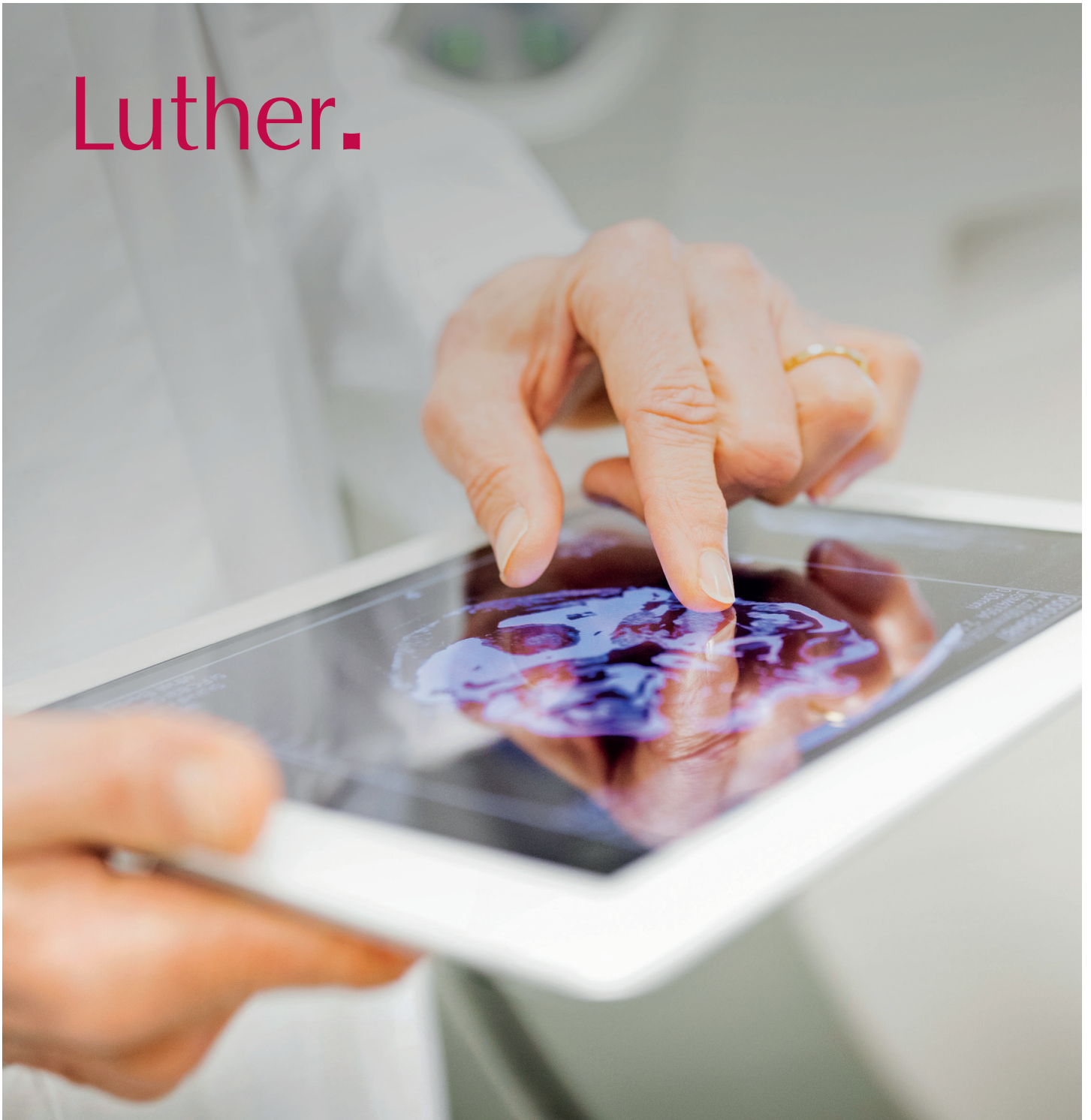


# Luther.



## Health Care & Life Science

# Health Care & Life Science



**Luther stands for focused legal and tax advice in the entire Health Care & Life Science sector in Germany and Europe. This includes health care structures, inpatient and outpatient, regulatory issues, the safeguarding of complex research projects, up to and including transactions and litigation.**

The highly regulated healthcare sector in Germany is constantly changing. Demographic developments are increasing the demand for medical services. Thanks to technological progress, pharmaceuticals medical devices research, production and therapy are linked with big data, gene sequencing, AI and biogenetics. Large technology companies and highly specialised start-ups have contributed to the fact that old structures in the health sector, biotechnology and chemistry have altered and now have to be redefined. Numerous challenges, therefore, that our clients are now facing.

