

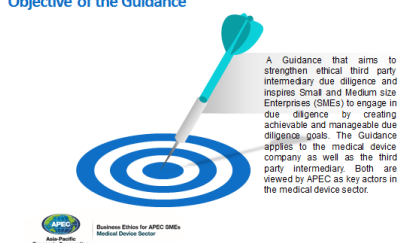
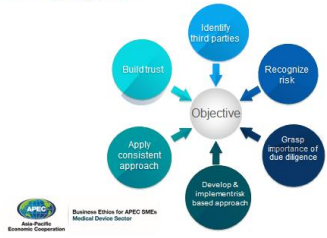


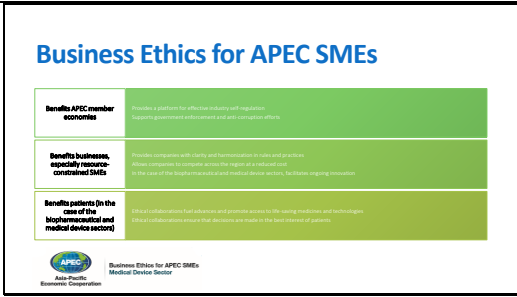


<p>Slide 1</p>	 <p>SME Webinar on APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector</p> <p>This webinar has been prepared for the Business Ethics for APEC SMEs Initiative as a contribution by: <b>IQVIA</b></p> <p><small>APEC Asia-Pacific Economic Cooperation</small> <small>Business Ethics for APEC SMEs Medical Device Sector</small></p>	<p>Welcome, everyone! Thank you for joining us for today's webinar for SMEs on the APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector. My name is Chrisoula Nikidis and I'm the Canadian Head of Compliance and Ethics Solutions at IQVIA. IQVIA is a multinational company serving the combined industries of health information technologies and clinical research. Our organization is proud to provide this webinar as a contribution to this initiative's important work.</p>
<p>Slide 2</p>	<p><b>Table of Contents</b></p> <ul style="list-style-type: none"> <li>• Webinar Objective</li> <li>• The Business Ethics for APEC SMEs Initiative and the APEC Kuala Lumpur Principles</li> <li>• Mitigating Challenges and Risks</li> <li>• Understanding the APEC Guidance for Ethical Third Party Intermediaries in the Medical Device Sector</li> <li>• Guidance Implementation</li> <li>• Questions and Answers</li> </ul> 	<p>I will be spending about 30 minutes with you today to walk you through the APEC Guidance for Ethical Third Party Intermediary and why it represents such an important milestone in the medical device sector. Most important, why your company should care about it.</p> <p>Before I begin I also want to make sure that people are comfortable to ask questions throughout the webinar. We will also allow time at the end of the presentation for questions and recommendations.</p>


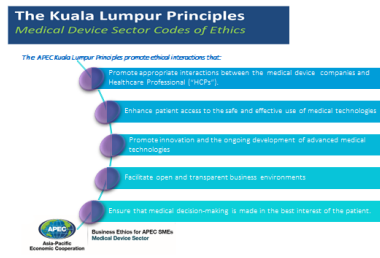
<p>Slide 3</p>	<p><b>Objective of the Guidance</b></p>  <p>A Guidance that aims to strengthen ethical third party intermediary due diligence and inspire Small and Medium size Enterprises (SMEs) to engage in due diligence by creating achievable and manageable due diligence goals. The Guidance applies to the medical device company as well as the third party intermediary. Both are viewed by APEC as key actors in the medical device sector.</p> <p><b>APEC</b> Asia-Pacific Economic Cooperation</p> <p><b>Business Ethics for APEC SMEs</b> Medical Device Sector</p>	<p>SMEs are often on the receiving end of burdensome due diligence procedures of large multi-national companies. These requirements can be overwhelming and often companies feel they do not have sufficient resources to meet them.</p> <p>SMEs must also develop robust anti-corruption ethics and compliance procedures to ensure they minimize the risk of corruption and adhere to international anti-corruption standards .</p> <p>Understandably, many SMEs are overwhelmed by the extensive international anti-corruption legislation and the complex ethics and compliance procedures in place in larger, multi-national companies. However, ethics and compliance does not necessarily need to be on a grand scale and supported by a dedicated legal department. There are manageable ways in which smaller companies can protect themselves by better managing corruption risks.</p> <p>A key element to a simple but effective ethics and compliance program is due diligence.</p> <p>This Guide aims to address these concerns and inspire Small and Medium size Enterprises (SMEs) to engage in due diligence by creating achievable and manageable due diligence goals</p>
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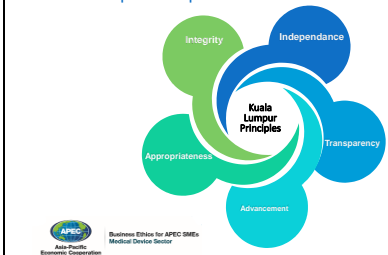
<p>Slide 4</p>	<p>Learning Objectives</p> 	<p>After completing this webinar participants should be able to</p> <p>Describe and identify third party intermediaries;</p> <ul style="list-style-type: none"> <li>• Recognize potential compliance risks;</li> <li>• Grasp the importance of due diligence</li> <li>• Identify problem areas and red flags</li> <li>• Develop and implement a risk based, integrated and consistent approach to anti-bribery management of third parties across the company's operations.</li> <li>• Apply a comprehensive consistent approach to conducting due diligence</li> <li>• Build trust and constructive relationships: Aim to develop an environment in which integrity can be fostered and bribery countered.</li> </ul>
<p>Slide 5</p>	 <p>APEC</p> <ul style="list-style-type: none"> <li>• APEC is the premier Asia-Pacific economic forum</li> <li>• Asia-Pacific Economic Cooperation (APEC) operates as a cooperative, multilateral economic and trade forum</li> <li>• Its primary goal is to support sustainable economic growth and prosperity in the Asia-Pacific region</li> </ul>	<p>Let's first start off by telling you a little about The Asia Pacific Economic Cooperation</p> <ul style="list-style-type: none"> <li>• APEC is the premier Asia-Pacific economic forum. operates as a cooperative, multilateral economic and trade forum which was established in 1989</li> <li>• Its primary goal is to support sustainable economic growth and prosperity in the Asia-Pacific region.</li> <li>• It is the only international intergovernmental grouping in the world committed to reducing barriers to trade and investment without requiring its 21 members to enter into legally binding obligations.</li> </ul> <p>APEC achieves its goals by promoting dialogue and arriving at decisions on a consensus basis, giving equal weight to the views of all members.</p>

