



PRACTICE OVERVIEW

Healthtech



“DLA has been an important legal adviser on a myriad of first-of-kind issues with limited precedent.”

– Life Sciences respondent

Rapid advancements in technology, including the development and adoption of AI and data analytics, are dramatically transforming the healthcare industry – outpacing traditional regulatory and risk frameworks. Companies operating in this environment require a team that understands healthcare, technology and AI at an engineering, regulatory and operational level.

Our cross-practice, integrated DLA Piper Healthtech team combines globally recognized strengths in medical devices, digital health, AI governance, product engineering, data strategy, IP protection and defense, government and regulatory investigations, litigation and arbitration, private equity and global regulatory frameworks to deliver pragmatic and commercial solutions that seamlessly integrate with the manner in which cutting edge businesses operate.

Our ability to think creatively, look around corners, and truly partner with our clients is why so many of the world’s leading pharmaceutical, medical device, technology and healthcare companies choose DLA Piper.

Defining Healthtech

Healthtech is the broad umbrella term for the use of any technology to improve health and to facilitate healthcare delivery, encompassing everything from software to wearable sensors to physical devices, hardware and artificial intelligence. While Healthtech and Digital Health are often used interchangeably, Digital Health is a subset of Healthtech, specifically focusing on digital tools (software, apps, wearables, telehealth, electronic health records) to improve health and wellness and streamline healthcare delivery for both patients and providers of care. While all Digital Health is Healthtech, not all Healthtech is Digital Health (e.g., a surgical robot).

The DLA Piper difference

Implementing healthcare technologies requires practical experience and bold thinking. We understand the Healthtech regulatory environment and competitive market, its nuances and its complexities. We have deep knowledge not only of the applicable laws and regulations addressing these technologies but also of the technologies themselves. Many of our team members are former policymakers, agency representatives, entrepreneurs, and/or hold advanced degrees in scientific and technological fields of study, allowing us to truly understand our clients' products and strategic goals. We bring life sciences and technology lawyers together into one Healthtech practice; you get sound, integrated advice, on a global scale.

Whether you're a Healthtech startup, big pharma, software or applications company, medical device company, or a leading tech company, we advise all players in the Healthtech ecosystem and at all stages of the product or service lifecycle.

You may be optimizing R&D or improving screening and diagnosis with AI. You may be enhancing care delivery with telehealth or digital pharmacies, or supporting health and wellness with wearable sensors. You may be improving clinical management with electronic records systems and tools, increasing operational efficiency. You may be managing significant customer, investor, or IP litigation disputes, or looking to understand the risks and value of investing in Healthtech companies.

Whatever your objective, our industry knowledge and experience will help you succeed.

Awards and accolades



Leading Firm
**Healthcare: Pharmaceutical/
Medical Products Regulatory**
Chambers USA 2025

Band 1
TMT: Multi-Jurisdictional
Chambers Global 2025

Band 1
**Technology: International
and Cross Border**
Chambers USA 2025

Tier 1
Patent Litigation: ITC
The Legal 500 US 2025

Band 1
Healthcare: Nationwide
Chambers USA 2025

Winning firm
Healthcare Team of the Year
Mergermarket Awards, 2025





Healthcare industry expertise and sector approach

DLA Piper's sector-focus ensures that you have the right legal specialists – regulatory, IP, employment, corporate, litigation and government advocacy – with a specific focus and understanding of the healthcare industry.

Our Healthtech team brings together various practices across jurisdictions to deliver cohesive and comprehensive advice and strategic direction to efficiently advance and support your initiatives, keeping you head of the curve. Our team is well-versed in the regulation of AI/ML tools, including Software as a Medical Device (SaMD), clinical decision support (CDS) tools, and cybersecurity issues, digital platforms, litigation risk mitigation and the protection of company-critical IP.

Members of our team co-founded the Health AI Partnership with Duke Health, Mayo Clinic, and UC Berkeley; advised the American Medical Association on its AI liability policy; and serve as lead AI, Digital Health and Healthtech counsel to numerous companies in life sciences, healthcare, software and applications, insurance and tech.

Experience in medical devices and digital health

Across the United States, Europe, Canada, China, Australia and the Asia-Pacific (APAC), as well as in emerging markets, our team assists clients in navigating classification, design, testing, commercialization, privacy/security, safety, compliance and product lifecycle risks – all through a coordinated, global platform.

Our combination of experience with United States Food and Drug Administration (FDA), the European Union Medical Device Regulation (MDR) and Artificial Intelligence Act (AI Act), Health Canada, and Australian Therapeutic Goods Administration (TGA) regulatory requirements and China and Asia-Pacific (APAC) market entry pathways, provides clients with coordinated classification, testing, engagement, and compliance strategies across jurisdictions.