We can meet these challenges head on together with you and ensure that you are well advised in your competitive environment on all legal and tax issues relating to the healthcare and life science industry. Our experts are familiar with the structures within the healthcare market, know the regulatory conditions and understand the economic goals of our clients. This allows them to concentrate fully on their core business: be it patient care, research into new pharmaceuticals or the development of state-of-the-art medical technology.

# Our range of advisory services

## Medical law for inpatient and outpatient service providers (acute, rehab)

### For dentists and doctors/medical-care centres

- Professional law for healthcare professions (doctors, dentists, etc.)
- Panel doctor law/panel dentist law including remuneration law and licensing procedures
- Opening a surgery and medical-care centre, developing medical-care centre group structures, advice on taking over a surgery
- Law on medical services, including liability and accounting issues

### For hospitals/clinics

- Hospital planning law, administrative/court planning law proceedings
- Hospital subsidisation and hospital financing law
- Public procurement procedures, advising construction projects for outpatient facilities
- Law regarding hospital remuneration and accounting disputes
- Employment law in hospitals, senior consultant service contracts
- Approval issues for psychiatric and rehabilitation medical facilities (inpatient, outpatient)

### For all service providers

- Drafting and reviewing cooperation agreements between service providers
- Employment law for service providers as well as the public sector
- Company pension plans/law regarding Federal and State Government Employees Retirement Fund (VBL), law regarding supplementary pension funds (ZVK), law regarding church supplementary pension funds (KZVK)
- Structural personnel measures, outsourcing, collective bargaining law
- Data protection law
- Anti-corruption law, compliance advice

## Old-age and nursing homes

- Law regarding (inpatient/outpatient) care

- Proceedings before arbitration boards according to the German Social Insurance Code XI (SGB XI)
- Legal advice regarding setting up cooperations and management systems/interface consulting
- Drafting contracts (transfer/release management; ordinance management)
- Law regarding remuneration of care fees
- Advice regarding real estate law (including construction/development, transactions)

## M&A for investors/strategies

- Advising complex, structured bidding procedures, company acquisitions and transactions
- (Partial) privatisation, developing individual investment solutions
- Restructuring, insolvency advice for service providers
- Advice on transformation law (hive-downs, mergers), insourcing and outsourcing
- Advice regarding creating a cooperation and holding (private, public as well as non-profit organisations)
- Public procurement law (structuring public procurement processes, tenders, litigation), PPP projects
- State aid law
- European and German merger control in the hospital and insurance markets
- Antitrust law advice regarding cooperations
- Further developing university medicine, monitoring of legislative processes
- Financing and reorganisation-related advice
- Tax law advice relating to transactions and cooperations
- Non-profit law

## Pharma, biotech and life science

- Pharmaceutical law (national, European)
- Approval of pharmaceuticals, clinical trials
- Market access and reimbursement
- Drafting pharmaceutical supply contracts
- Import and cultivation permits for medical cannabis
- Supplier and service contracts
- Research funding and cooperation with national, European and international organisations
- Joint ventures/cooperations
- Protection of Intellectual Property
- M&A
- Pharmaceutical advertising law, competition law, copyright law

## Medical technology

### For manufacturers/importers

- Advice on all regulatory aspects of medical device law (national and international)
- Providing support when dealing with the competent authorities
- Certification of medical devices, conformity assessment, risk classification, clinical trials and support when dealing with Notified Bodies
- Launch and market access of new medical devices
- Advising on product recall actions
- Legal structuring of distribution channels in Germany and abroad
- Defence against claims asserted against the manufacturer under the manufacturer's liability act
- German Social Insurance Code V (SGB V)
- Supplier and service contracts
- Joint ventures/cooperations

### For operators/users

- Advice on legal obligations regarding the use and operation of medical technology
- Providing legal advice and support in the procurement process of medical devices from the competitive bidding stage, through the dialogue phase, to the drafting of the contract and the selection procedure
- Individual and innovative drafting of contracts for the procurement, management, maintenance and renewal of medical equipment
- Advice on all aspects of liability law and on the enforcement and defence of liability claims
- Comprehensive advice on employment law including advice on occupational safety, special safety regulations for employees dealing with medical technology and the implementation of training courses

