



Luther.

Outpatient and inpatient health care providers in Germany

Our Health Care & Life Science Industry Group

Health Care & Life Science represents one of the largest and at the same time socially most important industry sectors in Germany and Europe. With currently over seven million employees and health expenditure of around EUR 380,000 million (2018) – equivalent to over 11.5% of Germany's gross domestic product – successful commercial enterprises focus on the health care industry. It is also a significant growth sector in Europe and on the world market. With its Health Care & Life Science Industry Group Luther is one of the leading advisers for your commercial success in the health care industry.



Germany's health care market comprises a large number of services and products. The focus of the health care industry is the provision of medical care to the population in addition to the pharmaceutical and medical technology industry that supports it. Furthermore, the so-called "second health care market" (home spa products, self-payer market) is making a significant and ever-increasing contribution to the health care industry.

Like no other sector of the economy, the provision of medical care to the population, the core area of the health care industry, is subject to legislative amendments nearly every year that are sometimes substantial: inpatient care (acute medicine and psychiatric hospital market) with ever new reform bills regarding hospital structure and strengthening of care and constant changes in the system of diagnosis-related groups for the remuneration of hospitals, in short DRG, and the lump-sum remuneration system in the field of psychiatry and psychoso-

matics, called PEPP, outpatient care and care provided by SHI-registered physicians with new structural requirements, introduced for instance by the so-called *Terminservice- und Versorgungsgesetz* (law regarding quicker appointments and better care) as well as rehabilitation medicine and provision of care for senior citizens and persons in need of care as outpatients and inpatients.

The objective is the provision of health care that is modern, patient-oriented, integrated across sectors but also very cost-efficient. At the same time, service providers and health insurance companies compete for "patients" in the face of increasing cost pressure. Providers of outpatient and inpatient services in such a heavily regulated market need an experienced and knowledgeable legal adviser who has in-depth knowledge of the market besides regulatory expertise.

We support service providers in all matters ranging from the structuring and approval of their range of medical care services offered, compliance of the service provider with the legal framework to remuneration for and billing of their services – on a comprehensive, targeted and pragmatic basis, in terms of forward-looking health care.

In combination with health care, but also operating in its own global market, the pharmaceutical and medical technology industry more than hardly any other sector is at the heart of advances in medicine and the driving force behind digitisation in health care. We advise clients on legal issues in the areas of medical technology as well as pharmaceuticals, organic products & life science, ranging from the approval, manufacture to the distribution of the products.

With regard to the new regulatory requirements of the EU Medical Device Regulation (MDR) and the German Act on Medical Devices (*Medizinproduktegesetz*, MPG) we ensure that we provide comprehensive and individual advice tailored to the clients' requirements. For example, we provide you with advice regarding the conformity assessment procedures, risk classification or CE certification process. Other examples are requirements regarding the provision of clinical data and for transition plans for old certificates.

The statutory regulations for medical devices cover any trade in such products and therefore affect both manufacturers and users of medical technology. Our expertise goes beyond regulatory issues and includes all legal aspects relating to medical technology.

In addition to their own business – promoting and maintaining human health –, "health care entrepreneurs" must today more than ever meet the challenge of keeping an eye on numerous statutory requirements, systemic regulations and guidelines for self-governing organisations, of providing statistical information and entering into cooperation agreements in order to optimise cost-effectiveness.

We also face this challenge – together with you!

Luther's Health Care & Life Science Industry Group stands for industry experience, legal expertise across sectors and sound, networked advice for the health care industry. With more than 30 specialised lawyers and tax advisers and extensive experience we assist companies in all matters relating to

the health care industry. Our team is familiar with the structures in the health care market, knows the regulatory environment and understands the economic objectives of our clients. We are in constant contact on the ground with governmental decision-makers, with health insurance companies, self-governing organisations, licensing authorities and a large number of cooperation partners from the medical economy in order to develop tailor-made solutions for you.

