DRAFT AGENDA

2016 Global MedTech Compliance Conference
Convention Center, Dublin
24-26 May

Last update: 20 May 2016 (subject to change)

DAY	TIME	PROGRAM
TUESDAY 24 May	10.00 – 12.30	**AdvaMed Device and Diagnostics Compliance Group (DDCG)** *(Wicklow Hall 1)- Members only*
	10.00 – 12.30	**MedTech Europe Compliance Network (CN)** *(Ecocem Room) - Members only*
	10.00 – 16.30	**Global MedTech Compliance Bootcamp for Small & Medium-Sized Enterprises (SMEs): *Navigating Global MedTech Compliance*** Separate Registration Required *(Wicklow Hall 2)*
	12.30 – 13.45	***Joint DDCG-CN Lunch*** *together with participants of the SME Bootcamp (Level 3)*
	13.45 – 17.00	**Joint DDCG-CN Session** *(Wicklow Hall 1)- Members only*
	17.30 - 19.00	**SME Bootcamp Reception** *(The Marker Hotel, Shannon Suite)*
	19.00 – 20.30	**PwC Compliance Achievement Award & Networking Cocktail** *The Guinness Storehouse* *Sponsored by PwC* *(Transportation will be provided)*
	20.30	**GMTCC Dinner** *The Guinness Storehouse – Arrol Suite* *Sponsored by Red Flag Group* *(Transportation will be provided to The Marker and Gibson hotels)*

DRAFT AGENDA

DAY	TIME	PROGRAM
WEDNESDAY 25 MAY	08.00 – 09.00	***GMTCC Registration and Welcome Coffee*** *(Convention Center of Dublin – Level 2)*
	09.00 – 09.30	**Welcome and Introduction with Associations CEOs** *(Auditorium)* Speakers: - Serge Bernasconi, CEO, MedTech Europe *(confirmed)* - Sinead Keogh, Director, MedTech & Engineering, IBEC/IMDA *(confirmed)* - Scott Whitaker, President & CEO, AdvaMed *(confirmed)* Description: The aim of this session is to briefly discuss the associations' strategy and priorities in ethics & compliance, including how the different associations collaborate in this field in order to ensure that industry abides by the highest ethical and professional standards, what are best practices from a Trade Association perspective, in particular in the collaboration with medical societies.
	09.30 – 10.15	**Keynote Speech: "Why Good People Do Bad Things?"** *(Auditorium)* Speaker: Guido Palazzo, Director, Professor, Department of Strategy, Globalization and Society, HEC Lausanne *(confirmed)* Description: Professor Guido Palazzo will show the latest research in psychology and sociology and will advance ideas about how to better protect organizations and individuals against rule breaking.
	10.15 – 10.45	***Networking break*** *(Level 3)*
	10.45 – 12.15	**Parallel Session 1**: **Procurement in Emerging Markets: New Compliance Challenges** *(Wicklow Hall 1)* Speakers: - Christian Cuneo, Director Compliance Europe, Stryker Corp. *(confirmed)* - Rami Rajab, VP Government Affairs Intercontinental, LivaNova *(confirmed)* - Tanya Vogt, Executive Office, SAMED (South African Medical Device Industry Association) *(confirmed)* - Anna Udalova, Head of IMEDA Code of Ethics Task Force, Legal & Compliance Manager Russia & CIS, Beckman Coulter

