

Luther.



Pharma, Biotech & Life Science

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The pharmaceutical, biotech and life sciences industry is one of the most dynamic sectors of the global economy. Innovations in research and development, strict regulatory requirements and growing global competition characterise this sector and present companies with complex legal and strategic challenges. This is where Luther Rechtsanaltsgesellschaft mbH comes into play: with our in-depth understanding of the industry and our many years of experience, we can provide you with expert support in all legal matters, from product development and market authorisation to the successful marketing of your products.



Our counselling services

Luther advises you in particular on strategic partnerships, relocation projects, research & development, licensing, market access and reimbursement, the protection of intellectual property, compliance issues, antitrust and merger control issues, e-health, employment law issues, the drafting and negotiation of contracts, health data protection, the use of artificial intelligence and regulatory issues. We also support you in the assertion and defence of claims.

M&A

Mergers and acquisitions are becoming increasingly important in the pharmaceutical, biotech and life sciences sectors. Dynamic developments, rising innovation costs, and the need to create synergies are constantly driving the M&A market forward. We offer you comprehensive expertise and practice-oriented advice so that you can implement your M&A



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Our expertise in the area of regulatory law was recently recognised with the prestigious JUVE Award as 'Law Firm of the Year'.

Below you will find a specification of individual advisory services – we would be happy to introduce ourselves personally and provide further details.

transactions efficiently, legally compliant and successfully. Our experienced lawyers will guide you through all phases of a transaction – from strategic planning and due diligence to contract negotiations, regulatory approval and post-merger integration.

Antitrust and merger control law

Our experienced antitrust law experts advise you on all questions of German and European antitrust law, e.g. in the areas of co-operation with competitors (co-promotion/co-marketing, R&D co-operation, production agreements), information exchange, measures to restrict parallel imports, pricing and discounting, (late) life cycle management as well as distribution channels (direct-to-pharmacy, direct-to-hospital, exclusive distribution, co-operation with selected wholesalers).

We represent you in antitrust investigations and fine proceedings by the European Commission, the German Federal Cartel Office, and the state antitrust authorities.

In addition, we support you in setting up and implementing effective compliance management systems and in the context of internal company investigations.

We also specialise in advising on German and EU merger control and the coordination of merger control proceedings worldwide. We also advise you on investment control under German foreign trade law (FDI) and on questions of EU state aid law (in particular FSR).



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Settlement projects

The establishment of pharmaceutical, biotech or life science companies requires not only strategic planning, but also the consideration of numerous legal and regulatory requirements. We assist you throughout the entire process, in particular with site selection (including leasehold issues / land acquisition), applications for subsidies, the authorisation process and the negotiation of contracts for the construction or expansion of

industrial and research facilities. This includes, in particular, issues relating to (international) plant construction (EPC, EPCM) and requires a special technical understanding, which must be translated into contract documents and legal project management from a legal perspective.



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Regulatory

We offer regulatory advice for pharmaceutical, life science and biotech companies along the entire value chain. Whether you want to authorise a medicinal product, market a digital health application or have a medical device certified – we help you to ensure efficient and legally compliant market access. Our services include in particular:

- Classification and differentiation of products (foodstuffs including food supplements, medicinal products, medical devices, cosmetics)
- Pharmaceutical law: Support in implementing and complying with national and European pharmaceutical regulations in the research process, in the authorisation, marketing and reimbursement of medicinal products (including advice on manufacturing, labelling,

quality management and pharmacovigilance) and advice on parallel import issues. Our advice also extends to specific products such as blood and tissue products, gene and cell therapeutics. Medical cannabis, anaesthetics

- Therapeutic Products Advertising Law: Legally compliant design of advertising measures in accordance with the Therapeutic Products Advertising Act (Heilmittelwerbegesetz, HWG)
- Data protection, data security and AI: Establishment of data protection-compliant processes; advice on pseudonymisation and anonymisation techniques, use of patient data, international data transfer and transfer of data to third countries, training of AI models and certification of AI-based medical devices and other software.



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Commercial

Luther also supports you along the entire value chain in the commercial sector: from research and development (drafting contracts for collaborations, licence agreements and clinical studies) to production (contract development and contract manufacturing agreements; purchasing conditions) and distribution (supply contracts, sales conditions).



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We also provide support in setting up accelerators to promote start-ups and SMEs.

We work with you to ensure that your innovative projects can be implemented in a partnership and with legal certainty.

Litigation / Arbitration and Product Liability

Luther also assists you in disputes before courts and arbitration tribunals, whether in regulatory proceedings, contractual disputes or product liability cases. A particular focus is on representing clients in disputes relating to pharmaceutical and medical device law, for example in matters relating to marketing authorisation, recalls or disputes with authorities, competitors and contractual partners. In the area of commercial litigation, we have particular experience in the enforcement of and defence against claims arising from licence, distribution and supply agreements, including in complex, international matters.



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We also advise on the defence of cross-border and complex product liability claims. With strategic vision and pragmatism, we defend our clients in and out of court, develop international defence strategies and coordinate teams of lawyers and technical and medical experts from Germany and abroad.



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IP/IT and KI

Especially in the pharmaceutical, life science and biotech sectors, the protection of intellectual property is essential in order to secure competitive advantages. We therefore support you in the development and enforcement of protection strategies for patents, trade marks and designs. We also ensure that your rights are comprehensively protected and that IP strategies can be implemented profitably in licence agreements and R&D collaborations.

In the field of information technology (IT), we support you in the introduction of digital technologies. Our advice includes compliance with data protection requirements, safeguarding

IT security and drafting contracts for software licences and cloud solutions.

