ASIA-PACIFIC HEALTHCARE COMPLIANCE CERTIFICATION PROGRAM

SETON HALL LAW

Working Draft Only: Session topics & faculty are subject to change

PROGRAM FACULTY

- *Wilson ANG, Of Counsel, Norton Rose (Singapore)*
- *Gordon SCHATZ, Partner, Reed Smith (Washington, D.C.)*
- *Gareth Lee, Associate Gen. Counsel & Head of Compliance, Asia Pacific, Allergan (Singapore*
- *Jay YAN, Partner, Reed Smith (Shanghai)*
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- *Simone HANDLER-HUTCHINSON, Seton Hall Law School (Newark, NJ)*
- *Kathleen BOOZANG, Professor of Law, Seton Hall Law School (Newark, NJ)*

TIME	DAY 1 CURRICULUM -- MARCH 4, 2013
09:00-09:50	Welcome & Self-Introductions Preview of the Week: - Program Goals & Objectives - How is Compliance Best Achieved? A discussion of Values vs. Rules
09:50-10:50	Ethics as a Foundation for Corporate Compliance Programs (business ethics, professional codes of conduct and corporate governance)
10:50-11:10	*Morning break*
11:10-12:10	Global Corruption Risks and Enforcement Efforts (OECD, UNCAC, etc.)
12:10-13:10	*Lunch*
13:10-14:20	Extraterritorial Impact of US Foreign Corrupt Practices Act & UK Bribery Act: • Legal Requirements & Defenses • Cases, settlements and enforcement • Implications for third party due diligence
14:20-14:40	*Afternoon Break*
14:40-15:40	Anti-Corruption Laws Emanating from Asia-Pacific Countries.
15:40-16:40	Enforcement & Monitoring of Clinical Research Activities
16:40-17:20	Interactive Session—Hypothetical exercise or share a particular compliance challenge

TIME	*DAY 2 CURRICULUM -- MARCH 5, 2013*
09:00-09:10	Key Concept Review
09:10-10:40	Focus on China: The regulatory approval Process for New Drugs & Devices
10:40-11:00	*Morning Break*

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11:00-12:30	Government Investigations: local, national, and int'l enforcement • Being the Focus of a Government Investigation • Risk to and rights of employees • Legal privilege • Responding to inquiries • Business continuity plans • Third Party Risk
12:30-13:30	*Lunch*
13:30-14:30	Data Privacy Laws as Related to Anti-corruption Compliance & Internal Investigations
14:30-15:20	Focus on Japan Pharmaceutical Affairs Law: - JPMA Guidelines - FTC Guidelines - Transparency initiatives - Sexual & Power Harassment Issues - Pharmacovigilance
15:20-15:40	*Afternoon Break*
15:40-17:00	Interactive Session**:** Moderated Compliance Officers Panel Discussion and Audience Q&A
	Welcome Reception for Faculty & Attendees (location tbd)
TIME	***DAY 3 CURRICULUM—MARCH 6, 2013***
09:00-09:10	Key Concept Review
09:10-10:40	Advertising and Promotion of Prescription Drugs and Medical Devices: - Korea - Japan
10:40-11:00	*Morning Break*
10:50-12:20	Panel Session: Industry Codes of Practice/Ethics (SAPI, JPMA, Medicines Australia, IFPMA) • setting a code • enforcing a code/vigilance • to what extent do voluntary codes have legal ramifications • new initiatives & updates
12:20-13:20	*Lunch*
13:20-14:40	Global and Regional Transparency Trends - National laws & pending legislation - Sampling of Voluntary industry codes (JPMA, Medicines Australia, IFPMA)
14:40-15:00	*Afternoon Break*
15:00-16:30	Competition Law in the Healthcare Sector: Korea, Singapore, Malaysia, Japan
16:30-17:30	Focus on Scientific Exchange & Educational Activities (Advisory Boards, Speaker Programs, etc.)

TIME	***DAY 4 CURRICULUM—MARCH 7, 2013***
09:00-09:10	Key Concept Review
09:10-10:00	Public Procurement Rules & Processes for Healthcare Products and Services
10:00-10:20	*Morning Break*
10:20-12:30	*Interactive Session:* Group Case Studies Workshop • Team Instructions • Teamwork evaluations of proposed activities, risk, and recommend-dations. • Classroom discussion
12:30-13:30	*Lunch*
13:30-14:30	Panel: Do Local Labor Laws Impede Compliance Efforts? (e.g., how to respond to noncompliant behaviour)
14:30-14:50	*Afternoon Break*
14:50-16:30	Regional Focus: A closer look at the secondary markets (Malaysia, Thailand, Taiwan, Vietnam, etc.)
16:30-17:00	*Closing remarks & awarding of program certificates*