<p>Slide 6</p>	<div data-bbox="394 207 581 485"> <p>Corruption impedes economic stability</p> </div> <div data-bbox="607 254 873 415">  </div>	<p>Many of the world’s fastest-growing economies have been designated as relatively “highly corrupt” by global transparency monitoring groups.</p> <p>APEC member economies recognize that corruption impedes economic sustainability and development, threatens social security and fairness, undermines the rule of law, and erodes government accountability, as well as public trust</p> <p>It is important that medical device companies take steps to mitigate bribery and corruption risk by building a strong internal control infrastructure and by taking measures to assert corporate ethical standards as their operations expand into new markets.</p> <p>Medical device companies should be sensitive to the possibility of continued and increased enforcement scrutiny given several key characteristics that tend to be unique to their business operations:</p> <p>A business model that involves the commercialization of a broad and often diverse product portfolio, including capital equipment and consumable and disposable products</p> <p>An increased demand in markets with quickly growing economies where product purchases are funded through nationalized healthcare</p> <p>A fragmented and unwieldy distribution network with numerous individual arrangements—often thousands of small, niche market distributors</p> <p>Distribution operations, customer composition and sales models that are fragmented and decentralized</p> <p>Government tenders with the distributor as the contracting entity, with limited to</p>
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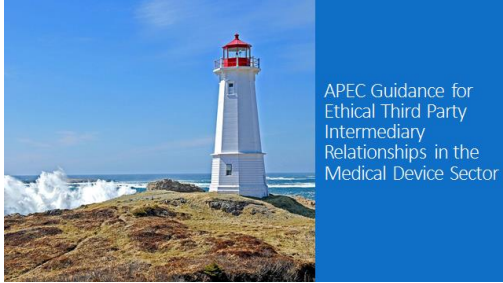
		<p>no involvement of the manufacturer in the governmental tender process</p> <p>Financial interactions with healthcare providers whose services are oftentimes reimbursed by government funds, thus designating them as 'government officials' for purposes of FCPA</p> <p>Commercial needs expanding in emerging, high-risk global markets faster than the corporate control infrastructure</p> <p>Routine cash business transactions in markets where purchases are not made on credit (e.g., Russia, Colombia)</p> <p>In order for medical device companies to mitigate the risks and address these vulnerabilities, a focused and coordinated effort can be developed and implemented to create a sustainable control environment within their global operations.</p>
Slide 7	 <p>The infographic titled 'Business Ethics for APEC SMEs' is divided into three horizontal green sections. The top section, 'Benefits APEC member economies', states it 'Provides a platform for effective industry self-regulation' and 'Supports government enforcement and anti-corruption efforts'. The middle section, 'Benefits businesses, especially resource-constrained SMEs', states it 'Provides companies with clarity and harmonization in rules and practices' and 'Allows companies to compete across the region at a reduced cost in the case of the biopharmaceutical and medical device sectors, by streamlining processes'. The bottom section, 'Benefits patients (in the case of the biopharmaceutical and medical device sectors)', states it 'Allows collaborations that enhance and promote access to the latest innovations and technologies' and 'Ensures collaboration across the industry and region in the best interest of patients'. At the bottom left is the APEC logo (Asia-Pacific Economic Cooperation) and at the bottom right is the text 'Business Ethics for APEC SMEs Medical Device Sector'.</p>	<p>To address this issue, in 2010 APEC SME Ministers called for the implementation of high standard codes of ethics in several priority sectors across the region.</p> <p>This call launched the Business Ethics for APEC SMEs Initiative, now the world's largest public-private partnership focused on advancing ethical business practices in the medical device, biopharmaceutical, and engineering/construction sectors.</p> <p>The initiative benefits resource-constrained SMEs by providing clarity and harmonization in industry practices, addressing unethical behavior through collective action, and promoting sustainable SME growth and cross-border trade.</p> <p>The initiative has focused on:</p> <ul style="list-style-type: none"> <li>the development of APEC</li> </ul>