We have the right answer for any legal question asked by our clients: our Health Care & Life Science Industry Group can call upon experts who, with their specialised expertise in the "M&A for investors/strategists", "Medical law for inpatient and outpatient service providers", "Medical technology", "Pharma, biotech and life sciences" and "Digital health" segments, ensure that a quality-based and solution-oriented advice is provided to you.

However, Luther not only provides specialised advice from the Health Care & Life Science Industry Group, but offers you comprehensive support in all other fields of law, which are important for your success and essential for complete advice.

We are looking forward to our future cooperation.

Recommended in medical law by JUVE and Legal500 Germany



Juve 2021/2022
Health care sector: hospitals,
medical care centres and
pharmacies



Legal500 Germany
Industry focus health

Medical law for outpatient and inpatient health care providers

Our team provides comprehensive advice to outpatient and inpatient health care providers: The focus is not only on the operative business, i.e. all questions concerning the provision of services and the cooperation with patients, customers and cooperation partners or authorities. We also support you in the planning and implementation of new structures, in the search for new partners or in the realisation of innovative ideas. Advice on medical law is the focus of our expertise. However, due to the close inter- and intradisciplinary cooperation of the experts within the Luther Industry Group Health Care & Life Science, Luther offers you much more: A broad range of knowledge and experience that covers all legal fields relevant to you. Thanks to their excellent sector and industry expertise, the colleagues master even the most complex legal settings based on a targeted and pragmatic approach. They are at your disposal at all times. Our team is familiar with the most current topics and the clients' interests through the regular exchange of industry-specific information with leading stakeholders of the health care industry.

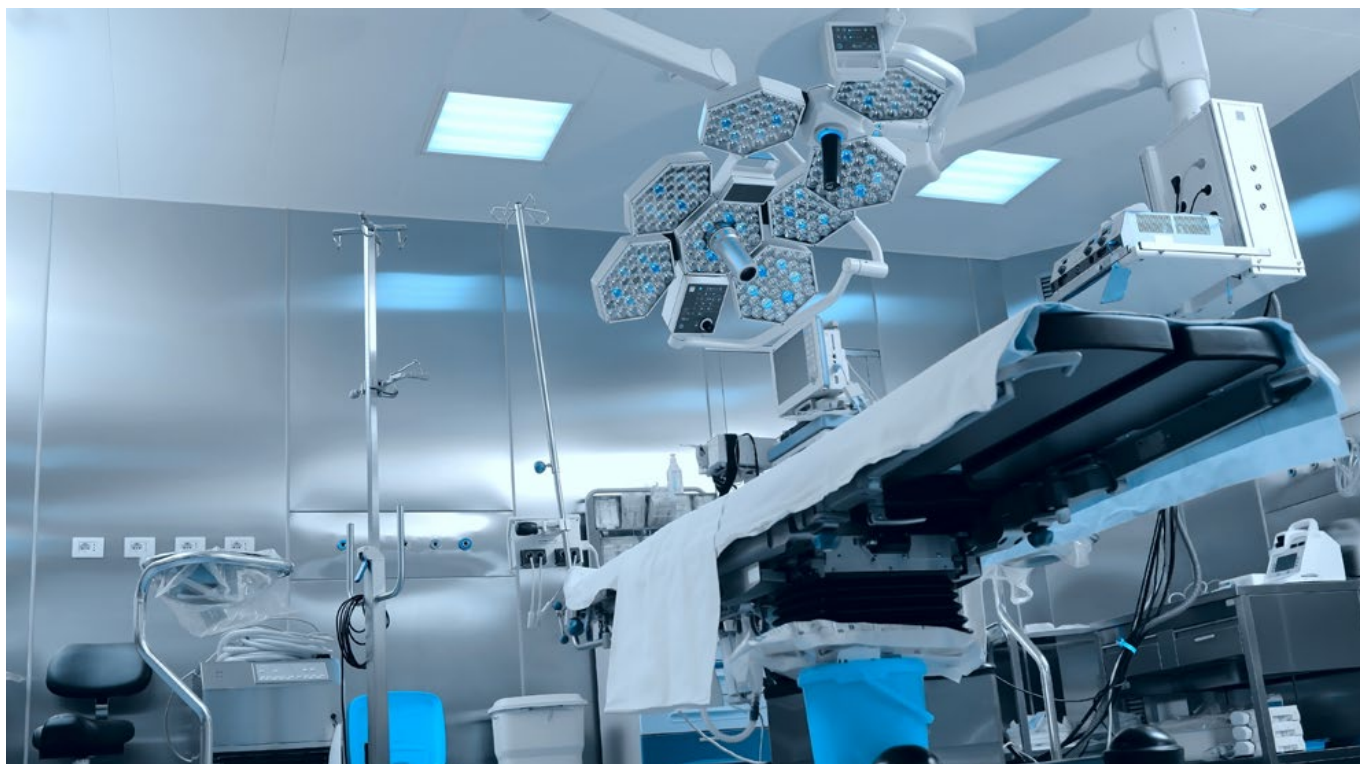
Our consulting offer for you:

SHI-registered physicians/outpatient service providers

- Professional law of the medical professions (doctors, dentists, providers of remedies and medical aids)
- Law of medical and therapeutic services, including liability and billing issues
- Law relating to SHI-registered physicians/dentists including remuneration law (incl. fee review, efficiency and plausibility checks)
- Accompaniment of registration proceedings for SHI-registered physicians/dentists and advice on authorisations, negotiations with associations of statutory health insurance physicians/dentists, registration committees, appointment committees
- Foundation of (dental) medical practices
- Advice on practice acquisitions/purchases of practices/ practice succession
- Establishment of medical care centres (MVZ), development of MVZ holding/group structures, expansion of MVZ by practices
- Drafting and review of cooperation agreements with other service providers

Inpatient care providers (acute medicine, psychiatry)

- Transactions/combinations, acquisition of inpatient facilities
- Hospital planning law, administrative and legal proceedings under planning law
- Hospital promotion and hospital funding law
- Hospital remuneration law together with disputes related to billing/dispute with health insurance companies (legal proceedings before the social court)
- Labour law in hospitals, in particular employment contracts with chief physicians/senior hospital physicians, employment of third parties (provision/temporary employment), development of working time models, advice on collective labour law issues (works council, public service staff representation) and pension issues (ZVK, VBL), church labour law
- Advice on authorisations for individual institutions to perform tasks of SHI-registered physicians (*Institutsermächtigung*) and authorisations of individuals
- Mental health facility registration issues
- Advice within the scope of the operative business (contract design, general terms and conditions for health and medical care, contract reviews, cooperation agreements)
- Acute crisis management (compliance-relevant cases liability incidents, pandemic situations)



Rehabilitation medicine (outpatient and inpatient facilities)

- Transactions, acquisition/sale of outpatient/inpatient rehabilitation service providers
- Registration and remuneration law (SGB V)
- Advice within the scope of the operative business (contract design, legal disputes, cooperation with other service providers)

Nursing care facilities (outpatient/inpatient)

- Registration and remuneration law (SGB XI)
- Accompaniment of proceedings before the arbitration boards in accordance with SGB XI (framework agreements with federal states, lump-sum care allowances, etc.)
- Drafting and review of cooperation agreements between service providers
- Real estate law, support of investments in nursing homes
- Transactions, acquisitions of outpatient/inpatient care organisations

Supplementary legal fields

- Pharmaceutical advertising law, competition law, copyright
- Data protection law
- Anti-corruption law, compliance

Selected references



Your contacts

Medical Law/Regulatory Affairs



Dr Hendrik Bernd Sehy

Lawyer, Counsel, Certified Specialist in Medical Law

Hanover

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Dr Hendrik Bernd Sehy studied law from 1998 to 2003 at the Ruprecht Karl University in Heidelberg, Germany. He spent part of his traineeship at an international American economic law firm in Frankfurt and worked in the Corporate/M&A Department. He was admitted to the bar and joined the Luther team in 2006. In 2014/2015, Hendrik Sehy completed the training course to become a certified specialist in medical law and is a certified specialist in medical law since 2018. He is a member of the German association dealing with the laws governing registered physicians who treat persons insured under the statutory health insurance system (Deutsche Gesellschaft für Kassenarztrecht e.V.), and he is also a member of the medical law working group of the association of Hanover-based lawyers and civil-law notaries (Rechtsanwalts- und Notarverein Hannover e.V.).

