

LATIN AMERICA HEALTHCARE COMPLIANCE CERTIFICATION PROGRAM

SETON HALL | LAW

	DAY 1: SEPTEMBER 24, 2018	
8:30 a.m.	Program Registration	
9:00 - 9:30	Welcome & Overview Ice-Breaker/Self-introductions	Kathleen Boozang, Seton Hall Law School (New Jersey) Ela Bochenek, Seton Hall Law School (New Jersey)
9:30 – 10:30	Ethics as a Foundation for Corporate Compliance Programs (<i>A look at why business ethics is an important part of compliance and a company's culture</i>)	Kathleen Boozang, Seton Hall Law School (New Jersey)
10:30 – 10:50	Break	
10:50 – 12:10	Data Protection Risks in the Health Care Industry (<i>Overview of the key data protection risks facing multinationals; the complex regulatory landscape for privacy and data protection in LATAM & globally</i>)	Erick de Jesús Pérez Patiño, Alcon (Mexico) Dirceu Santa Rosa, Montaury Pimenta, Machado & Vieira de Mello (Rio de Janeiro)
12:10 – 1:10	Lunch	
1:10 – 2:40	Building a Compliance Team & Creating a Culture of Compliance (<i>An examination of ways to recruit, develop, and promote a team of compliance professionals; interactive exercise describing methods that companies can use with employees to help build an ethical business culture</i>)	Cory LaBarge, Grünenthal Group (Panama) Michael Mayes, Astellas (Illinois)
2:40 – 4:10	Assessing Third Party Risk (<i>Best practices on how to conduct tiered due diligence and implement internal controls to mitigate the risks associated with third parties</i>)	Antonio Caram, Johnson & Johnson (Miami) Ariadna Quesada, AbbVie Inc. (Netherlands)
4:10 – 4:30	Break	
4:30 – 5:30	Monitoring Programs (<i>Monitoring, auditing, and how to improve upon these programs within your companies</i>)	Sergio Alberto Pinto, Johnson & Johnson (São Paulo)

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	DAY 2: SEPTEMBER 25, 2018	
8:45 a.m.	<i>Sign-In</i>	
9:00 – 9:15	Day 1 Overview	Kathleen Boozang, Seton Hall Law School (New Jersey)
9:15 – 10:30	Drug & Device Development & Approval Process <i>(A comprehensive overview of the laws/regulations and key requirements involved in the new drug and device approval process, including classifying and testing new products, the application process, and the various pathways to marketing a product)</i>	Patricia Fukuma, Fukuma Advogados & Consultores (São Paulo) Martiza Moncayo, IRIS GLOBAL (Chicago)
10:30 – 10:45	<i>Break</i>	
10:45 – 11:40	Transparency & Disclosure Reporting <i>(An overview of the disclosure reporting requirements for transfers of value to health care professionals; what are the risks and what have we learned from other regions)</i>	Diva Duong, IQVIA (Paris)
11:40 – 1:00	Advertising & Promotion of Drugs & Medical Devices <i>(A discussion of the key requirements and regulations for advertising and promoting prescription drugs and medical devices, special risk areas for pre-launch activities, and social media)</i>	Angela Kung, Pinheiro Neto (São Paulo) Ignacio Gillmore, Carey Law Firm (Santiago) Adrián del Paso, Ibarra, del Paso, y Gallego, S.C. (Mexico City) <i>Moderator:</i> Felipe Kietzmann, former ABIMED Chairman (São Paulo)
1:00 – 2:00	<i>Lunch</i>	
2:00 – 3:30	Industry Interactions with Patient Organizations/Judicialization of Health in Brazil <i>(Discussion of the types of industry interactions with patients and patient organizations and how to identify and manage the ethical issues and potential conflicts of interest that may arise)</i>	Marcos Lobo de Freitas Levy, A. Lopes Muniz (São Paulo)
3:30 – 4:30	The Future of Compliance	Michael Mayes, Astellas (Illinois)
4:30 – 4:45	<i>Break</i>	
4:45 – 5:45	Compliance Officers' Panel Discussion	Sergio Abreu, Merck (Uruguay) Cory LaBarge, Grünenthal Group (Panama) Michael Mayes, Astellas (Illinois) Marcelo Nogueira, Novartis (São Paulo) <i>Moderator:</i> Richard Sobkiewicz, Norton Rose Fulbright (Rio de Janeiro)
5:45 – 7:30	<i>Networking Reception for All Program Faculty & Attendees at Living Lounge Bar & Sushi, Hotel Lobby - sponsored by EY</i>	

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	DAY 3: SEPTEMBER 26, 2018	
8:45 a.m.	<i>Sign-In</i>	
9:00 – 10:15	Anti-Corruption Risks & Enforcement in LATAM Markets <i>(Key risk areas for the life sciences industry, including with respect to third parties, global anti-corruption laws, industry trends, and lessons learned from other high-risk markets)</i>	Vanina Caniza, Baker McKenzie (Buenos Aires) Henrique Frizzo, Trench Rossi Watanabe (São Paulo) Gregory Paw, Pepper Hamilton LLP (Philadelphia)
10:15 – 10:35	<i>Break</i>	
10:35 – 12:05	FCPA/UK Bribery Act <i>(A session focusing on the Foreign Corruption Practices Act, the UK Bribery Act, and global anti-corruption enforcement)</i>	Gary Giampetruzzi, Paul Hastings (New York) Jonathan Stevens, Paul Hastings (California)
12:05 – 1:05	<i>Lunch</i>	
1:05 – 2:20	Conducting an Internal Investigation <i>(An examination of what conduct triggers the need for an internal investigation, who should be involved, and how to handle the results)</i>	Gildas Durand, E&Y (Miami) Diana Borges, Merz Americas (North Carolina)
2:20 – 3:35	Enforcement Landscape in Brazil <i>(The risks associated with third parties and importance of conducting due diligence within the Brazilian market)</i>	Benny Spiewak, SPLAW Advogados (São Paulo)
3:35 – 3:55	<i>Break</i>	
3:55 – 5:15	Group Exercise	Kathleen Boozang, Seton Hall Law School (New Jersey)

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	DAY 4: SEPTEMBER 27, 2018	
8:45 a.m.	<i>Sign-In</i>	
9:00 – 10:00	Country Review Session – Argentina, Peru, Chile	Pedro Serrano Espelta, Marval, O’Farrell & Mairal (Buenos Aires)
10:00 – 10:20	<i>Break</i>	
10:20 – 11:05	Culture and Compliance	Ela Bochenek, Seton Hall Law School (New Jersey) Marcos Lobo de Freitas Levy, A. Lopes Muniz (São Paulo)
11:05 – 12:05	Strengthening Compliance Programs Through Data Analytics <i>(A look at what data analytics is and how it can be used to help detect, predict, and prevent future compliance risks)</i>	Toni Hahn, Johnson & Johnson Corporate Internal Audit (New Jersey) Patricia Miguel, E&Y (São Paulo)
12:05 – 1:05	<i>Lunch</i>	
1:05 – 2:05	Building Relationships While Maintaining Compliance <i>(Practical discussion on the dos and don’ts of interacting with HCPs in Latin America)</i>	Marcelo Nogueira, Novartis (São Paulo)
2:05 – 2:25	<i>Break</i>	
2:25 – 4:45	Interactive Team Case Study	Cory LaBarge, Grünenthal (Panama) Sergio Alberto Pinto, Johnson & Johnson (São Paulo)
4:45 – 5:15	Conclusion of Program – Closing remarks & awarding of program certificates	

- Conclusion of Program –