		<p>principles for high standard codes of ethics in both the Medical Device and Biopharmaceutical Sector;</p> <ul style="list-style-type: none"><li>• capacity building to assist interested organizations in implementing codes consistent with APEC principles on a sectoral basis; and</li><li>• facilitating consensus based, multi-stakeholder ethical frameworks across health systems.</li></ul> <p>Since 2010, the Business Ethics for APEC SMEs Initiative has raised nearly \$5 million (USD) in APEC funds as well as financial and in-kind contributions from member governments and industry.</p> <p>This investment has enabled more than 1,250 individuals from nearly 1,000 organizations across all 21 APEC member economies (and beyond) to participate in 14 initiative programs to-date hosted by Japan, Malaysia, Mexico, Viet Nam, the United States, Brunei, Chinese Taipei, Indonesia, China, the Philippines, and Peru.</p> <p>Hundreds of additional organizations engage with the initiative remotely.</p>
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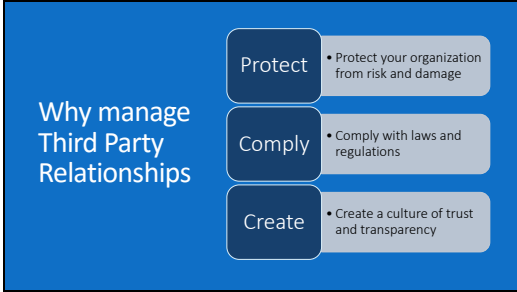
<p>Slide 8</p>	 <p><b>Business Ethics for APEC SMEs Initiative</b></p> <p>World's largest public-private partnership to strengthen ethical business practices</p> <ul style="list-style-type: none"> <li>More than doubled the number of medical technology and biopharmaceutical industry association codes of ethics</li> <li>Trained over 1,350 stakeholders and expanded high-standards to 18,000+ companies (13,000+ SMEs)</li> <li>Designed and implemented model consensus agreements to strengthen ethical business practices across health systems</li> </ul>	<p>From 2012 to 2016, the initiative more than doubled the number of medical technology and biopharmaceutical industry association codes of ethics – from 37 to 74 – across the APEC region, including within 10 economies where they previously did not exist.</p> <p>This has expanded high-standards to over 18,000 member companies (of which over 13,000 are SMEs)</p> <p>This speed of this achievement is understood when recognizing that the region's first 37 codes in these sectors took over three decades to develop.</p> <p>Work is underway in 2018 to begin scaling curriculum as well as to facilitate new model consensus frameworks that strengthen ethical practices across entire health systems, building on the first launch of such models in Canada and Peru in 2016, Vietnam in 2017 and Australia and Japan in 2018.</p>
<p>Slide 9</p>	 <p><b>The Kuala Lumpur Principles</b> Medical Device Sector Codes of Ethics</p> <p>The APEC Kuala Lumpur Principles promote ethical interactions that:</p> <ul style="list-style-type: none"> <li>Promote appropriate interactions between the medical device companies and Healthcare Professionals ("HCPs")</li> <li>Enhance patient access to the safe and effective use of medical technologies</li> <li>Promote innovation and the ongoing development of advanced medical technologies</li> <li>Facilitate open and transparent business environments</li> <li>Ensure that medical decision-making is made in the best interest of the patient</li> </ul> <p>APEC Business Ethics for APEC SMEs Asia-Pacific Economic Cooperation Medical Device Sector</p>	<p>The Kuala Lumpur Principles for the Medical Device Sectors were the first industry-specific initiative in APEC to lay out a series of voluntary, self-regulatory guidelines for organizations to assist in the creation and alignment of their own codes of ethics.</p> <p>The Kuala Lumpur Principles are based on the following premise:</p> <ul style="list-style-type: none"> <li>The Medical technology sector Codes of Business Ethics promote ethical interactions between medical device and diagnostics companies and Healthcare Professionals<sup>1</sup> ("HCPs").</li> <li>Ethical interactions enhance patient access to the safe and effective use of medical technologies by ensuring appropriate training of HCPs by</li> </ul>