Areas of practice

Dr Hendrik Bernd Sehy advises mostly companies that operate in the health care market on all issues pertaining to corporate and medical law, as well as during transaction processes and restructurings. He primarily advises service providers, such as hospitals, medical care centres, large medical practices, and rehab and nursing care providers, inter alia on regulatory and financing issues, and he further advises the public sector on structural measures in the health care industry. Hendrik Sehy also provides advice to start-ups and well-established manufacturers of medical products, for example, when they launch new products or with regard to reimbursement issues.

Hendrik Sehy additionally focuses on advising the public sector (inter alia, German states, municipalities and medical associations) on structural measures (in particular in the hospital market) or other regulatory issues relating to the health care industry and on providing support during arbitration proceedings pertaining to social law.

Together with Dr Eva Rütz, Dr Hendrik Sehy heads the working group „In-patient and out-patient service providers“, which is part of Luther's Health Care & Life Science industry group.

Your contacts

Pharmaceutical Law



Cornelia Yzer

**Lawyer, Of Counsel, Former member of the Berlin Senate
Berlin**

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Cornelia Yzer not only has many years of experience as a lawyer but also demonstrable expertise as a manager, chairwoman/member of supervisory boards of companies and major research institutions and also from government positions.

In the past, she inter alia held the following positions:

- Executive employee at Bayer AG
- Chief Managing Director of the German Association of Research-based Pharmaceutical Companies (vfa) (1997-2012)
- Member of the German Parliament (1990-1998)
- Parliamentary State Secretary at the Federal Ministry for Education, Science, Research and Technology (1992-1997)
- Senator for Business, Research and Technology of the State of Berlin (2012-2016)
- Chairwoman of the Administrative Board of Investitionsbank Berlin, Chairwoman of the Supervisory Board of BWB, Member of the Strategic Advisory Board of Medidata Inc., New York (USA), Member of the European Advisory Board of the medical products manufacturer Guidant
- Chairwoman of the Boards of Trustees of major research institutions (German Cancer Research Centre (DKFZ), Max Delbrück Centre for Molecular Medicine (MDC))
- Board Member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Cornelia Yzer studied law and business at the Universities of Bochum and Münster (both Germany). She was admitted to the German Bar in 1990.

Areas of practice

Cornelia Yzer advises domestic and foreign companies on mergers and acquisitions and on regulatory issues, making them benefit from her many years of experience in industry and in government positions. A particular industry focus of Cornelia Yzer is life science and the digital economy. At Luther, Cornelia Yzer coordinates the industry group Health Care & Life Science and the practice group Digital Health. Furthermore, Cornelia Yzer advises her clients on all aspects of research funding.

Your contacts

Real Estate



Tatjana Giutronich, LL.M. (UNSW)

Lawyer, Senior Associate

Hanover

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Tatjana Giutronich studied law at Leibniz University in Hanover (Germany). After carrying out her legal training at the Higher Regional Court of Berlin (Germany), she was admitted to the German Bar in 2008. Tatjana Giutronich additionally completed a Master's programme (LL.M) at the University of New South Wales in Sydney (Australia) and later went on to obtain an LL.B. degree, enabling her to practise as an Australian lawyer. Tatjana Giutronich has more than 10 years relevant professional experience from working in large, renowned international law firms in Germany and abroad. She joined Luther's Hanover office in 2021 and is a member of the Real Estate team.