AI governance, safety, and lifecycle strategy

Our team includes lawyer-data scientists, lawyers with medical qualifications, PhDs and regulatory practitioners who work on Artificial Intelligence/Machine Learning (AI/ML) platforms, Software as a Medical Device (SaMD), Clinical Decision Support (CDS) tools, cybersecurity, algorithm transparency, validation, monitoring and post-market compliance. We help companies adopt and scale Artificial Intelligence (AI) safely, aligning product development with regulatory expectations and emerging global AI frameworks.

We bring an exceptional understanding of life sciences and healthcare—built on decades of experience. This combination of scientific, technical, and regulatory knowledge means we understand the science behind your products, as well as the legal, regulatory and commercialization landscape. That critical crossover of deep tech, life sciences and healthcare experience enables us to guide clients from concept through development, testing and trial, to market launch, with confidence.

Engineering-level understanding of tech infrastructure

We advise companies designing products that rely on cloud, Kubernetes, containerized environments, sensor technologies, device-to-cloud communication, and cross-platform software architectures. This allows us to advise on risk, classification and regulatory strategy with technical precision.

Coverage, reimbursement, and compliance

We help clients assess the available coverage and payment options and pathways for their innovative technologies early in the development process, understanding that the design of a clinical trial and the resulting approvals could have a significant impact on potential government and commercial payor coverage. Members of our Healthtech team include former health policymakers, health agency representatives, and healthcare regulatory attorneys with decades of experience in achieving CPT codes and product coverage under existing and new payment pathways. We also ensure that our clients' financial relationships with business partners, vendors, and healthcare providers comply with applicable fraud and abuse laws and when necessary, defend against government investigations and enforcement actions.

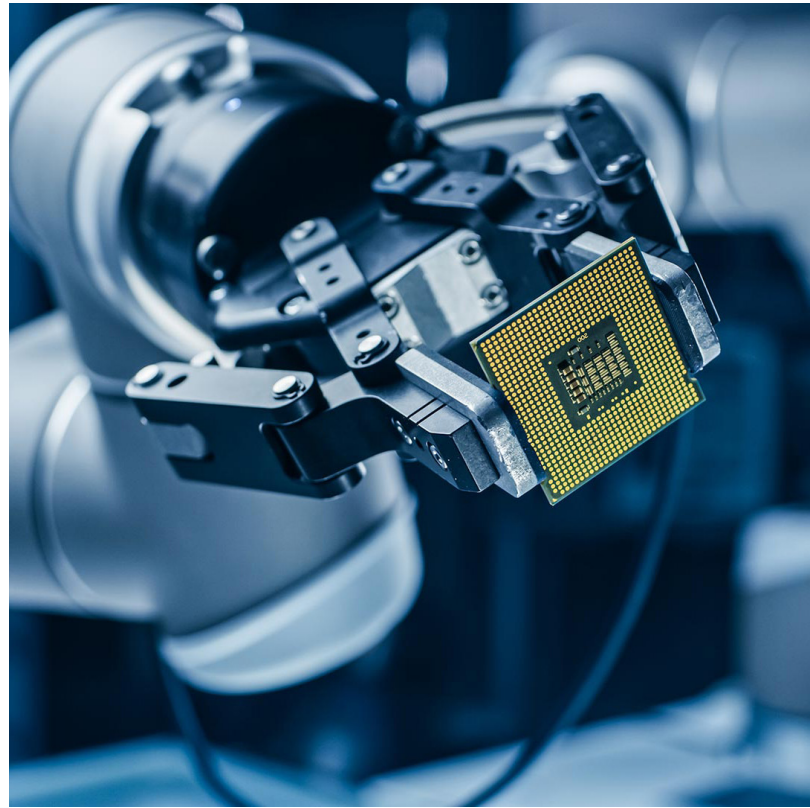
Healthtech venture capital, M&A, and strategic ventures

We advise Healthtech and AI driven organizations operating at the intersection of healthcare delivery, data, software, and advanced analytics, combining sophisticated transactional execution with a practical understanding of regulatory, reimbursement, data, and scalability considerations. Our team supports investors, founders, operators, and strategic buyers across the full transaction lifecycle—from early stage capital formation to complex, multi jurisdictional exits—drawing on deep experience in mergers and acquisitions, private equity, and leveraged buyouts, emerging growth, and venture financings, recapitalizations, and creative joint ventures. We regularly guide clients through sponsor led, and strategic transactions, platform build ups, structured growth investments, and alternative partnership models in a rapidly evolving, and highly regulated Healthtech and AI. landscape.

Intellectual property protection, risk management, and trials

We help clients develop IP asset management and protection strategies designed to manage risk, continue growth and protect market share. We advise on how to best leverage IP assets into revenue streams through licensing agreements, royalty structures and other dispositions. We also undertake IP due diligence and IP audits for clients looking to make acquisitions or venture capital investments.