DRAFT AGENDA

		(confirmed) Moderator: Jean McKiernan, Director, PriceWaterhouseCoopers Description: The aim of this session is to discuss current and emerging compliance challenges in key markets. This includes global compliance issues such as anti-trust, anti-bribery, and evolving regulatory requirements in emerging markets, such as the Middle-East, Brazil, South Africa, Russia, China, or India. This session will discuss how companies are addressing distributor relationships, tenders, and general procurement with governments. The panel will explore the manufacturer's perspective as well as the insights of representatives from industry local trade associations.
	10.45 – 12.15	**Parallel Session 2**: **Exchanges of Best Practices on Educational Grants/Indirect Sponsorship** *(Wicklow Hall 2A)* Speakers: - Richard N. Peterson, General Counsel, American Academy of Orthopaedic Surgeons (AAOS) *(confirmed)* - Michelle Scharfenberg, Chief Compliance Officer, Integra LifeSciences Corporation *(confirmed)* - Linda Sneddon, Compliance Officer for MPD EMEA, W.L. Gore & Associates *(confirmed)* - David Wilson, Health Care Compliance Officer, DePuy Synthes EMEA, J&J *(confirmed)* Moderator: Timothy Moore, Senior Associate, Shook, Hardy and Bacon LLP Description: With industry moving away from direct sponsorship across the world and most recently in Europe, China and Brazil, there are many challenges to address to help ensure a smooth transition. These challenges include, for example: how educational grants will evolve in the future; what are creative models for the education and training of HCPs; best practices how to continue supporting medical education; how to best communicate with customers about the transition away from direct sponsorship; how to set up good processes for managing the compliance risks existing with indirect sponsorship, among others.
	10.45 – 12.15	**Parallel Session 3: Fair Market Value** *(Wicklow Hall 2B)* Speakers: - Aoife Delmas, Deputy Director Industry Relations, European

DRAFT AGENDA

		Society of Cardiology (ESC) *(confirmed)* - Daniel Garen, VP Global Compliance Lead Counsel, Danaher Corporation *(confirmed)* - Heidi Jauch, VP Compliance Officer EMEA, Zimmer Biomet *(confirmed)* - Mark A. Petrille, VP and Head of Compliance, North America Region & Global Ultrasound Business Area, Siemens Healthcare *(confirmed)* Moderator: Jeffrey A. Garfield, Director Forensic Services, KPMG Description: Fair Market Value is a key element of any effective compliance program. It affects key areas of the relation between healthcare professionals and industry, and it is a good indicator of compliance risks, but its exact determination has always posed problems for companies wanting to comply with legal requirements around the world, as its definition varies from jurisdiction to jurisdiction. This session will try to tackle these problems through case studies showing how Fair Market Value can be determined in a complex scenario.
	12.15 – 13.30	***Networking Lunch*** *(Level 3)*
	13.30 – 14.00	**Keynote Speech: "Public Perception: Views on MedTech Business Ethical Behaviour"** (Introduction by Bill Doherty, VP EMEA, Cook Medical) *(Auditorium)* Speaker: Pat O'Mahony, Deputy Secretary, Head of Governance and Performance Division, Department of Health, Ireland (confirmed)
	14.00 – 15.00	**CEO Roundtable on Global Compliance** *(Auditorium)* Speakers: - Nacho Abia, CEO, Olympus *(confirmed)* - Benson F. Smith, CEO, Teleflex *(confirmed)* - Nadim Yared, President and CEO, CVRx Inc. *(confirmed)* - Derek Young, CEO, i360 Medical *(confirmed)* Moderator: Kathleen Meriwether, Principal, Assurance Services - Fraud Investigation & Dispute Services, Ernst & Young Description: A diverse panel of MedTech CEOs share thoughts on ethics and compliance; explain how they voice the compliance "tone at the top;" comment on the value and role of compliance within a MedTech company and comment on the role of trade associations in

