

# Legal Services Pharma

Eastern Europe, Central Asia,  
Caucasus and Balkans  
Since 2003

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Since 2003, SCHNEIDER GROUP has supported international companies in their market entry and expansion in Eastern Europe, Central Asia and the Caucasus. As a bridge builder between East and West, Ulf Schneider founded his company with the aim of making it easier for international companies to enter the markets in these regions.

Today SCHNEIDER GROUP has offices in Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Lithuania, Moldova, Poland, Russia, Serbia, Ukraine, and Uzbekistan.

Local competence, global perspective and the highest quality standards unite our more than 500 employees into a cross-border service centre for your business interests.

## CONTACT

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# Legal Services Pharma

## Description of potential services

- General regulatory matters
- Advice on regulatory matters
- Clinical trials: agreements and procedures
- Advice on registration
- Licensing
- Labelling (serialisation)
- Consumer protection
- Anti-monopoly regulations

## Distribution & Marketing

- Agreements with distributors and supply chains
- Support of promotion campaigns
- Promotion and advertisement of pharmaceuticals and medical devices
- Distant sales of pharmaceuticals and medical devices
- Trade mark and intellectual property protection

## Localisation

- Advice on preferences in government procurements/tenders
- Requirements and procedures for “made in Russia”
- Incentives for foreign and local investors
- Greenfield and Brownfield

## Compliance

- Due diligence of pharmaceutical companies, including regulatory matters
- Development of internal policies and standard procedures
- Advice on compliance matters

## Dispute resolution

- Advice at the pre-trial stage: prepare a claim, negotiate an amicable settlement of the dispute
- Representing clients' interests in the court of first instance
- Assisting in challenging/defending the judgement of the court of the first instance in higher instances
- Support throughout the process of the execution of the court judgement
- Disputes with state authorities, including representing in the administrative cases, support through procedural actions of the law enforcement authorities
- Intellectual property disputes
- Commercial disputes
- Corporate disputes
- Bankruptcy cases

## Registration of Drug Products, APIs & Food Supplements and Medical Devices in the EAEU (RF, KZ, BY, AM, KIR) and the CIS countries (UA, UZ, AZ, GE)

- Consulting on regulatory matters for registration of Drug Products, APIs & Food Supplements and Medical Devices
- New registrations & maintenance of Drug Products, APIs & Food Supplements and Medical Devices in the EAEU (RF, KZ, BY, AM, KIR) and the CIS countries (UA, UZ, AZ, GE)
- The EAEU upgrade procedures
- Biosimilar registrations in the EAEU and the CIS countries
- Clinical bioequivalence trials: applications (CTA), CRO audits & monitoring in the RF
- Toxicological trials in the RF (strategy, CRO audits & monitoring)
- Due Diligence of registration dossiers in the EAEU and the CIS countries
- GMP inspections by local authorities of the EAEU and UA (applications, pre audits, audit support)
- Support in development projects.
- Training of DRA staff

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## CLIENTS



Leading international pharmaceutical company conducting research in cosmetics, prescription drugs and patient care products.

Services rendered: Legal, Accounting and Reporting



One of the oldest European pharmaceutical manufacturers.

Services rendered: Legal, Interim Management, Market Research



A NASDAQ listed multinational clinical studies contract research organisation with a representative in Russia.

Services rendered: Legal



A worldwide operating importer for chemical raw and intermediate products, polymers, and native products for industrial use.

Services rendered: Legal and Tax consulting, Accounting, Import, Management



A company specialising in the development and application of performance chemicals and technologies with an LLC in Russia.

Services rendered: Legal and Tax consulting, Accounting and Reporting



Family-owned German pharmaceutical manufacturer with an LLC in Russia.

Services rendered: Legal and Tax consulting, Accounting and Reporting, Interim Management



Developer, producer and distributor of homeopathic preparations

Services rendered: Legal consulting and coordination



Swiss multinational healthcare company focused on pharmaceuticals and diagnostics

Services rendered: Accounting, HR Administration and Payroll



US based international contract research organisation

Services rendered: Legal and Tax consulting



Swiss multinational biopharmaceutical company specialising in such areas as reproductive health, maternal health, gastroenterology and urology

Services rendered: Interim Management



Multinational biopharmaceutical which focuses on research and development on epilepsy, Parkinson's disease, and Crohn's disease

Services rendered: Legal and Tax consulting, Interim Management



Multinational company that produces beauty products and naturopathic medicines

Services rendered: Legal and Tax consulting



Mindray

Services rendered: Advice on localisation requirements for production of medical devices



Merit

Services rendered: Advice on labelling of medical devices; preparation of set of documents on personal data protection

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