		<p>Companies</p> <ul style="list-style-type: none"> <li>• Ethical interactions also promote innovation and the ongoing development of advanced medical technologies through legitimate and transparent collaboration between HCPs and Companies to identify, and bring to market new products</li> <li>• ethical interactions facilitate open and transparent business environments free from the high costs of corruption, enhancing the ability of Companies, especially small and medium size Companies, to participate in global markets</li> <li>• Ethical interactions ensure that medical decision-making is made in the best interest of the patient</li> </ul>
Slide 10	<p>The Kuala Lumpur Principles</p> 	<p>To ensure that relationships meet this standard, interactions between Companies and HCPs should be conducted in accordance with the following principles: Integrity, Independence, Appropriateness, Transparency and Advancement:</p> <ul style="list-style-type: none"> <li>• Integrity - this means dealing honestly, truthfully and fairly with all parties</li> <li>• Independence means that HCP interactions with companies should not skew the HCP's medical decision making from the best interests of the patient</li> <li>• Appropriateness means that all arrangements conform to proper commercial standards, and are accurate and free from corrupt purposes</li> <li>• Transparency means that companies and HCP's are open regarding significant financial relationships between the parties</li> <li>• Advancement means that</li> </ul>

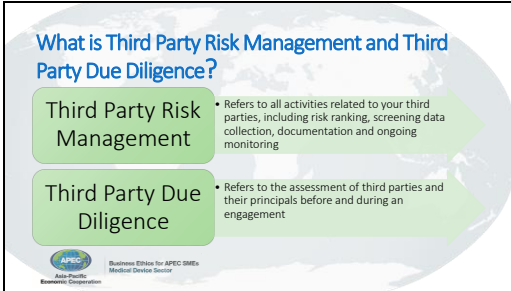


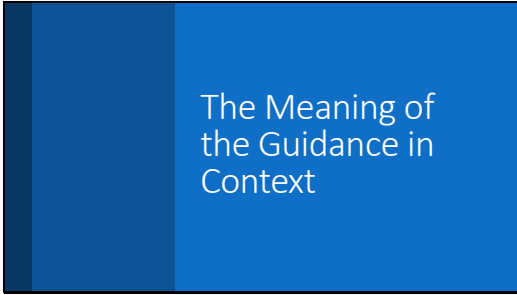
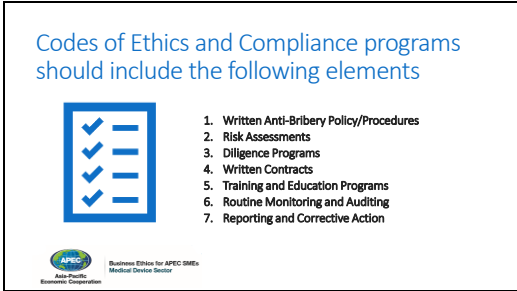
		relationships are intended to advance medical technology innovation and patient care.
Slide 11		<p>Now that I have provided you with the foundation for the Guidance I would like to take a few moments to introduce the topic of third party intermediary's and their importance in the Medical Device Sector.</p> <p>To ensure and improve ongoing access for patients and health care professionals ("HCPs") to innovative, reliable, and effective medical devices, it is often necessary for medical device researchers and manufacturers to contract with third parties to support their commercial activities.</p> <p>Medical devices are highly interactive and differentiated products often requiring sophisticated users and unique serve and distributor arrangements</p> <p>Many medical devices are distributed through multiple smaller specialty distributors with technology specific expertise</p> <p>Many small device companies depend on multiple overseas distributors to manage international sales.</p> <p>These third parties operate as distributors, wholesalers, distribution or sales agents, marketing agents or consultants, brokers, commission agents, and/or independent sales representatives ("Third Party SMIs").</p> <p>They serve an integral role in the medical device sector and health systems, connecting Company products and services to HCPs and other end-users. A</p>