DRAFT AGENDA

		ethics and compliance. This panel will also examine CEOs' perspectives on current trends in compliance (e.g. transparency, developing markets, and direct sponsorship of physicians).
	15.00 – 15.30	***Networking break*** *(Level 3)*
	15.30 – 17.00	***"Coffee Talk":* Get Your National Update, and Discuss the Latest Developments with Your Peers** *(Wicklow Hall 2)* Session moderator: Michael Lee Koon, Partner, Norton Rose Fulbright LLP Moderators: - **Australia/Japan:** Diva Duong, VP Compliance EMEA-APAC, IMS Health *(confirmed)* - **Brazil:** Carlos Gouvea, Executive Director, Câmara Brazileira de Diagnóstico Laboratorial (*confirmed*) - **China distributors:** Susan Murr, Non-Executive Director, The Red Flag Group *(confirmed)* - **France:** Laure Le Calvé, Associate Lawyer, LCH *(confirmed)* – in co-moderation with Anne-Sophie Bricca, Director Legal Affairs & Compliance EMEA, Terumo BCT *(confirmed)* - **Germany:** Adem Koyuncu, Partner Lawyer and Medical Doctor, Head of Life Sciences Germany, Covington & Burling LLP *(confirmed)* - **India:** Rajiv Joshi, Partner, FIDS India, Ernst & Young *(confirmed)* - **Italy & Southern Europe:** Fernanda Gellona, Director, Assobiomedica *(confirmed)* - **Middle East region:** Ghadeer Al Yacoub, Regional Compliance & Regulatory Manager, Johnson & Johnson Middle East (Inc.) *(confirmed)* – in co-moderation with Arwa Asiri, Compliance Officer, Ethical MedTech *(confirmed)* - **Russia**: Marc Miller, Partner, KPMG *(confirmed)* – in co-moderation with Ivan Tyagoun, Forensic Leader, KPMG Russia *(confirmed)* - **Poland & Eastern Europe:** Suzanne Durdevic, General Counsel EMEA, Boston Scientific International SA *(confirmed)* - **UK:** Milana Chamberlain, Partner, Solicitor qualified in England & Wales, Norton Rose Fulbright LLP *(confirmed)* - **US and Global Transparency: Horizon scanning & Watch list:** Alexis Wong, Director, Pharmaceutical & Life Science Practice, PriceWaterhouseCoopers *(confirmed)*

DRAFT AGENDA

	18.30 – 20.00	***Welcome Cocktail Reception*** *U.S. Ambassador Kevin O'Malley's Residence* *Sponsored by Ernst & Young* *(Transportation will be provided back to The Marker and Gibson Hotels)*

DAY	TIME	PROGRAM
THURSDAY 26 May	08.00 – 09.00	***GMTCC Registration and Welcome Coffee*** *(Level 2)*
	09.00 - 10.15	**Global Transparency** *(Auditorium)* Speakers: - Julie Bonhomme, Deputy Director Legal Affairs & Compliance, EFPIA *(confirmed)* - Anne-Sophie Bricca, Director Legal Affairs & Compliance EMEA, Terumo BCT *(confirmed)* - Hollie Faust, Senior Vice President Ethics & Compliance, Cardinal Health *(confirmed)* - Ilana Shulman, Chief Compliance Officer, Hill-Rom Holdings Inc. *(confirmed)* Moderator: Alexis Wong, Director, PriceWaterhouseCoopers Description: "Let the Sunshine in" - The United States, France, Belgium, the Netherlands, and other countries have enacted, or are currently contemplating, the implementation of physician-industry transparency systems that would require the medtech sector to disclose publicly payments and transfers of value made to physicians and certain other providers. This session will examine the different transparency models around the world, company concerns, and best practices to address emerging requirements.
	10.15 - 10.45	***Networking Break*** *(Level 3)*
	10.45 - 12.00	**Upcoming Changes in the Industry Compliance Landscape and Impact on Other Stakeholders** *(Auditorium)* Speakers:

