

Aiko Yamada

Counsel

Tokyo
+81.3.6205.3630

Aiko.Yamada@klgates.com

OVERVIEW

Aiko Yamada is a counsel and a member of the firm's Corporate Mergers and Acquisitions; Data Protection, Privacy, and Security; Emerging Growth and Venture Capital; Healthcare and FDA; and Technology Transactions and Sourcing practice groups.

Aiko has over two decades experience in the legal profession. She has represented a broad range of clients with a focus on global pharmaceutical companies, global medical device companies, Japanese and US biotechnology companies, but also including global mobile telecommunications and IT companies and Japanese trading companies.

PROFESSIONAL BACKGROUND

Aiko was admitted to practice law in Japan in 2000 and the state of New York in 2007, she joined the firm in 2020.

Prior to joining the firm, she served as a counsel at a multinational law firm for 20 years, where she gained experience in structuring, negotiating, and implementing various business and finance transactions. She focused her work on mergers and acquisitions and investment transactions, including both domestic and cross-border deals, compliance and corporate governance, and general corporate counseling. She also focused her work on policy and regulatory enforcement in the pharmaceuticals, biologics and medical devices industry and the technology and telecom industry, including regulatory and compliance advice on digital health, Medtech, AI, blockchain, cybersecurity and privacy, Fintech, data analytics, and software and app development.

ACHIEVEMENTS

- Recognized in *The Best Lawyers in Japan*™ for International Business Transactions, 2024-2025
- Recognized by *Chambers Asia-Pacific* for Life Sciences in Japan, 2018-2019

PROFESSIONAL / CIVIC ACTIVITIES

- Research Committee on the Judicial System, Dai-ichi Tokyo Bar Association

SPEAKING ENGAGEMENTS

- Legal and regulatory issues in the life sciences and healthcare industry (Financial Management Forums, Inc., December 2016)
- Legal and business issues on medical big data and gene and cell remedies (Financial Management Forums, Inc., May 2017)

EDUCATION

- LL.M., Columbia Law School, 2006
- The Legal Training and Research Institute of Japan, 2000
- LL.B., Sophia University, 1996

ADMISSIONS

- Bar of New York
- Japan (Dai-ichi Tokyo Bar Association)

LANGUAGES

- English
- Japanese

THOUGHT LEADERSHIP *POWERED BY HUB*

- 26 August 2024, Japanese Government Published Checklist and Guidance Related to AI and Copyrights
- 7 December 2023, Regulating AI: Part II—The Potential Impact of Global Regulation of Artificial Intelligence
- 25 September 2023, Japanese Government Identified Issues Related to AI and Copyrights
- 6 July 2023, Japanese Privacy Regulator Cautioned Businesses Regarding Issues Relating to Generative AI Services
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part I: HIPAA
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part II: HIPAA (Continued) & Additional Important Privacy Considerations
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers - Part III: FDCA

- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part IV: Other Potential Applicable Laws
- 1 October 2020, Japanese Government's Recent FAQs Clarify How to Recognize E-Contract Services Under E-Signature Act

OTHER PUBLICATIONS

- Co-author, "A quick regulatory guide to telehealth services in Japan, *Healthcare IT News*, 9 June 2022
- Co-author, Cross-border M&A Practice (Chuokeizai-sha, Inc., July 2008)

NEWS & EVENTS

- 16 April 2026, More Than 80 K&L Gates Lawyers Across Asia-Pacific Recognised in 2027 Best Lawyers, Ones to Watch Editions
- 1 March 2022, Understanding Digital Health Regulations for MedTech in Asia Pacific Markets, hosted byAPACMed

AREAS OF FOCUS

- Mergers and Acquisitions
- Data Protection, Privacy, and Security
- Emerging Growth and Venture Capital
- Food, Drugs, Medical Devices, and Cosmetics (FDA)
- Healthcare and FDA
- Private Equity Transactions
- Securities Enforcement / Financial Regulatory Enforcement
- Technology Transactions and Sourcing

INDUSTRIES

- Digital Assets and Blockchain Technology
- Digital Health
- Financial Services
- Healthcare
- Lab, Pharmacy, and Durable Medical Equipment

- Pharmaceuticals, Biologics, and Medical Devices
- Private Equity
- Technology
- Telecommunication and Mobile