We also help you to use AI applications in research, development and diagnostics in a legally compliant manner. We advise on regulatory requirements and ethical standards, the protection of intellectual property in AI-generated innovations and the safeguarding of data and cybersecurity standards required for the use of AI in healthcare research. Finally, we make it possible for your data to be used for AI projects in compliance with data protection regulations.



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Selection of credentials



BPI Bundesverband der
Pharmazeutischen Industrie e.V.



ottobock.



BERLIN-CHEMIE
MENARINI



B|BRAUN

:medac



biosaxony

vitos:



serumwerk
bernburg



skbs

Smith+Nephew



SPRIN-D

DKMS
WIR BESIEGEN BLUTKREBS

AstraZeneca

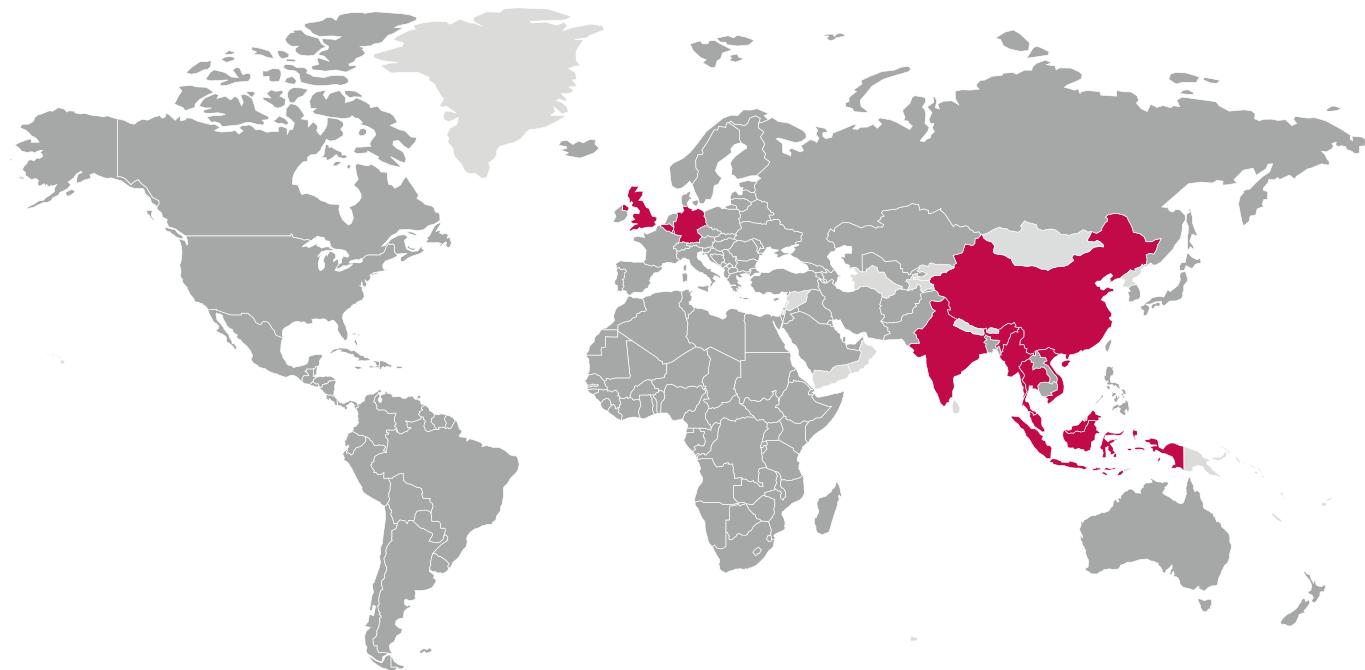
Our practice areas

Antitrust Law	Capital Markets & Banking	Commercial & Distribution Law, Product Liability/ Product Compliance	Complex Disputes
Compliance & Internal Investigations	Corporate/M&A	Data Protection Law	Employment Law
Energy Law	Environment & Planning Law Regulatory	Financial Services Investment Funds & Alternative Investments	Insurance Law
International Trade Law	IP & Copyright Law	IT Law	Media & Entertainment
Notarial Services	Public Procurement Law	Public Subsidies/ State Aid Law	Real Estate
Restructuring & Insolvency	Start-ups & Venture Capital	State, Administration, Public Undertakings	Tax Law
Telecommunications Law	White-Collar Crime & Tax Offences		

Our locations

We have a global outlook, with international offices in 11 key economic and financial centres in Europe and Asia. We also maintain close relationships with other commercial law firms in all relevant jurisdictions. Luther is a founding member of unyer (www.unyer.com), a global organisation of leading professional services firms that cooperate exclusively with each other. This way, we ensure a seamless service for our clients throughout their demanding international projects.

Our partner firms are based in Africa, Australia and New Zealand, Europe, Israel, Japan and Korea, the Middle East, Russia and the CIS, South and Central America, the US and Canada.



- Luther locations
- Best friends

Our locations

Bangkok	Jakarta
Berlin	Kuala Lumpur
Brussels	Leipzig
Cologne	London
Delhi-Gurugram	Luxembourg
Dusseldorf	Munich
Essen	Shanghai
Frankfurt a.M.	Singapore
Hamburg	Stuttgart
Hanover	Yangon
Ho Chi Minh City	

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For reasons of better legibility, the simultaneous use of gender-specific language forms is dispensed with. Corresponding terms apply in principle to all genders in the sense of equal treatment. The abbreviated form of language has editorial reasons and does not imply any valuation.

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**Bangkok, Berlin, Brussels, Cologne, Delhi-Gurugram, Dusseldorf, Essen,
Frankfurt a.M., Hamburg, Hanover, Ho Chi Minh City, Jakarta, Kuala Lumpur,
Leipzig, London, Luxembourg, Munich, Shanghai, Singapore, Stuttgart, Yangon**

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www.luther-services.com