## Digital Health

- EU GDPR, German Federal Data Protection Act, sector-specific requirements for the protection of sensitive health data
- Quality management and "Internal Audit" guidelines
- E-Health-law
- Big Data in clinical trials

- Market access and reimbursement, pilot projects and selective contracts, new validation requirements, Digital Health Service Act
- E-Health-Apps, E-Health-Platforms
- Subsidy programmes, innovation funds
- Contracts with specialised IT providers
- Creating competence centres "Medicine 4.0", incubators and accelerators
- Conception and implementation of partnerships ("joint ventures") with medical service providers and IT providers
- Innovative structuring of investment financing
- Public procurement law for the integration of digital processes and products in clinics and surgeries; innovative contract design

## IT/IP, Dispute Resolution and Public Health law

- Advice on patents and trademarks
- Know-how protection and IP
- Advice on the competition law framework and compliance with antitrust regulations, comprehensive compliance advice
- Representation in arbitration and court proceedings and in dispute settlement negotiations
- Preparing and supporting tender procedures both on the part of the tendering company and on the part of the bidders



# Your contacts



## **Prof. Dr Christian Burholt, LL.M.**

**Lawyer, Certified Specialist in Medical Law, Partner  
Berlin**

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**[christian.burholt@luther-lawfirm.com](mailto:christian.burholt@luther-lawfirm.com)**

Prof. Dr Christian Burholt studied law at the University of Bonn (Germany) and also earned an LL.M. from the University of Durham (England). As part of his legal training at the Higher Regional Court of Berlin (Germany), Christian Burholt inter alia worked at the Directorate-General for Competition of the European Commission. He was awarded his doctorate in 2005.

Christian Burholt was admitted to the German Bar in 2002 and has been a certified specialist in medical law since 2014. He was most recently a partner in an internationally operating law firm, before moving to Luther in 2023. In addition, he has been a judge at the Constitutional Court of the State of Berlin since 2019 and an honorary professor at the Berlin School of Economics and Law (HWR) since 2022.

### **Areas of practice**

Prof. Dr Christian Burholt is an antitrust partner in Luther's Berlin office and co-head of the Health Care & Life Science industry group. He has more than 20 years of experience representing German and international clients in antitrust, abuse of market dominance and merger control cases and in leniency procedures, in Germany, the EU and worldwide. He further advises on antitrust compliance issues and carries out internal company investigations. Moreover, he also has comprehensive knowledge and many years of experience in the area of health law (pharmaceuticals/MedTech/health care/life science).

Christian Burholt is a regular lecturer and author on topics regarding antitrust and merger control law, often in relation to health care and life science.

# Your contacts



## Dr Oliver Kairies

**Lawyer, Partner**

**Hanover**

**T +49 511 5458 17643**

**[oliver.kairies@luther-lawfirm.com](mailto:oliver.kairies@luther-lawfirm.com)**

After finishing his vocational training in banking, Dr Oliver Kairies studied law in Hanover, which included training posts in Frankfurt and London. He received his doctorate in 2001 and was admitted to the bar the same year. He joined Luther's predecessor firm in 2001.

### Areas of practice

Dr Oliver Kairies specialises in assisting and coordinating complex, competitive tendering procedures, privatisations, and restructuring projects. He also coordinates national and international corporate transactions as well as assisting investors, sponsors, and athletes in issues concerning sports law. At Luther, Dr Kairies leads the Health Care & Life Science sector.

# Your contacts



## Cornelia Yzer

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

**T +49 30 52133 21148**

**[cornelia.yzer@luther-lawfirm.com](mailto:cornelia.yzer@luther-lawfirm.com)**

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.

# 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 2,550 lawyers and advisors in more than 10 countries in Europe and Asia. In September 2021, Pirola Pennuto Zei & Associati joined the international organisation. In the spring of 2023, the Austrian law firm KWR joined the group. [www.unyer.com](http://www.unyer.com)