EMERGING ISSUES

- Artificial Intelligence (AI)

REPRESENTATIVE EXPERIENCE

- Represented a Japanese pharmaceutical company in connection with various transactions such as launch of new business other than traditional Rx business; termination of partnership with a foreign pharmaceutical company; establishment of joint development with a US partner (AI venture company).
- Represented a Japanese biotechnology and pharmaceutical company in connection with clinical trials and studies, especially investigator initiated clinical studies; various life sciences related, multi-jurisdictional regulatory and compliance matters.
- Represented a Japanese mobile telecommunications company in connection with multi-jurisdictional advice on several ITC related projects and programs - e.g. point program, connected car project, SMS, video distribution services; documentation and negotiation for several partnership agreements with overseas partners - e.g. global IT companies, global platformers.
- Represented a Japanese and US biotech venture company in connection with receiving investments from investors; drafting related legal documents and legal memorandum; supporting applicable filing with regulatory authorities.
- Represented a global medical device company in connection with launching a new promotional scheme in Japan (localization of its global scheme in Japan); establishing and maintaining relationships with patient associations; documentation and negotiation for several distribution arrangements; establishing internal policies for information security -e.g. privacy policies.
- Represented a Japanese trading company in connection with several cross-border M&A and reorganization transactions such as spin-out deal for an overseas JV, a post-merger integration project in Mexico.
- Represented a global pharmaceutical company in connection with supply agreement and warehousing and logistics agreement to launch new products into the Japanese market.
- Represented a global pharmaceutical company in connection with various regulatory and compliance advice for Japanese regulations and overseas regulations (e.g. clinical trial sponsorship; relationship with patient group; pharmacovigilance).

- Represented a global pharmaceutical company in connection with research and development agreements and related documents; several out-licensing agreements with Japanese partners/distributors; ongoing disputes with a Japanese partner on distribution rights; product recall; authorized generic deals.
- Represented a global biotech company in connection with marketing and distribution agreement to launch new products into the Japanese market.
- Represented a global medical device company in connection with Japanese regulations on promotional activities and marketing authorization in Japan.
- Represented a global pharmaceutical company in connection with launching and marketing new products into the Japanese market; partnership deal with a Japanese distributor.
- Represented a global medical device company in connection with marketing and distribution agreement to reorganize distribution scheme from its own channel use to distributor's channel use; partnership agreements with a Japanese partner to comply with the Japanese regulations on quality and safety control; termination with ex-Japanese partner.
- Represented a global pharmaceutical company in connection with ongoing disputes on distribution rights on the client's products in Japan.
- Represented a global medical device company in connection with medical advisor agreements.
- Represented a global medical device company in connection with possible structures to launch new products in Japan; potential disputes with a Japanese partner.
- Represented a global pharmaceutical company in connection with establishing business in Japan.
- Represented a global pharmaceutical company in connection with ongoing disputes with a Japanese partner; documentation and negotiation of related documents.
- Represented a global medical device company in connection with regulations on product registration, defect reporting, recall, labeling and promotional and/or advertising activities in Japan; negotiation with authorities in Japan.
- Represented a Japanese manufacturing company in connection with newly entering into the medical device industry.
- Advised Konica Minolta from the regulatory perspective at its acquisition of Ambry Genetics.
- Represented a European medical device company in connection with termination of its distributorship with a Japanese partner and with the establishment of its own distribution channel and obtaining the necessary regulatory licenses and approvals in Japan.
- Represented a US pharmaceutical company in connection with its global reorganization.
- Represented a US medical device company in connection with its domestic and cross-border alliances.
- Represented a Japanese pharmaceutical company in connection with its acquisition of a Swiss pharmaceutical company.

- Advised many Japanese and foreign pharmaceutical companies and medical device companies with respect to regulatory and compliance issues, including genetic information management and relationships with healthcare professionals.
- Represented a Japanese telecommunications company in connection with its domestic and cross-border acquisitions and alliances.
- Represented a Japanese advertising company in connection with its acquisition of an advertising agency group headquartered in Singapore with operations in 12 Asia Pacific countries.
- Represented a global medical device company in connection with a tax and regulatory dispute with the authorities; import and distribution of overseas manufactured products in Japan; localizing its global policies of recycling products; reorganization of import and distribution scheme in Japan from the tax and regulatory perspective.