Areas of practice

Tatjana Giutronich advises German and international clients on the purchase and sale of real property, on REITs and hotel transactions. Her expertise in this area includes advising investors at all stages of a project, from acquisition to project development and asset management up to and including the sale. She also has a wealth of experience in preparing and assisting real estate funds with initial public offerings and cross-border portfolio transactions. In this field, she has special expertise at the interfaces between real estate law and corporate law as well as real estate financing.

Tatjana Giutronich is an experienced real estate lawyer who focuses on economic aspects and has a sound understanding of real estate law issues.

Hits the mark. Luther.

Luther Rechtsanwaltsgesellschaft mbH is one of the leading corporate law firms in Germany. With some 420 lawyers and tax advisors, we can advise you in all fields of German and international corporate law. In addition to having offices in every economic centre throughout Germany, we are also present in 11 locations abroad: in Brussels, London and Luxembourg in Europe, and in Bangkok, Delhi-Gurugram, Ho Chi Minh City, Jakarta, Kuala Lumpur, Shanghai, Singapore and Yangon in Asia.

Our advisory services are tailored to our clients' corporate goals. We take a creative, dedicated approach to achieving the best possible economic outcome for each of our clients. The name "Luther" stands for expertise and commitment. With a passion for our profession, we dedicate all our efforts to solving your issues, always providing the best possible solution for our clients. Not too much and not too little – we always hit the mark.

We know how crucial it is to use resources efficiently and to plan ahead. We always have an eye on the economic impact of our advice. This is true in the case of strategic consulting as well as in legal disputes. We have complex projects on our agenda every day. At Luther, experienced and highly specialised advisors cooperate closely in order to offer our clients the best possible service. Thanks to our fast and efficient communication, permanent availability and flexibility, we are there for you whenever you need us.

Luther has been named "Law Firm of the Year: Germany 2021" and also "European Law Firm of the Year 2021" by The Lawyer, one of the most well-known legal magazines worldwide.



About unyer

unyer, founded by Luther and Fidal in 2021, is a global organisation of leading international professional services firms. Besides law firms, unyer is also open to other related professional services, especially from the legal tech sector. unyer is based in Zurich as a Swiss Verein. unyer is globally connected but has strong local roots in their respective markets.

unyer has an exclusive approach and only accepts one member firm from each market. unyer members offer its clients full services across all jurisdictions with a compelling industry focus. The organisation has an annual turnover of more than EUR 650 million and includes over 2,500 lawyers and advisors in more than 10 countries in Europe and Asia. In September 2021, Pirola Pennuto Zei & Associati joined the international organisation.

