

Compliance Lessons from Medical Devices

- Building Global Compliance Organizations
- Global Monitoring Programs
- Managing Distributors and Sales Agents

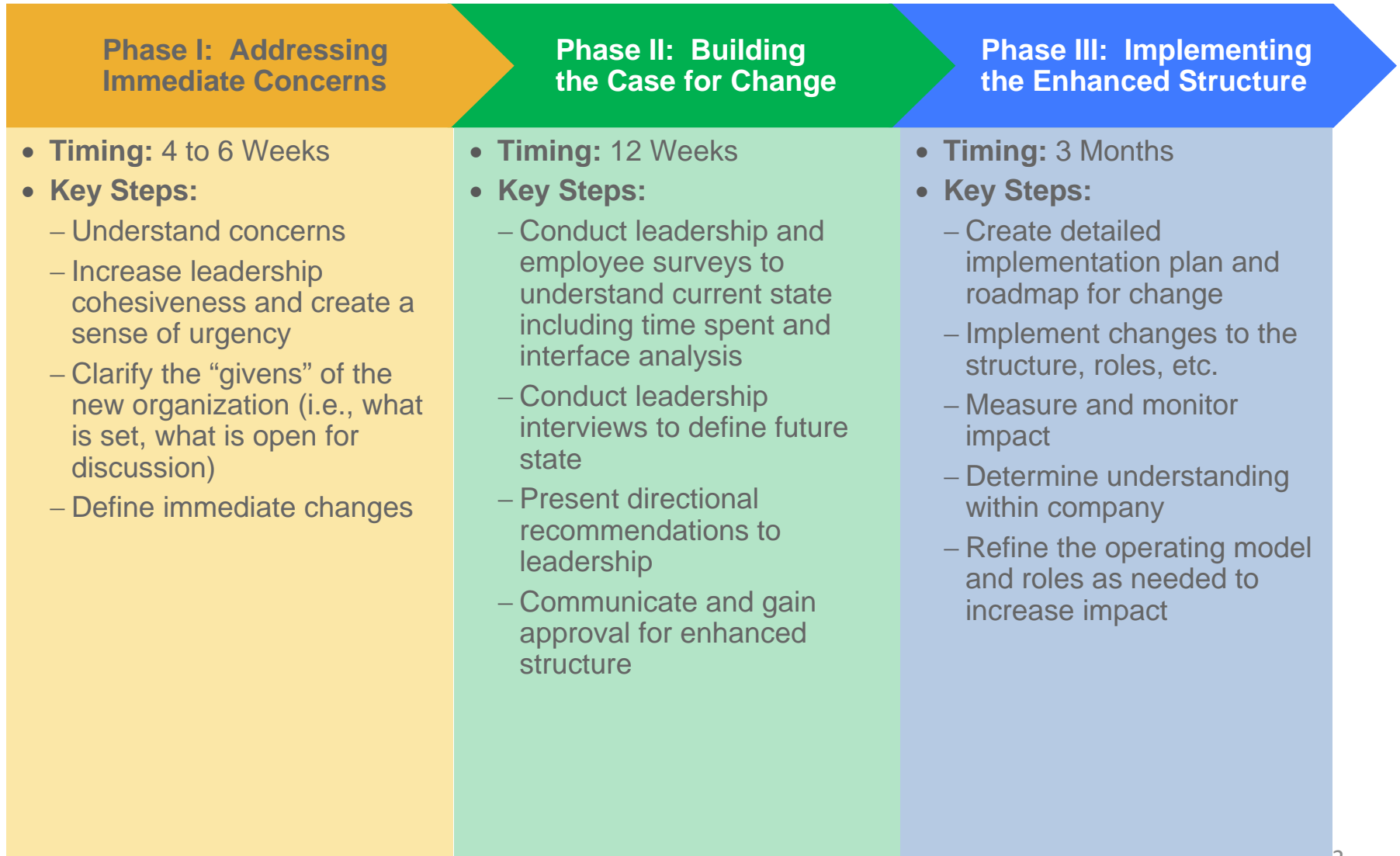
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Sujata Dayal, Biomet

Arjun Rajaratnam, Smith & Nephew

Organizational Design Process (Example)



Driving Force for Change (Example)

Internal and External Forces Drive Increased Needs on the Global Compliance Organization



Compliance Organization Requirements (Example)

Requirements define what the organization must achieve and maintain.