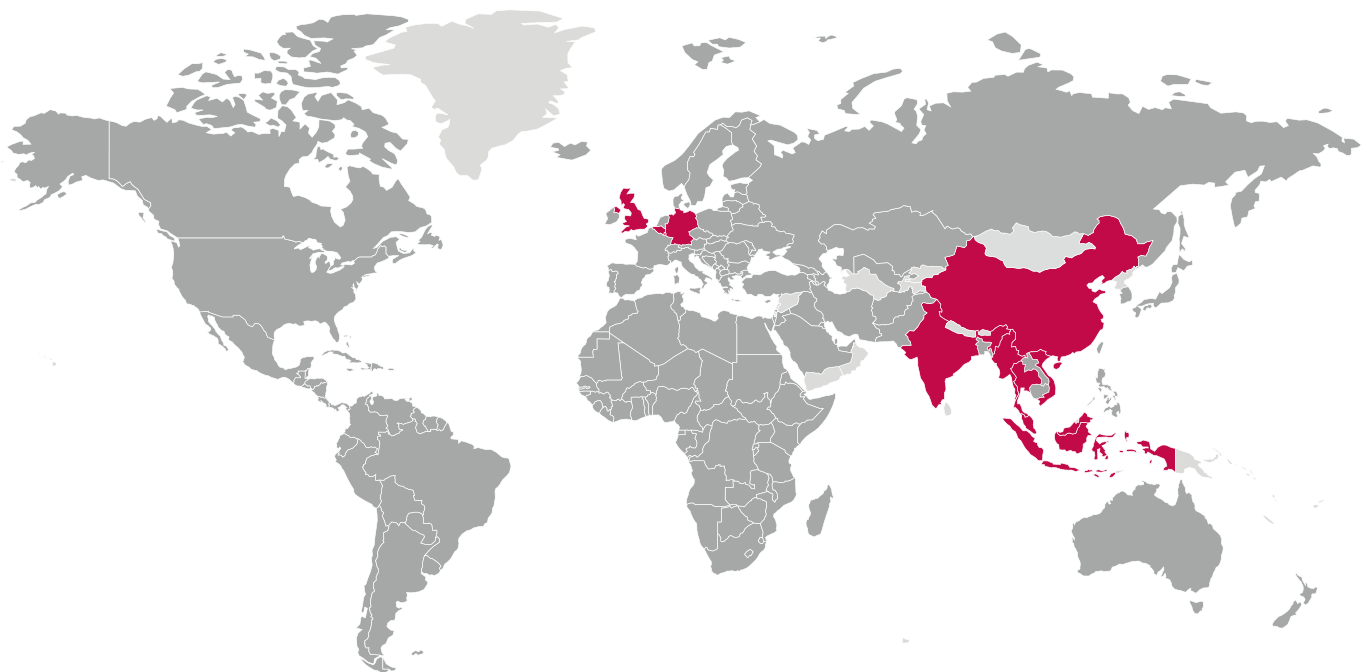




# Our locations

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](http://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

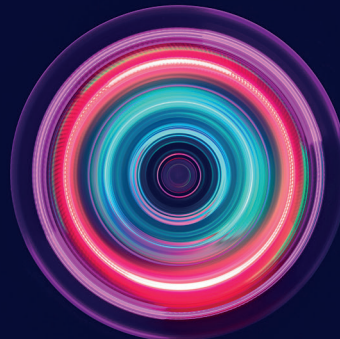
### Our locations

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

# Digitalisation

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 team also considers relevant topics and changes in commercial and distribution, employment, IT and data protection law.**

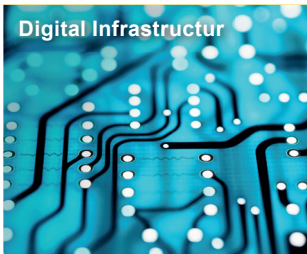
**Protecting Intellectual Property**



**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**





# 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 2023 recommends Luther in 30 areas of law, with “Top Tier” rankings in two of these areas. 72 lawyers are being recommended, 12 of whom have been specially recognised as “Leading Individual” or “Next Generation Partner”. 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 2023, Luther was recognised by Chambers Europe for 13 practice areas in Germany as well as in two practice areas in Luxembourg. Moreover, 15 partners were included in the Individual Ranking. Additionally, in 2023, Luther was recognised by Chambers Global in three advisory areas in Germany and Myanmar, while five 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 2024“

For the year 2024, 99 lawyers have been recommended by Luther as “Best Lawyers in Germany 2024”, an award presented by the US publisher “Best Lawyers” in cooperation with the German Handelsblatt, including one partner as “Lawyer of the Year” for his area of law, and 19 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.



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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.

Release: August 2023

# 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](http://www.luther-lawfirm.com)

[www.luther-services.com](http://www.luther-services.com)