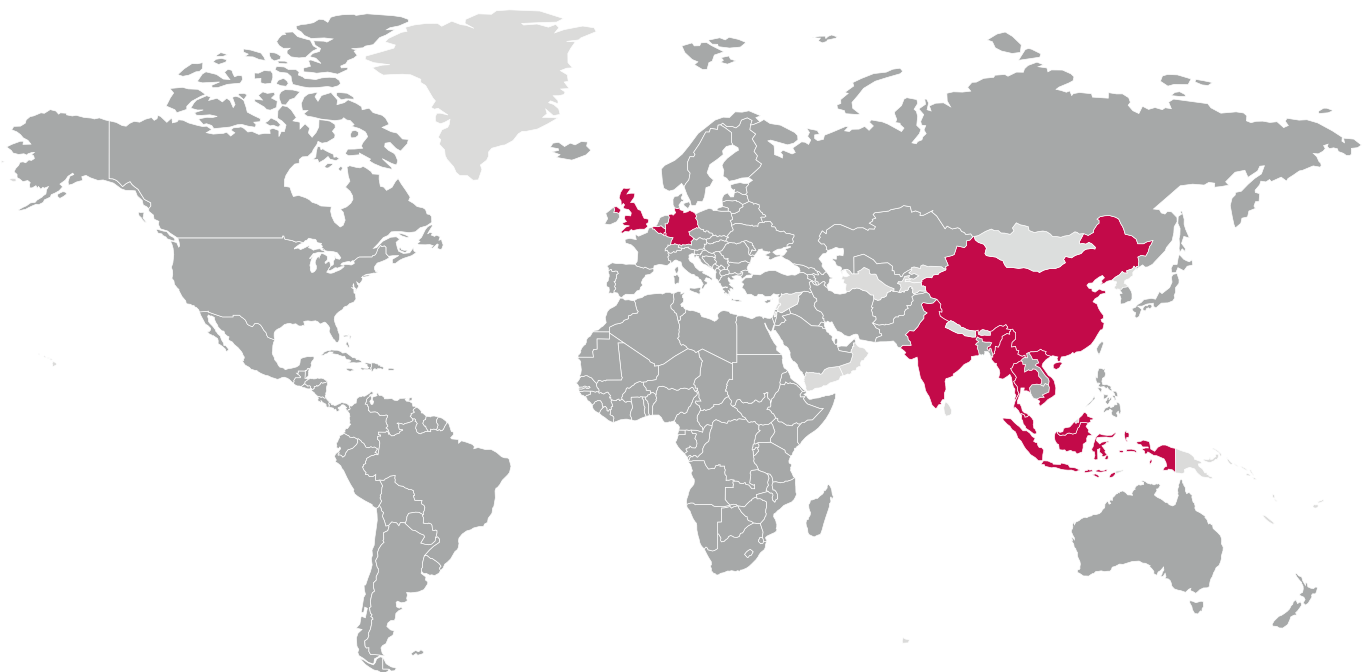
www.unyer.com



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	

Our industries

We focus on advising transactions with respect to targets in five industries.

Energy



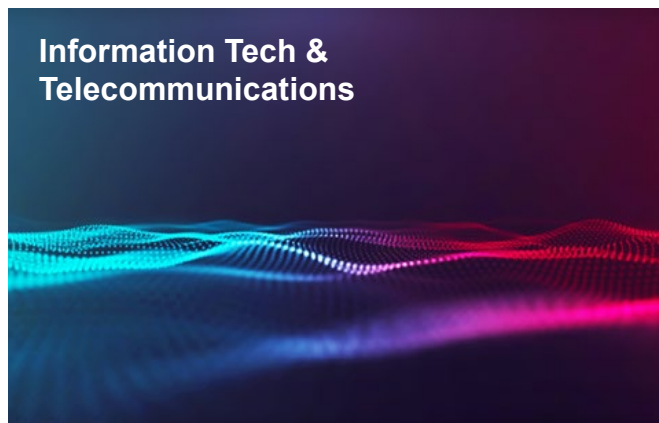
Conventional or renewable energies: We work efficiently and sustainably.

Health Care & Life Science



With our expertise, we have our finger on the pulse of time.

Information Tech & Telecommunications



We connect today with tomorrow.

Mobility & Logistics



We understand what gets you moving and can set you on the right course.

Real Estate & Infrastructure



We lay the foundation for you to build on.

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 awards



JUVE

In the 2022/2023 JUVE Guide to Commercial Law Firms, 52 lawyers from Luther were recommended, and 10 of these were also listed as “leading advisors”. The legal publisher JUVE ranked Luther in 31 areas of law. In 2022, Luther was nominated for the JUVE award “Employment Law” as well as “Real Estate” and was named “Law Firm of the Year” by JUVE in 2019. In the past, Luther already won the JUVE award “Law Firm of the Year 2017 for Environmental and Regulatory Law”.



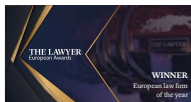
The Legal 500

The Legal 500 Germany 2022 recommends Luther in 28 areas of law, with “Top Tier” rankings in two of these areas. 76 lawyers are being recommended, 10 of whom have been specially recognised as “Leading Names” or “Next Generation Names”. Luther has also been included for Germany in the first edition of **The Legal 500 Green Guide EMEA 2022**. This guide provides an overview of law firms’ engagement with sustainability, including both work for clients as well as firms’ own best practices and initiatives.



