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Preconference III
Global Compliance Update

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Agenda

8:00 am: Organizing and Operating a Global Compliance Program
Resources, Reporting, Scope, International Codes and Local Standards

8:45 am: Key Issues in Global Compliance -
Relationships with Physicians/Customers, CME, Donations, Post-Market, Third-Party Arrangements

9:30 am: Rolling Out Policies, Training and Compliance Guidance in the Global Setting

10:15 am: Break

10:45 am: Incorporating FCPA Compliance into Program Operations

11:30 am: Comments, Questions and Answers

12:00 pm: Adjournment

Disclaimer

- All views expressed are the personal opinions and perspectives of the speakers and do not reflect the views or policies of any company

Overview

- Organizational Issues
- Scope of Compliance Efforts
  - Legal Standards
  - Operations
  - Responsibilities
- Structure and Resources
- Pivotal Issues
  - Foundational Elements
  - Substantive Areas
- Understanding the Landscape & Selling Compliance
- Implementation
- Observing Trends in Enforcement
- Sample Tools

Organizational Issues

- Endorsement and Ownership by Top Executives and Executive Committees
- Scope
  - Legal standards
  - Operations
- Responsibilities
- Structure and Resources

Scope: Legal Standards

- Regulation of products
- Fraud and corruption
- Antitrust and competition
- Data privacy
- Environmental
- Other

Scope: Operations

- Research and development
- Manufacturing and distribution
- Sales and marketing
- Finance/accounting
- Human resources and “people”
- Corporate security
- Physical assets

Scope: Responsibilities

- Policies, standard operating procedures (SOPs)
- Education and training
- Communications and “ethics” hotlines
- Auditing and corrective action plans
- Investigations
- Reporting to management
- Implementation of business actions on compliance issues
- Design, implementation and testing
- Coordination and feedback

Structure and Resources

- Reporting (senior executive vs. stand-alone)
- Compliance team
  - Geographical vs. business focus
    - EMEA, ASIA/PACIFIC, CANADA/LATIN AMERICA
    - PHARMACEUTICALS, MEDICAL DEVICES, CONSUMER
  - Budget and headcount
  - Support liaisons and partnerships
    - Internal audit and corporate security
    - Outside experts and easily deployable resources
    - Compliance counsel
- Resources and priorities outside the compliance function
- Organizational complexities, e.g., matrix, functional versus geographical, versus activity based
- Functional silos

Organizing and Operating a Global Compliance Program

- Remit of, and interaction with, other assurance functions:
  - Legal
  - Internal audit
  - GXP
  - Security
- Differences in legal practice, legal privilege and duties of lawyers

Broad Issues: Foundational Elements

- Surveying existing standards and seeking legal advice
  - Laws
    - United States
      - Food and Drug Administration (FDA)
      - Foreign Corrupt Practices Act (FCPA) & "red flags"
      - Other
    - Outside United States: Regional level (e.g., EU) and country-specific
      - Medicines regulatory agencies
      - Anti-corruption
      - Anti-unfair competition
      - Privacy
      - Other (e.g., tax)

Broad Issues: Foundational Elements

- Surveying existing standards and seeking legal advice
  - Local Codes
    - Regional (e.g., EFPIA) – Mandatory/Guidance
    - Country-specific – Mandatory/Guidance

Broad Issues: Foundational Elements

- Facilitating employee communications and reporting
  - Hotline services in applicable languages
  - Using Sarbanes-Oxley channels
  - Understanding attitudes towards reporting and management hierarchy
  - Ensuring consistency in how the company approaches similar topics and practices across geographies and business units

Substantive Issues

- Gaining an understanding:
  - Gift and hospitality practices
    - Switzerland's 300 SFR limit
    - China's gold-plated white lotus moon cakes
  - Corporate giving and charitable contributions
    - Japan's "*shogaku*" and "*tokubetsu*" *kifuki*
    - Charitable donations
      - recipients
      - sponsors
  - Sponsorship (stand-alone education) and "CME"
  - Congresses and satellite symposia
  - Government partnerships

Substantive Issues

- Gaining an understanding:
  - Equipment grants to under-funded hospitals
  - Outcome and observational studies, and non-registrational trials
  - Pricing negotiations
  - Tender process
  - Payment to physicians for fee-for-service activities
    - Made by sales representatives
    - In cash
  - Role of sales and marketing in education, clinical trials, grants/donations, etc.