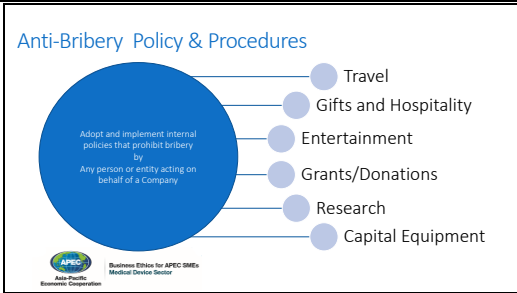
		<p>significant majority of Third Party SMIs in the medical device sector across APEC member economies are small and medium-sized enterprises.</p> <p>All companies find it inherently difficult to manage third parties given the cultural, language and local laws differences</p> <p>All companies are liable for these third parties --- all may raise FCPA and UK Bribery act risk.</p> <p>To support the Industry APEC developed a guidance that is intended to help all medical technology suppliers clarify responsible and ethical behaviour in high risk areas and to provide best practices decisions to mitigate the significant exposer and reputational risk associated to third party engagements.</p>
<p>Slide 12</p>	<p>APEC Guidance for Ethical Third Party Intermediary Relationships</p> 	<p>Leveraging third-party business partners can help companies</p> <ul style="list-style-type: none"> <li>• find innovative ways to bring products to market,</li> <li>• enter new geographies,</li> <li>• access specialized talent not available in-house,</li> <li>• reduce time to market, and</li> <li>• lower service delivery costs.</li> </ul> <p>To do all those things more effectively, many companies are working with third-party intermediaries (TPIs) for logistics, sales, distribution, marketing/research, licensing/permitting, human resources, and more.</p> <p>The development and implementation of APEC Guidance for Ethical Third Party Intermediary Relationships will</p> <ul style="list-style-type: none"> <li>• will help to ensure that third parties – including distributors, wholesalers, distribution or sales</li> </ul>

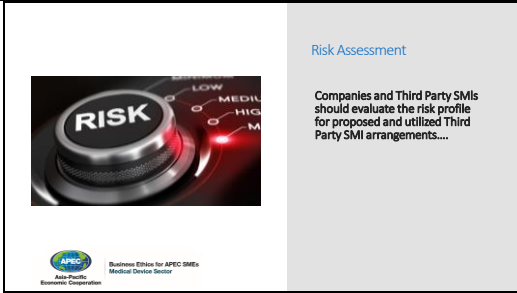

		<p>agents, marketing agents or consultants, and others who are critical to the medtech sector and health systems</p> <ul style="list-style-type: none"> <li>• can strengthen adherence to high-standard ethical business practices in accordance with the APEC Kuala Lumpur Principles for Medical Device Sector Codes of Business Ethics.</li> </ul> <p>We know that Joint work between medical device companies and third parties to develop ethical business practices will strengthen health systems and instill patient confidence that the best treatments are available when needed and delivered in their interest.</p>
Slide 13		<p>Third Party risk management is a top concern within compliance leadership. For many organizations the risk 3rd parties represent a challenge over which they feel like they have little control</p> <p>In an ever changing risk landscape, many organizations weigh the perceived the cost of screening and continuous monitoring all of their third parties against their ability to mitigate audits, investigations or penalties.</p> <p>The approach taken to managing third party risk can make a big difference in how well your organization can identify, manage and limit the liability a third party can represent</p> <p>So why do we try to manage Third Party Due Diligence</p> <p><b>Ethically &amp; morally – its the right thing to do</b></p> <ul style="list-style-type: none"> <li>• Third Party Due Diligence can</li> </ul>

		<p>help Mitigate reputational harm</p> <p><b>Third Party Due Diligence is also a legal requirement</b></p> <ul style="list-style-type: none"> <li>There is increased global regulatory enforcement activity . The risk of being penalized is higher than ever - more and more jurisdictions fining companies that bribe</li> </ul> <p><b>Helps Create a culture of trust and transparency with your third party intermediary</b></p> <ul style="list-style-type: none"> <li>Building trust and constructive relationships with third parties helps Foster positive relationships and shared goals to enable better understanding and identification of risks.</li> </ul>
<p>Slide 14</p>	<p><b>INCREASING EXPECTATIONS:</b> What the regulator is looking at ....</p> <p>While regulators may have different priorities and focus areas when it comes to anti-corruption compliance and third party management there are a number of commonalities.</p> <div data-bbox="391 1108 574 1205"> <p>Careful consideration and Sound decisions</p>  </div> <div data-bbox="581 1003 716 1136">  </div> <div data-bbox="732 1031 867 1136"> <p>Re-categorizing Risk over time</p>  </div> <div data-bbox="581 1157 727 1247"> <p>Process of continual monitoring</p>  </div> <div data-bbox="732 1157 873 1247"> <p>Consistently applied approach</p>  </div> <p> <small>Asia-Pacific Economic Cooperation</small>  <small>Business Edition for APEC SMEs</small></p>	<p>Compliance has become increasingly demanding</p> <p>While regulators may have different priorities and focus areas when it comes to anti-corruption compliance and third party management there are a number of commonalities</p> <p>Regulators generally like to see:</p> <ul style="list-style-type: none"> <li>Compliance frameworks that are carefully considered, based on sound decision making amid documented evidence</li> <li>A consistently applied approach</li> <li>A process of continual monitoring with structured regular reviews</li> <li>A process for re-categorising risk overtime</li> </ul> <p>Companies state that business success is being challenged by increasing regulation and slower than expected economic</p>