Requirements
1. Independent oversight for senior management and Board
2. Business head ownership for compliance
3. Support and service levels to Business
4. Training and tools to support manager and employee compliance
5. Best practice through shared compliance practices/center of excellence
6. Equitable cost sharing across Business
7. Oversight and support for third-party compliance
8. Timely and effective investigations and discipline
9. Regular risk identification and mitigation and monitoring
10. Cross-division communication/coordination

Organization Design Results (Example)

- Resource Levels for oversight and service:
 - More resource for certain regions or due to new risk areas
 - More resource for certain divisions due to new business areas
 - Less resource for certain divisions due to lower risks
- Shared Service for best practices and efficiency:
 - Central monitoring team
 - Regional compliance officers across all divisions
 - Project management support
 - Training and communication
- Other:
 - Spend more time on internal customers and process improvements
 - Account for resource spent on HCP contract management

Global Monitoring Overview

Objective

- To use testing techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems

Key Components

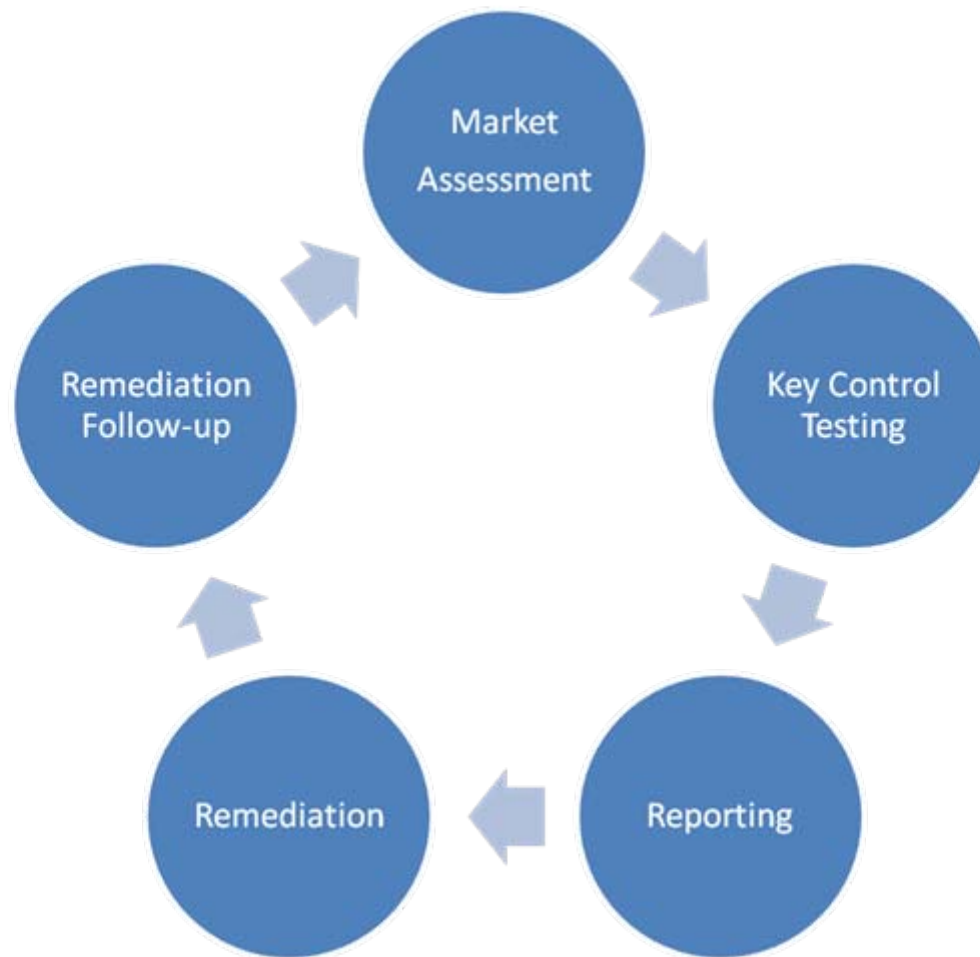
- Monitoring
 - Compliance risk register
 - Monitoring program process
 - Key control testing
 - Reporting & remediation