Substantive Issues

- Gaining an understanding:
  - "Government official"
    - Central and provincial governments
    - Hospital management and employees/staff
    - DOJ/SEC's views based on FCPA vs. country standards
  - Promotional expenditures (e.g., "books and records")
  - Government "visits" and "doing business" in the country
  - Physician-owned businesses and physician-led foundations
  - Agents and Distributors
    - Activities in discharge of obligations
  - Occupational fraud

Understanding the Landscape

- Conducting assessments
  - Legal obligations profile
  - Current state assessment
    - Identify existing processes (including practices)
    - Identify controls in place
    - Identify gaps and opportunities for improvements
  - Getting a sense for local “culture” and issues
  - The experience of the “assessment” – Mutual benefits

"Selling Compliance"

- Support of Leadership
  - Obtaining buy-in from business leaders (e.g., regional executives, country managers)
    - Message from the top (headquarters)
    - Instilling importance despite absence of an environment comparable to the US's
    - Respect for autonomy and country "differences"
  - Finding strong leaders
  - Producing regional or country-specific gap analyses
  - Involving local management in analyzing the strategic value vs. control relationship

Endorsement and ownership by top executives and executive committees

- Global Compliance Officer
- Clear authority, strong remit and personal standing
- Support from Board and audit committee
- Regular updates to and buy-in from audit committee

Selling compliance

- Risk-based approach
- Where to set the bar
- Value-added bureaucracy
- Need to seek consistency and simplicity across functions and geographies
- Strong leadership
- Respect for autonomy and country “differences”

Selling compliance

- Behaviours versus rules
- Corporate responsibility and reputation management
- Protecting licence to operate
- Compliance processes as improvements to good business controls and to assist with assurance
- Corporate benefit

Selling Compliance

- Exporting best practices and lessons based on US experience – sensitively, prudently
- Instilling importance and relevance despite absence of an environment comparable to the US's
- What are the equivalent anti-bribery/anti-corruption laws?
  - The US Foreign Corrupt Practices Act
  - UK and Swedish Anti-Bribery Laws
  - Equivalent laws in all Organization for Economic Co-operation and Development countries
  - Industry Codes, e.g. WHO Criteria, IFPMA Code, EFPIA Code, ABPI Code

Implementation

- Rolling Out a Global Compliance Initiative
  - Organizing the effort
    - Identify key players/influencers
    - Provide guidance or mandates (written charters)
    - Develop a roll out plan and timeline
  - Areas to cover
    - Policies and SOPs
    - Training
    - Communication and reporting
    - Auditing schedule
    - Investigative protocol

Implementation

- Rolling Out an Global Compliance Initiative
  - Other strategies
    - Sharing best practices
      - Exporting (prudently) best practices and lessons based on US experience
      - Compliance councils
      - Shared databases
      - Raising awareness
    - Self-assessments based on common baseline standards

Requiring third parties to meet certain standards

- What exactly are those standards?
- How do we satisfy ourselves that they are met?
- Due diligence
- Contractual reps and warranties
- Practical and relationship issues
- Ongoing monitoring of 3rd parties
- Other

Observing Trends in Enforcement

- Other Developments
  - Revised Code of Conduct of *European Federation of Pharmaceutical Industries and Associations (EFPIA)*
  - *Eucomed* code (resembling *AdvaMed* Code)
  - British Parliament's Select Health Committee's inquiry
  - Adjudications by *Association of British Pharmaceutical Industry's Prescription Medicine Code of Practice Authority (PMCPA)*
  - Italy's *Farmindustria* Code and audits
  - France's *Conseil de l'Ordre des Médecins*
  - Enhanced powers for the European Medicines Agency
  - Creation of the European Healthcare Fraud and Corruption Office (10/05)
- Other Sources
  - Transparency International and OECD
  - US State Department's *"Investment Climate Statement"*
  - SEC/DOJ websites
  - Competitor complaints

Defining bribery / corruption

- The company, its employees and those who act on its behalf must not offer or pay bribes.
- The company must not offer or give money or anything else of value either as an improper inducement to make, or as an improper reward for making, any decision favorable to the interests of the company.
- This includes providing improper benefits of any kind to government officials and other healthcare professionals and organizations, patients or suppliers, charities and patient groups, companies or individuals.

