- Assisted a major US med-tech company of the world in understanding the regulations, compliances and risks associated with conducting clinical trials in India and Sri Lanka.
- Assisted an importer of medical devices in setting up a compliance system with respect to laws related to logistics, warehousing and legal metrology.
- Assisted a subsidiary in setting up a business for importing medical devices to India from South Korea.
- Assisted four different medical device companies (start-ups) in their funding in two different investment rounds; handholding in all legal, regulatory and contractual requirements under retainership for more than 5 years.
- Assisted a major European pharma company in understanding the roles, regulations and risks in its role as a sponsor in clinical trials in India.
- Assisted a major US pharma manufacturing company in setting up compliance management system for their India operations.
- Assisted a company in understanding the regulations, compliances and policies related to manufacturing, import, testing and sale of condoms in India.
- Assisted an e-commerce company in setting up their health care market place business in India by branding hospitals in their unique brands and provide them online services for listing patients and online treatment.
- Assisted an NGO (*a collaborative initiative of American, European and Indian NGOs*) in their initiative to offer online medical consultancy in the rural areas of North & West India.



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- Assisted a major pharma company in understanding the regulations pertaining to providing online health care by medical practitioners.
- Assisted a major pharma company in understanding the several aspects of medical negligence.

Documentation:

- Assisted a pharma MNC in review of their approx. 1000 contracts and revamping the existing templates to align them with changing Indian laws and jurisprudence.
- Drafted the Immunization Strategy Plan and Policy Document for a leading American medical technology company that manufactures and sells medical devices, instrument systems and reagents for implementation in India.
- Drafted all necessary paperwork and documentation for engaging CROs and subjects and seek necessary approval from the committee.
- Assisted a company running fertility clinics in South India in creating template of their agreements.

Dispute Resolution:

- Assisted a major manufacturer of IV Fluid sold in patented self-collapsible pouches in a dispute with the NPPA in relation to the pricing of the product beyond the ceiling price. Prepared all responses/representations for the show-cause issued. Briefed senior counsel Mr. Siddharth Luthra and assisted in the matter while representing the client before NPPA.
- Assisted a medical devices company in their ongoing labour dispute with the union and helping in reaching the Wage Settlement Agreement.
- Assisted a manufacturing arm of a pharma company in their contractual dispute with a distributor and another with their contract manufacturer, which were settled through mediation.