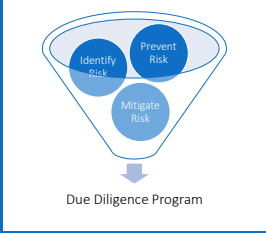
		<p>growth.</p> <p>Stronger local anti-corruption enforcement is a major challenge. These expanding regulatory demands are requiring companies operating internationally to look at increasing numbers of financial transactions and relationships in greater depth.... And they need to do so with limited compliance resources.</p>
Slide 15		<p>Understanding who you conduct business with has become more than just good business practice; it is increasingly becoming a smart compliance imperative.</p> <p>Multinational organizations are rapidly adjusting to enforcement standards according to which companies are responsible for the actions of their business partners and vendors, and need to conduct effective third-party due diligence on them. Be it the Foreign Corrupt Practices Act (FCPA) in the US, the UK Bribery Act or the recently enacted anti-corruption regulations in India, Brazil, Russia, China and Mexico, governments are taking clear steps against the practice of making improper payment through third parties.</p> <p>So what is the Due diligence and Third Party Risk management ?</p> <p><b>Third party risk management</b> refers to all activities related to your third parties, including risk ranking, screening, Data collection, documentation and ongoing monitoring</p> <p>It can also include conducting a business culture and ethics review of third party via questionnaires and interviews as well</p>


		<p>as analysis of critical databases and reputational reporting of searching for red flags</p> <p><b>The Term Third Party Due Diligence</b> Refers to the assessment of third parties and their principals before and during an engagement.</p> <p>The key to the effective use of a 3rd party in any capacity is for the organization to appropriately assess, measure, monitor and control the risks associated with the relationship.</p>
Slide 16		<p>Where the company has effective control over a third party, it should implement its compliance program with respect to that third party; and where it lacks “effective control,” it should undertake well-documented risk-based due diligence prior to entering into a relationship with the third party, and encourage the third party to implement an equivalent compliance program.</p> <p>In addition to an overall compliance program as recommended in the APEC Kuala Lumpur Principles, these following 7 elements should form part of the overall compliance program</p>
Slide 17	<p>Codes of Ethics and Compliance programs should include the following elements</p> 	<p>Taking into account a variety of risk-based factors, as well as international and local laws, such codes of ethics and compliance programs should include the following elements:</p> <ul style="list-style-type: none"> <li>• Written Anti-Bribery Policy/Procedure</li> <li>• Risk Assessment</li> <li>• Diligence Program</li> <li>• Written Contract</li> <li>• Training and Education</li> <li>• Monitor and Audit</li> <li>• Reporting and Corrective Action</li> </ul>

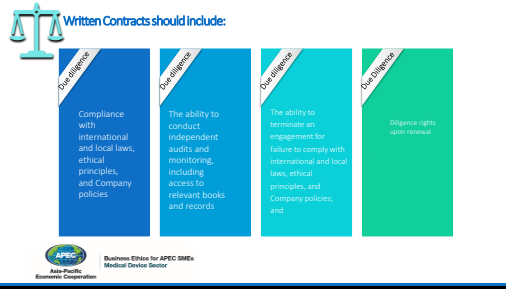

		and improvements
Slide 18		<p>An organization should have an established set of compliance standards and procedures.</p> <p>These standards should not be a “paper only” document, but a living document that promotes organizational culture that encourages “ethical conduct” and a commitment to compliance with applicable regulations and laws.</p> <p>SMEs should establish a clearly articulated and visible policy that prohibits bribery in any form, carried out either directly or through third parties.</p> <p>The policy should provide guidance on the meaning and scope of the prohibition against bribery, particularly with respect to “high risk” aspects of the company’s business operations.</p>
Slide 19		<p>SMEs should adopt and implement internal policies that prohibit bribery By Any person or entity acting on behalf of a Company</p> <p>Develop and implement detailed policies for particular risk areas</p> <p>These policies and procedures must address the most high-risk and prevalent forms of bribery such as</p> <ul style="list-style-type: none"> <li>• Travel,</li> <li>• gifts and hospitality,</li> <li>• entertainment,</li> <li>• grants and donations</li> <li>• research and</li> <li>• capital equipment</li> </ul> <p>Its important to ensure that all gifts, entertainment, and hospitality are reasonable, and that bona fide business expenses cannot be perceived as</p>