Persons and Entities within Scope

- Government Officials
- Healthcare Professionals
- Healthcare Organizations
- Persons affiliated with Healthcare Organizations
- Anyone

Healthcare Professionals and Organizations

- Any persons who or which may prescribe, administer, recommend, purchase, pay for, reimburse, authorize, approve or supply a medicine or medical device.
- Includes:
  - any members of the medical, dental, pharmacy or nursing professions, or relevant associated administrative staff; and/or
  - hospitals and other care organizations, health insurers (including managed care organizations), pharmacies, and formulary or benefit administrators, and relevant staff at such entities.

Generally accepted expenditures

- Modest and customary meals, gifts and activities are acceptable, provided they comply with any local laws and applicable codes and policies and not intended to influence
- Facilitating payments
- Fair market value payments for legitimate services required
- BUT: If only one purpose is improper, bribery is implicated

Core activities that can implicate anti-bribery laws

- Engaging the services of HCPs
- Post-marketing studies and other clinical studies
- Sponsoring HCPs to attend meetings and events
- Gifts and entertainment
- Visits to Company facilities and other travel
- Charitable and community support contributions
- Sponsorship and grants
- Political contributions
- Facilitating payments
- Actions by agents, consultants, joint-venture partners, distributors and other third party representatives

Core Activities: Detailed Analysis

- For each core activity engage in a through review of policy and internal controls
- Review the process by which each activity is reviewed/approved
- Develop a mechanism to determine that each activity reviewed meets internal standards
- Review mechanism for controls and decision-making
- Review recordkeeping and ongoing review practices for each activity

FCPA Due Diligence

- Potential gaps in companies' existing protections around relationships with third parties, incl. HCPs, suppliers and distributors
- Effective due diligence processes in place, appropriate to the size and scope of the risk, to assess potential contracting partners
- Should be an integral part of ongoing supplier management efforts across the organization

What might due diligence look like?

- Identify and categorize third parties/vendor types
- Develop criteria to evaluate risk by vendor type and assign to tiers
- Develop due diligence procedures related to tiers of risk
- Assess as-is processes and procedures to determine gaps between existing and proposed due diligence requirements
- Develop a triage process to review results of due diligence
- Develop system to maintain due diligence results
- Develop monitoring protocols for compliance with enhanced due diligence processes (e.g. vendor spend analyses)

- CASE STUDY

Medical Education – Cross Border Sponsorship

- Medical Education Event Organized by a Healthcare Organization – In Spain
- Healthcare Professionals in attendance from following countries
  - » Spain
  - » UK
  - » France
  - » Czech Republic
  - » Bulgaria
  - » Romania
- Healthcare Professional from U.S hired to speak at event

QUESTION 1:

- What hurdles must we consider when planning this event?
- 1. Corporate Regulations
- 2. Local Laws
- 3. IFPMA Code
- 4. All of the Above

QUESTION 2

- What corporate or company requirements may we need to consider when planning this event?
  1. Company Policies addressing Sponsoring HCP's
  2. Corporate Code of Conduct
  3. Both 1 & 2 are correct

- What other company requirements may we need to consider?

QUESTION 3

- What U.S. laws or requirements may we need to consider for this event?
- 1. Pharma Code
- 2. Foreign Corrupt Practices Act (FCPA)
- 3. EFPIA Code
- 4. Both 1 and 2 are correct

QUESTION 4

- What LOCAL (Country Specific) laws and requirements may we need to consider when planning this event?
  1. Spain's Code of Ethics - Farmaindustria
  2. UK's Code of Ethics - ABPI
  3. Both 1 and 2 are correct
- What other local requirements may we need to consider?