Our Chambers-ranked DLA Piper Healthtech litigation team also helps our clients develop IP enforcement campaigns and defend against risks in US federal courts and the US International Trade Commission. DLA Piper defends and wins more US patent cases than any other full-service law firm. DLA Piper's trademark and copyright lawyers are frequently called upon to litigate high-stakes disputes where trademark, regulatory, and advertising issues have important ramifications



for the marketing of Healthtech functionality and devices. DLA Piper's powerful global platform allows us to seamlessly manage complex patent litigation matters across jurisdictions and venues worldwide.

Our disputes team assists our Healthtech clients in obtaining their business and financial goals by defending and prosecuting claims or responding to investigations. By virtue of our understanding of the underlying technologies, systems and applications, we are positioned to quickly assist when an implementation fails or a challenge is made by a customer, business partner or government agency as to the efficacy of the technology. In addition, we understand the intricacies of financing and governance in the Healthtech area and are able to steer companies and investors to their preferred outcomes when disputes arise between management and investors.

Cybersecurity and privacy

Our Privacy team advises extensively on the collection and use of individuals' data, including for marketing, research, AI development and testing, and data analytics. We routinely advise on cybersecurity and privacy requirements under HIPAA, GDPR, state law (e.g. CCPA) and laws pertaining to email, text messaging and telemarketing, such as the CAN-SPAM Act, the Telemarketing Sales Rule and the Telephone Consumer Protection Act, as well as laws pertaining to the cybersecurity of medical devices. We help clients facilitate data transfer and data sharing arrangements in compliance with applicable laws.



“DLA Piper is very well connected with offices around the world, and are very strong in terms of delivering a seamless experience across jurisdictions”

– Technology respondent

Our services

Regulatory strategy and global product classification

- Classification assessments for software, wearables, sensor-enabled devices, AI/ML tools, remote monitoring, and SaaS platforms (including when AI or digital devices become a regulated medical device)
- Evaluation of FDA, EU MDR/AI Act, Health Canada, Australian TGA and broader APAC requirements
- Preparation for FDA Pre-Subs, De Novo, 510(k), PMA strategy and global engagement plans
- Design input for multi-function platforms mixing regulated and unregulated components
- Clinical validation and testing expectations
- Cybersecurity and safety-critical software requirements
- Product liability, safety, and risk governance across cloud and hardware environments.

AI and digital health governance

- AI lifecycle governance frameworks
- Algorithmic validation, monitoring, model drift strategies
- AI bias, interoperability, liability and indemnity considerations for data sets
- Safety, transparency, labeling, and risk disclosures
- Ethical AI principles integrated with regulatory expectations
- Contracting and allocation of AI risk between developers, deployers, and healthcare providers

Product development and engineering alignment

- Intended use analysis
- Verification/validation requirements
- Clinical evidence strategies
- Software development practices, documentation, and quality management
- Multifunction device platform guidance
- Privacy, security, and data strategy
- Building and maintaining compliance programs for HIPAA, state laws, and global data-transfer frameworks, including breach notification guidance, patient rights/requests, and interoperability for data access
- Health data classification, risk scoring, and retention frameworks, operational resilience and business continuity planning,
- Integration of cloud infrastructure (Azure), communication platforms, and device interaction, telehealth, remote monitoring, and virtual care platform structuring

Commercialization and market access

- Labeling, promotion, and advertising compliance
- Post-market compliance, recalls, and surveillance
- Identifying potential coverage and reimbursement pathways and advising on product development and positioning to take advantage of existing payment opportunities
- When required, we also assist clients in exploring new coverage and reimbursement opportunities through agency advocacy and new AMA code requests
- Global commercialization frameworks for AI-enabled health solutions

Playbooks and deliverables

We design scalable, predictable deliverables that meet enterprise client expectations, including:

- Healthtech portfolio risk assessment
- Global product classification map
- Digital health compliance-by-design playbook
- AI in health blueprint
- BAA/DUA playbooks

Intellectual property protection, risk management, and trials

We develop global strategies to protect clients' IP and product assets, including:

- Developing IP strategy and securing IP in key jurisdictions
- Developing IP enforcement campaigns to protect IP, product, and business assets
- Identifying and mitigating litigation risk across the world's most important IP jurisdictions

Disputes

We generate business centric outcomes when disputes arise by:

- Developing strategic plans to respond to third-party claims
- Working with funders and investors to further their investment goals when disputes arise with management
- Advising management teams when their business interests might diverge from their investors
- Implementing 360° strategies to respond to government inquiries generating business centric resolutions
- Working with buyers and sellers to address and value potential risks in advance of transactions



For more information

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About DLA Piper

DLA Piper is one of the world's largest law firms, with more than 4,900 lawyers across 90+ offices in 45 countries. Our Life Sciences, Healthcare, and Technology sector teams work seamlessly across regulatory, transactional, litigation, privacy, and public policy disciplines to support clients during each phase of the Healthtech product lifecycle – from concept through global commercialization.

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