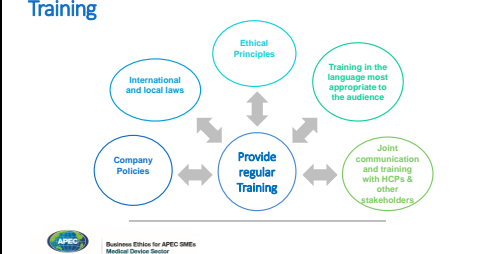
		<p>intending to improperly influence the outcome of business transactions; and ensure that management is involved in the approval process and that the process is well-documented. ·</p> <p>Ensuring that charitable or political contributions and sponsorships are transparent and not used as a subterfuge for bribery is also essential</p>
Slide 20		<p>Companies and Third Party SMIs should evaluate the risk profile for proposed and utilized Third Party SMI arrangements</p>
Slide 21	<p>Companies should assess the local risks through:</p> <ul style="list-style-type: none"> <li>Published corruption indices as well as specific risk profiles</li> <li>International and local legal requirements</li> <li>Information from Third Party SMIs for potentially unusual arrangements</li> <li>Information available from public sources or employees</li> </ul> 	<p>Companies should assess local risks through</p> <ul style="list-style-type: none"> <li>published corruption indices as well as specific risk profiles of planned or utilized Third Party SMIs</li> <li>International and local legal requirements</li> <li>Information from Third Party SMIs for potentially unusual arrangements, such as unusually high commissions, high degree of interaction with government officials, marketing budgets, health care provider corporate affiliation or ownership, and/or off-shore payment account</li> </ul>






		<ul style="list-style-type: none"> <li>Information available from public sources or employees for potential issues associated with a Third Party SMI.</li> </ul>
Slide 22		<p>THIRD Party SMIs should</p> <ul style="list-style-type: none"> <li>Support companies' risk assessments prior to and throughout engagement of activities conducted on the Company's behalf</li> <li>Assess and communicate international and local legal requirements</li> <li>Disclose potentially unusual arrangements and</li> <li>Maintain accurate records for review</li> </ul>
Slide 23		<p>Once an organization has decided which third parties are in scope for due diligence and what level of risk the third party business relationships poses, the main process of due diligence begins.</p>
Slide 24	<p>Companies and Third Party SMIs should establish</p> 	<p>Companies <b>AND</b> Third party SMIs should establish a risk-based pre-engagement and renewal due diligence programs to <b>identify, prevent and mitigate risks</b> relating to the market in which the third party SMI is engaged to operate as well as any specific activities the Third party SMI deploys on behalf of the Company</p> <p>Disciplined diligence is the only way for a company to demonstrate that it does not have the requisite mental state to be liable for any improper conduct that may</p>



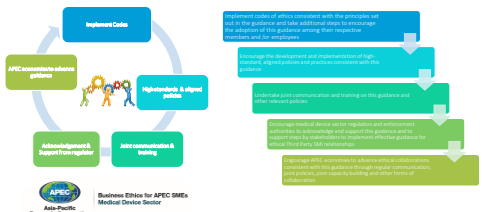
		<p>occur in the future</p> <p>The level of scrutiny necessary for an organization to reach reasonable confidence that it is engaged in normal legitimate business transaction varies with corruption risk.</p> <p>The level of corruption risk determines how much scrutiny is required to be able to defend before a judge or a prosecutor that the organization is confident it is dealing with a bona fide third party.</p> <p>The higher the risk... the broader and deeper the third party due diligence should be.</p>
Slide 25		<p>Another component of a due diligence program are written contracts</p>






<p>Slide 26</p>		<p>Companies and Third Party SMLs should reach contract terms with each other that include controls and implementation of anti-corruption policies, such as:</p> <p>Compliance with international and local laws, ethical principles, and Company policies;</p> <p>The ability to conduct independent audits and monitoring, including access to relevant books and records;</p> <p>The ability to terminate an engagement for failure to comply with international and local laws, ethical principles, and Company policies; and</p> <p>Diligence rights upon renewal.</p>
<p>Slide 27</p>		<p>Also essential to a complete due diligence program is communication and training.</p>

<p>Slide 28</p>	<p><b>Training</b></p> 	<p>Third Party SMIs are encouraged to engage with local industry associations to advance compliance and training on local code of ethics principles.</p> <p>Companies and SMIs should undertake initial and provide regular training and education for relevant Company and Third Party SMI personnel on:</p> <ul style="list-style-type: none"> <li>• International and local laws</li> <li>• Ethical principles</li> <li>• Company Policies</li> <li>• Training should be conducted in the language most appropriate to the audience.</li> <li>• And SMIs should consider : Joint communication and training with Healthcare Professionals and other stakeholders on APEC Third Party SMI ethics guidance and relevant Company and Industry Association ethics policies</li> </ul> <p>Third party due diligence Training could :</p> <ul style="list-style-type: none"> <li>• Include effective means to communicate facts relating to the company's anti-bribery program and ensure periodic internal and external communication about updates and changes to the program.</li> <li>• Provide documented anti-corruption training to all directors, executives, managers, employees and agents tailored to their duties and responsibilities, and, as appropriate, to contractors, suppliers, and employees of joint venture partners and subsidiaries.</li> </ul> <p>Examples of best practices include:</p> <ul style="list-style-type: none"> <li>• conducting targeted in-</li> </ul>
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		<p>person training of key personnel (e.g., senior site managers and regional controllers) utilizing a “train the trainers” methodology;</p> <ul style="list-style-type: none"> <li>• incorporating real-life scenarios and hypotheticals into the training, as well as quizzes; and conducting the training in the local language of the trainees.</li> <li>• Through such methods as emails, intranet postings and company newsletters create global awareness of company’s whistleblower policy, including the availability of the hotline, Communicate to all personnel that they have a duty to report suspected violations and provide a list of designated contacts to whom they can report a concern.</li> </ul>
Slide 29	 <p>Monitor and Audit</p>	<p>Periodic reviews and evaluations of the anti-corruption program and the updating of risk assessment periodically to meet changing circumstances is essential to a due diligence program.</p>