QUESTION 5

- What is the correct amount of money to compensate the US HCP that will be speaking at the event?
- 1. Your Daily Salary
- 2. EUR 1,000
- 3. Fair Market Value

QUESTION 6

- How do you calculate Fair Market Value?
- 1. Many factors must be considered:
  - » Must be reasonable
  - » Based on current market price within geographic region
  - » Consider professional qualifications of consultant or speaker
  - » Based on the amount of work / preparation required
- 2. Amount is based on your relationship with the HCP
- 3. Amount is always $1,000.00

What We Need To Consider

Company Standards	Local Standards	US Standards
•Code of Conduct •Application of IFPMA Code •*AntiTrust*	•EFPIA •Local Codes: • Spain – FarmaIndustria • UK – ABPI • France – LEEM • Czech Republic – MAFS • Bulgaria – ARPharM • Romania – ARPIM •*Local Laws*	•*FCPA* •*Fraud & Abuse* •Pharma Code

Components of Affiliate Compliance Program

- Code & Policies
- Communication & Training
- Corrective Action Process
- **Affiliate Compliance Committee**
- Process for Reporting Concerns
- Auditing & Monitoring
- System to Respond To Allegations

Sample Tools

Pharmaceutical and Medical Device Codes

Country		Pharmaceutical Association	Association Code	Med Device Association	Association Code
China		R&D-based Pharmaceutical Association in China - RDPAC	Code of Pharmaceutical Marketing Practices (.pdf)	Not available	Not available
Hong Kong		The Hong Kong Association of the Pharmaceutical Industry - HKAPI	Not available	Hong Kong Medical and Healthcare Device Manufacturers Association	Not available
Japan		Japan Pharmaceutical Manufacturers Association - JPMA	JPMA Promotion Code for Prescription Drugs (.pdf)	Japan Fair Trade Council of the Medical Devices Industry	Fair Competition Code Concerning Restriction on Premium Offers in the Medical Devices Industry (.pdf)
Korea		Korean Pharmaceutical Manufacturers Association - KPMA	Not available	Not available	Not available
Taiwan		Taiwan - International Research-Based Pharmaceutical Manufacturers Association - IRPMA	IRPMA Code of Marketing Practices (.pdf)	Not available	Not available

Sample Tools: Analysis

Interactions with Health Care Professionals and Institutional Customers

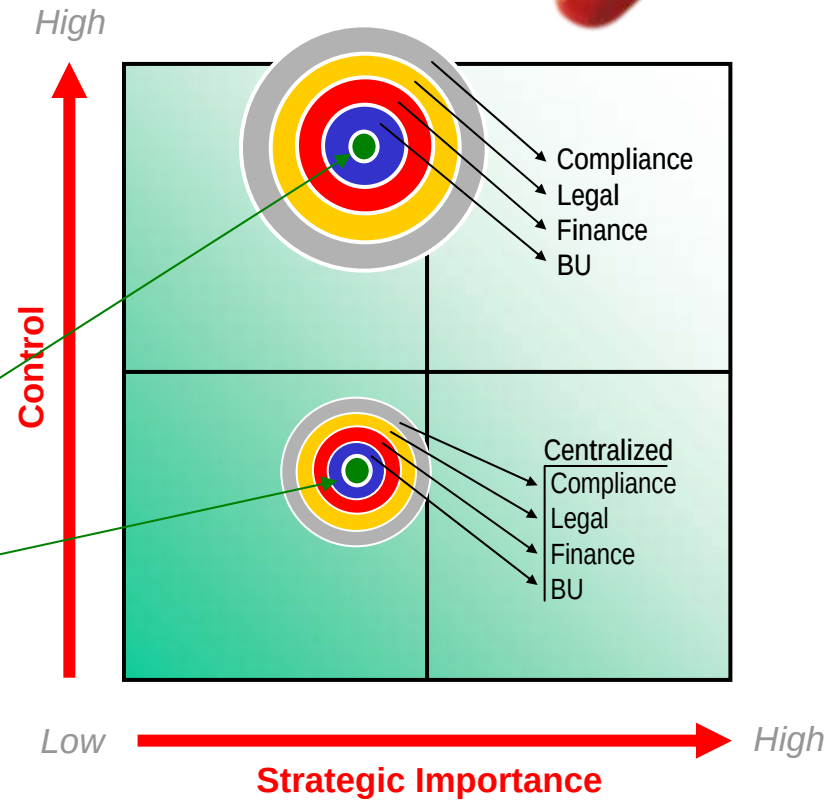
- **Fee-for-Service (FFS) Arrangements**
  - Speakers/Writers
  - Consultants/Advisory Boards
  - Non-Interventional Studies ("Observational Studies")
  - Retrospective Data Purchases
  - Outcomes Research Vendor

