

MICHELLE WHITE

Address: 1111 Main Street, Torrance, California 11111 Mobile: 123.456.7890 ▪ Email: resumewriter@gmail.com

REGULATORY COUNSEL

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS), FOOD & DRUG ADMINISTRATION (FDA)

Pay Scale and Grade: Title 21 Pay Band C–G | Citizenship: USA

PROFESSIONAL SUMMARY

Highly motivated and experienced attorney with a history of success advising pharmaceutical companies in multiple facets of legal risk and healthcare compliance management.

Recognized for proven leadership in multinational companies at both country and regional levels, adept at managing diverse legal and compliance challenges throughout the Asia region. Demonstrated success in driving key projects and enabling the business through expert legal consulting and in-depth knowledge of healthcare-related legal and compliance issues. Effective at collaborating with and influencing senior executives, while driving strategic and operational initiatives.

LEGAL EXPERIENCE

Global Biopharmaceutical Company | Seoul, South Korea (2013 – Present)

Associate General Counsel ▪ Head, *Asia 5 Legal and Compliance*

06/2020 – Present

Hours per week: 40+

- Lead regional legal and compliance for Asia 5 (ex-Japan/China), managing a multi-market team and enabling business objectives.
- Built and developed a 10-member legal team during the pandemic to support regional operations.
- Provide strategic counsel and oversight into regional initiatives, contract management, and risk mitigation.
- Represent the Intercontinental Region (ICR) on the global I.FIT team, driving global legal and compliance initiatives across international affiliates.

Notable Accomplishments:

- ✓ Successfully managed and delivered major legal and compliance projects, including:
 - Streamlined ICR medical affairs manuscript process.
 - Supported digital transformation initiatives (websites, omnichannel, GileadPro).
 - Developed International Legal's digital toolkit, ICR compliance framework, and complaint-handling guidance.
 - Implemented efficiency measures that reduced low/medium-risk legal reviews by ~80%.
- ✓ Advised the business in all legal aspects of the 2020 Veklury donation/commercial supply program, expediting approvals and launch across Asia 5.
- ✓ Managed and closed the Asia 5 Filgotinib commercialization/distribution agreement with Eisai HQ after a nine-month negotiation.

Senior Director

01/2013–01/2021

Head, Korea Legal and Compliance and Chief Privacy Officer (*Dual-role at Country/Region*)

Jun 2020-Jan 2021

Hours per week: 40+

- Provided strategic legal and compliance guidance on complex regulatory and business matters.
- Strengthened risk-management systems, led compliance communications, and established ongoing training and monitoring programs.
- Oversaw negotiation and review of extensive contract portfolios across commercial, clinical, operational, and employment areas.
- Served as Chief Privacy Officer and interim CISO, ensuring alignment with global privacy and cybersecurity standards.
- Supported diverse business functions (HR, finance, clinical, quality, PV, IT, supply chain) on a wide range of legal and risk issues.

Notable Accomplishments:

- ✓ Built foundational legal/compliance frameworks for Gilead's first Asia commercial affiliate.
- ✓ Launched the first Asia chapter of Women@Gilead and co-sponsored the Korea chapter through 2020.
- ✓ Mentored legal talent through Gilead's sponsorship program for three years.

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- ✓ Preserved a critical Korea business partnership by guiding a distributor through compliance remediation (2015–2017).
- ✓ Rolled out the third-party vendor due-diligence program across Asia 5, Japan, and China (2016).
- ✓ Led the global pilot for Gilead’s centralized, compliant events-management CRM solution (2016–2017).
- ✓ Managed legal/compliance operations for Gilead Taiwan during a stretch assignment (2017–2018).
- ✓ Built legal/compliance frameworks for government partnership–based public health initiatives (Asia 5, 2019).
- ✓ Achieved favorable settlement in a complex five-year wrongful-termination dispute.
- ✓ Earned multiple awards and recognitions, including:
 - Six Key Contributor Awards; 14 Values at Work Awards (including Asia’s first Tier 4 recipient).
 - Star Award (2017) for process-improvement excellence.
 - Fast-track promotion in 2017 and elevated to regional leadership in 2020.
 - Multiple regional and international legal award nominations: FT Innovative Lawyers (2023), Women in Business Law Awards (2023), Asia Legal Awards (2024), ALB Korea Law Awards (2018, 2021).

EARLIER CAREER

Global Healthcare & Pharmaceutical Company | Seoul, South Korea

Head, Korea | Legal/Senior Counsel | Asia Pacific Regional Legal Support,
Global Clinical Operations, J&J Law Department 08/2011–01/2013
Hours per week: 40+

Major Korean Pharmaceutical Company | Seoul, South Korea

General Counsel 03/2007–08/2011
Hours per week: 40+

U.S. Litigation & Corporate Law Firm | New York, NY, USA

Associate 09/2002–11/2005
Hours per week: 40+

Public Interest Legal Organization – Juvenile Advocacy Division | New York, NY, USA

Staff Attorney 10/2001–09/2002
Hours per week: 40+

U.S. Full-Service Law Firm | New York, NY, USA

Associate 09/2000–10/2001
Hours per week: 40+

EDUCATION

Sample University School of Law | New York, NY, USA

Master of Laws in Taxation, 05/2006

Sample University College of Law | Syracuse, NY, USA

Juris Doctor, 05/2000

- Graduated *cum laude* and member of the Justinian Honorary Law Society (membership based on class rank)
- Selected Invitee and Member of Editorial Board, *Journal of International Law and Commerce*
- Recipient, CALI Award (Highest Grade in Commercial Transaction)

Sample University | Medford, MA, USA

Bachelor of Arts in International Relations, 05/1995

BAR ADMISSION

New York State Bar