DRAFT AGENDA

		- Pascal Garel, Executive Director, HOPE *(confirmed)* - Pr. Colm O'Morain, President, BioMed Alliance *(confirmed)* - Adrian Ott, CEO European Federation of National Associations of Orthopaedics and Traumatology (EFORT) *(confirmed)* - Dr Ian Watson, EFLM Past President Cutting Edge of Laboratory Management in Europe (CELME) (*confirmed*) Moderator: Karen Hackett, FACHE, CAE, CEO, American Academy of Orthopaedic Surgeons (AAOS) Description: The compliance landscape has changed rapidly, and industry adopted new Codes and approaches to meet these challenges and advance ethical interactions. These changes affect the whole medical/patient care industry, not only MedTech companies. Medical societies, hospitals, congress organizers and other stakeholders also are adjusting or adopting new business models within this dynamic global environment. For example, new transparency requirements, the end of EU direct support to healthcare professionals to attend medical conferences (and the channeling of this support through educational grants), new industry Codes in China, Latin America and elsewhere bring great transformation to the larger medical industry overall, and this session will explore how leading US and EU societies are adapting and advancing new models.
	12.00 - 13.30	***Networking Lunch*** *(Level 3)*
	13.30 - 14.45	**Parallel Session 1**: **Prosecutor Panel** *(Wicklow Hall 1)* Speakers: - Kathleen Hamann, Partner, White & Case (*confirmed*) - Matthew Cowie, Partner, Dechert LLP *(confirmed)* Description: As the medtech industry expands globally and as engagements with third-party distributors and intermediaries increase, addressing anti-bribery and anti-corruption risks has become a top priority for compliance officers and general counsel. The Foreign Corrupt Practices Act, the U.K. Bribery Act, and many other laws around the world have a significant bearing on how compliance programs are shaped and how companies do business globally. This panel discussion is expected to feature government officials from the U.S. Department of Justice and the U.K. Serious Fraud Office, two key agencies charged with enforcing anti-bribery and anti-corruption laws around the world. Panelists will share their

		thoughts on the FCPA and UKBA, enforcement trends and ongoing developments, and anti-bribery and anti-corruption compliance in the medtech industry.
	13.30 - 14.45	**Parallel Session 2**: **Emerging Markets Risks When Onboarding Third Parties** *(Wicklow Hall 2A)* Speakers: - Ghadeer Al Yacoub, Regional Health Care Compliance Officer, Johnson & Johnson *(confirmed*) - Christian Cuneo, Regional Legal Counsel & Compliance Director, Stryker Australia Pty Ltd *(confirmed*) - Carlos Gouvea, Executive Director, Cậmara Brazileira de Diagnóstico Laboratorial *(confirmed*) - R. Jeff Layne, Partner, Norton Rose Fulbright LLP *(confirmed)* - Milana Chamberlain, Partner, Solicitor qualified in England & Wales, Norton Rose Fulbright LLP *(confirmed)* Moderator: Susan Murr, Non-Executive Director, The Red Flag Group Description: Distributors and third party intermediaries are often used by the industry in many countries to facilitate the distribution of their products. They bring local expertise and enable companies to market their products efficiently in countries where implantation may pose severe challenges. But this practice is not without compliance risks. This session will explore new due diligence requirements, the challenges in contracting with local suppliers, training of these intermediaries, etc., the focus being on emerging markets around the world.
	13.30 - 14.45	**Parallel Session 3: Hospital Access Requirements for Company Representatives: What you need to know** *(Wicklow Hall 2B)* Speakers: - Andrew Davies, Market Access Director, Association of British Healthcare Industries (ABHI) *(confirmed)* - Stephan Ekmekjian, Healthcare Compliance Officer, J&J Canada, and Chair of Code Committee MEDEC (Canada's Medical Technology Companies) *(confirmed)* - Rhett Suhre, Director, Health Care Credentialing, Abbott *(confirmed)*

DRAFT AGENDA

		Moderator: Bill Doherty, Vice President EMEA, Cook Medical Description: The issue of access management for representatives of Medtech companies to hospital premises, known as credentialing, has expanded out of the US and is now starting to appear in a number of countries. This round table will look at the principles of credentialing and the potential issues it raises for industry. We will hear about the situation in three countries and the lessons that can be learnt to prevent or minimise the issues with credentialing schemes. The merits of an industry led self-regulated approach will be discussed and the benefits of this approach for manufacturers, national associations and the health system.
	14.45 – 15.00	**Adjournment**