- **Use of Company Funds (Non-FFS Disbursements)**
  - Gifts
  - Hospitality
  - Congresses and Symposia
  - Investigator Meetings
  - Medical Education

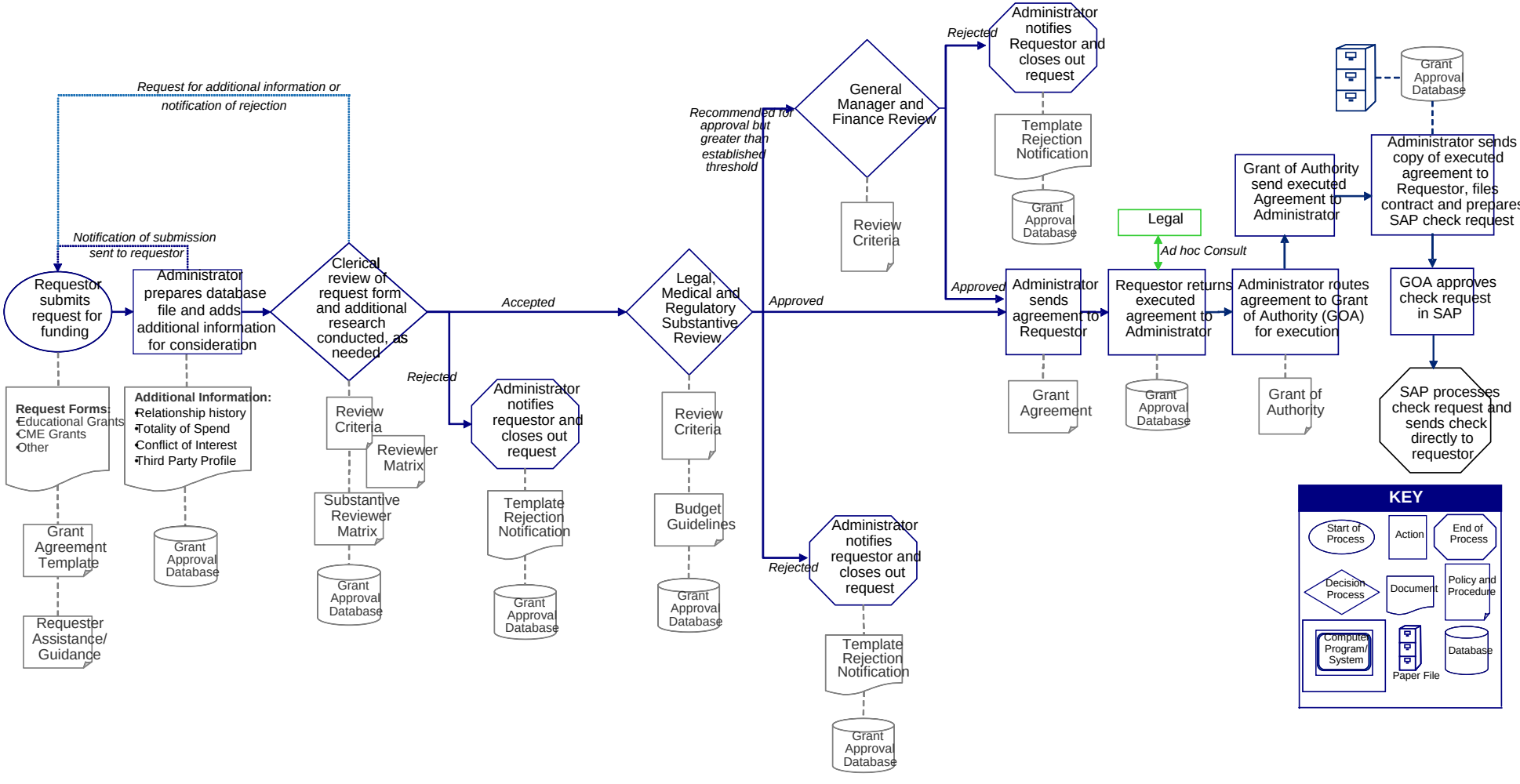
– Managed/approved by sales representative