<p>Slide 30</p>	<p><b>Periodic reviews and evaluations of the anti-corruption program</b></p>  <p>APEC Asia-Pacific Economic Cooperation</p> <p>Business Ethics for APEC SMEs Regional Director General</p>	<p>Company and Third Party SMIs should undertake</p> <ul style="list-style-type: none"> <li>• risk-based,</li> <li>• routine monitoring and auditing and</li> <li>• other assessments of their relationship</li> </ul> <p>for compliance with international and local laws, ethical principles and Company policies as well as relevant contract terms;</p> <p>Companies and Third Party SMIs should also assess</p> <ul style="list-style-type: none"> <li>• certification of Company and third Party SMI personnel on compliance with/on international and local laws, ethical principles, and Company policies</li> </ul> <p>Senior management should implement a systemic approach to monitoring the program, including for effectiveness in preventing, detecting, investigating, and responding to allegations of misconduct, and report its findings to the board of Directors</p> <p>An example of best practices includes, as a component of a company's monitoring program, a self-assessment by senior management of the level of compliance with the company's anti-corruption compliance program.</p>
<p>Slide 31</p>	 <p>Corrective Action</p> <p>APEC Asia-Pacific Economic Cooperation</p> <p>Business Ethics for APEC SMEs Regional Director General</p>	<p>An organization should make clear to managers and employees that any abuse or disregard of the third party due diligence process may lead to disciplinary sanctions</p>

<p>Slide 32</p>	<p>Appropriate Corrective Action</p> <p>Corrective measures should be taken if either a Company or Third Party SMI representative fails to comply with:</p> <ul style="list-style-type: none"> <li>• international or local laws</li> <li>• ethical principles</li> <li>• company policies</li> <li>• relevant contract terms or</li> <li>• engages in other impermissible or unethical conduct</li> </ul>  <p>Business Ethics for APFEC SMEs Medical Device Sector</p>	<p>Corrective measures should be taken by the relevant party consistent with applicable international or local laws if either a Company or Third Party SMI representative fails to comply with:</p> <ul style="list-style-type: none"> <li>• international or local laws,</li> <li>• ethical principles,</li> <li>• company policies</li> <li>• relevant contract terms or</li> <li>• engages in other impermissible or unethical conduct</li> </ul>
<p>Slide 33</p>	 <p>IMPLEMENTATION</p>	<p>This Due Diligence Guidance provides practical support to enterprises on the implementation of the Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector</p>
<p>Slide 34</p>	<p>Actions for Implementation</p>  <p>APFEC Logo</p> <p>Business Ethics for APFEC SMEs Medical Device Sector</p> <p>Privileged &amp; Confidential</p>	<p>The Guidance calls for the following actions:</p> <ul style="list-style-type: none"> <li>• Implementation of codes of ethics consistent with the principles set out in the guidance and take additional steps to encourage the adoption of this guidance among their respective members and /or employees</li> <li>• Encourage the development and implementation of high-standard, aligned policies and practices consistent with this guidance</li> <li>• Undertake joint communication and training on this guidance and other relevant policies</li> <li>• Encourage medical device sector regulators and enforcement authorities to acknowledge and support this guidance and to</li> </ul>

		<p>support steps by stakeholders to implement effective guidance for ethical Third Party SMI relationships</p> <ul style="list-style-type: none"> <li>• Encourage APEC economies to advance ethical collaborations consistent with this guidance through regular communication, joint policies, joint capacity building and other forms of collaboration</li> </ul>
Slide 35	<p>"If you think compliance is expensive, try non-compliance" - Former U.S. Deputy Attorney General Paul McNulty</p> <p>A very simple conclusion ....</p>  <small>APEC Asia-Pacific Economic Cooperation</small>  <small>Business Edition for APEC SMEs Small Business Starter</small>	<p><b>"If you think compliance is expensive, try non - compliance"</b></p> <p><b>Former U.S. Deputy Attorney General Paul McNulty.</b></p>
Slide 36	<p>Questions?</p>   <small>APEC Asia-Pacific Economic Cooperation</small>  <small>Business Edition for APEC SMEs Small Business Starter</small>	