Chambers

In 2022, Luther was recognised by Chambers Europe for 12 practice areas in Germany as well as in two practice areas in Luxembourg. Moreover, 15 partners were included in the Individual Ranking. Additionally, in 2022, Luther was recognised by Chambers Global in four advisory areas in Germany, Luxembourg and Myanmar, while six partners were also included in the Individual Ranking.



The Lawyer European Awards

Luther has been named “Law Firm of the Year: Germany 2021” and also “European Law Firm of the Year 2021” by The Lawyer, one of the most well-known legal magazines worldwide.



Kanzleimonitor

Kanzleimonitor 2022/2023 recommends Luther in 25 areas of law and has also included 16 Luther lawyers among the recommended lawyers mentioned by name.

Best Lawyers

“Best Lawyers in Germany 2023”

For the year 2023, 111 lawyers have been recommended by Luther as “Best Lawyers in Germany 2023”, an award presented by the US publisher “Best Lawyers” in cooperation with the German *Handelsblatt*, including three partners as “Lawyer of the Year” for their area of law and 12 colleagues who have received the recommendation “Best Lawyers - Ones to Watch”.



WHO'S WHO LEGAL

WHO'S WHO LEGAL listed 21 lawyers in December 2022, four of whom were recognised as Thought Leaders, which is the highest award, and three of whom were named Future Leaders.



Global Arbitration Review

In 2021, the English professional journal Global Arbitration Review (GAR) included Luther once again in its global “GAR100” list of arbitration practices rated by GAR.

Luther.Digital

The digital revolution is well under way. In a highly competitive market new business models are always being developed and existing processes are continually being challenged. Groups, medium-sized businesses and start-ups are all looking for the best possible ways to position themselves in this environment. In this way, new, innovative forms of cooperation are constantly being created. This revolution is being driven by numerous recent technological developments: cloud computing, digital platforms, Big Data and artificial intelligence, the Internet of Things and blockchain technology.

Luther advises on all legal topics relating to digital business models, agile architectures and technical levers. Our team provides support in all phases of the necessary transformation processes within the company, the law firm or the group, from strategic dialogue to conceptual work and the realignment of value chains, also including the subsequent change process. When providing advice, the Luther.Solutions team also considers relevant topics and changes in commercial and distribution, employment, IT and data protection law.

Protecting Intellectual Property



Artificial Intelligence & Big Data



Digital Infrastructure



Digital Value Chains



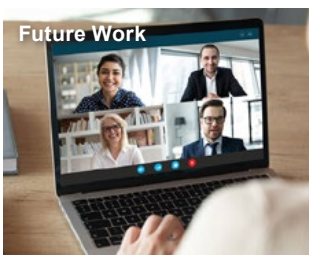
Blockchain & FinTech



Data Protection, Antitrust & Compliance



Future Work



Digital Media & Gaming



Platforms & Communities



Start-ups & Venture Capital



Luther.Solutions

In the field of legal services, digital building blocks have already frequently proven to be an important element for efficient, innovative client or project work. The digital transformation also poses new challenges for corporate legal departments: they must provide legal support for the change process within the company and proactively shape their own transformation.

With its four solution areas – Legal Design, Legal Tech, Legal Project Management and Managed Legal Services – Luther.Solutions provides support in all phases of the upcoming transformation of the legal sector, from strategic dialogue to process and organisational design, the use of legal tech solutions or the design of new forms of cooperation.



Luther.Solutions supplements our law firm's legal practice areas and portfolio of services to include digital solution modules (Legal Tech), elements and methods for designing workflows and processes (Legal Design) and Legal Project Management.



The **Luther.Solutions** team helps design efficient processes through the use of innovative, digital solutions when carrying out client work.

Luther Rechtsanwaltsgesellschaft mbH

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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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Luther.

**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**

You can find further information at:

www.luther-lawfirm.com

www.luther-services.com