  - **Donations**
  - Grants/Sponsorship
  - Medical Practice "Support" (*e.g.,* Books)
  - Samples
  - Investigator Sponsored Trials
  - Market Research

– Managed/approved by a committee



Sample Process Map: Educational Grants



Sample Approach to Written Standards

- **Activity**
  - Speakers

Determined by HDQ

- **Minimum Standards**
  - Needs Assessment and Project Approval
  - Required Speaker Qualifications
  - Selection Criteria
  - Qualification of Selecting Individuals
  - Written Agreement
  - Compensation
  - Training of Speaker
  - Proof of Service Delivery, Evaluation and Payment
    - Monitor Frequency
    - Measure Totality of Compensation
    - Benchmark Countries

- **Country-Specific Standards**
  - Approval of Hospital Administration
  - Local Code Requirements

- **Country-Specific Processes**
  - SOP *(HDQ + Country Standards)*

Determined by Country using Template *(approved by HDQ)*

Protocol developed by HDQ

- **Audit Processes**

Minimum Standards + Country Standards = Report & Self-Assessment

Summary Checklist

- ☑ Global compliance officer as a member of senior management reporting to CEO/President
- ☑ Responsibility for legal/regulatory compliance in the business:
  - Research and development
  - Manufacturing and distribution
  - Marketing and sales
  - Post-market activities and pharmacovigilance
- ☑ Direct a group of executives respectively in charge of:
  - Policy development and guidance
  - Education, training and communication
  - Audit and investigations
  - Regional compliance (e.g., US, Asia/Pacific, Europe/Middle East/Africa)
  - Operations compliance (e.g., sales and marketing, manufacturing, environmental)
- ☑ Form partnerships with other key company functions for support (i.e., legal, internal audit, corporate security) and with outside experts
- ☑ Direct strategies to ensure uniformity
  - Common standards/principles where appropriate (i.e., policies/SOPs)
  - Holds regions/countries accountable for implementation and self-assessments
- ☑ Allocate sufficient resources (headcount, budget) to direct and manage activities

Summary Checklist

- ☑ Develop a uniform framework (baseline) for compliance activities that apply to all countries (i.e., development of policies, training, audits, compliance resources and personnel)
- ☑ Develop a "roll out" plan and timeline for implementation of compliance framework

  Address multiplicity of laws and standards – aim at the highest degree of harmonization
  - Assess applicable legal standards and industry codes in countries of operation
  - Seek legal opinions and clarity on applicable standards
  - Develop policy statements informed by local country variations
- ☑ Instill accountability in the business by placing upon it responsibility for development of compliance processes (i.e., development of policies, approvals, audit standards)
- ☑ Name deputy compliance officers with real authority – place ultimate responsibility on president or country management
- ☑ Perform independent third-party assessments of current state of processes and controls in high-risk areas
- ☑ Require business units/countries to perform self-assessments against headquarter minimum standards
- ☑ Audit business units/countries (using knowledgeable internal audit resources and/or outside partners)
  - Compliance with baseline requirements
  - Specific focus areas (e.g., fee-for-service arrangements, grants/donations, sponsorship of congresses, consultants, post-market studies, investigator-initiated studies, medical liaisons, FCPA "red flags," OECD anti-bribery guidance)

Questions & Discussion

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