Compliance Risk Register (example)

Start by identifying the major risks to be monitored

- **Risk #1** – Inappropriate payments to HCPs/government officials (GO) in consulting
- **Risk #2** – Inappropriate payments to HCPs/GO in grants
- **Risk #3** – Inappropriate gifts or meals
- **Risk #4** – Payments relating to HCPs/GOs are not clearly identifiable
- **Risk #5** – Providing samples as inducements
- **Risk #6** – Placed capital and products provided as an inducement
- **Risk #7** – Excessive discounting and/or rebates
- **Risk #8** – Promotional/marketing materials not internally approved, contain false or misleading statements or promote off-label use
- **Risk #9** – Inaccurate prices and claims are reported to governments
- **Risk #10** – Third parties inappropriately selected, provided inappropriate payments, or known to circumvent policies and procedures

Monitoring Program Process



Key Control Testing

- Key control testing determines whether or not local compliance controls are operating effectively.
- A market is defined by a list of operating entities
- Guidance on testing requirements and considerations are provided.
- Testing is performed by a Compliance Monitoring Team and Regional Compliance Officers with support from the Local Finance and Compliance teams.

Key Controls (example)

General Controls which apply to all risks:

Compliance oversight committees

Existing Code, policies and local rules

Compliance training provided to cover above mentioned standards

Channels in-place for reporting instances of non-compliance

Reporting channels communicated to employees and follow-up on instances of non-compliance

Reports of violations of Code or local law investigated with appropriate discipline imposed where confirmed

Inappropriate payments to HCPs or government officials.

- Payments approved per procedures
- Payments supported by documentation
- Expenses within country guidelines
- Rendered services reconciled to a contract in Needs Assessment or approved Modification
- Signed contract on approved template within approved FMV guidelines
- HCP is qualified to provide services
- Employer notification and pre-approval where required
- Payments charged to account code for direct payments to HCPs
- Accounts Payables monitors payments

Monitoring Testing Report

Compliance Monitoring					TESTING SPREADSHEET			
Entity		<input type="text" value="0"/>			Monitor:		<input type="text" value="0"/>	
GR Number		<input type="text" value="GR1"/>			Period of Testing:		<input type="text" value="0"/>	
GR1 - Inappropriate payments are made to HCPs and Gos for arrangements such as Consulting and Royalties								
Key Control - Checked Supporting Documentation								
Frequency of Testing - Quarterly								
Testing Sample - As per Sample Size Table based on the number of payments of this type in the period								
					1	2	3	4
Sample Item No.		Sample Item Reference	Sample Item Description	Date of Sample Item	Payment has been approved per Arrangements Committee procedures	Payment is supported by WAR or invoice submitted by HCP/GO	WAR or invoice reconciles to contract for scope and rate	Expenses Comply with Policy and are appropriately supported
Example	Yes	Q4 09 Smith	Q4 09 WAR Payment for Dr. Smith	Feb-10	Acceptable	Acceptable	Acceptable	Acceptable

A simple template for each risk to be monitored was developed.

Monitoring Reporting and Remediation

A Compliance Monitoring Report

- Completed for each monitoring review
- Summarizes the review scope, results and deficiencies
- Provided to management, Business Compliance Officer, and Chief Compliance Officer
- Report sections:
 - Scope of review: controls tested, period covered, sample size, and number of deficiencies per control
 - Summary of deficiencies: description of deficiency and recommended remediation steps

Remediation

- Deficiencies identified reviewed in advance by the local business leader
- Deficiencies determined to need remediation must be corrected on a timely basis through action plans lead by General Manager
- Remediation must be verified by Regional Compliance Officer

Managing Distributors and Agents Overview

Objectives

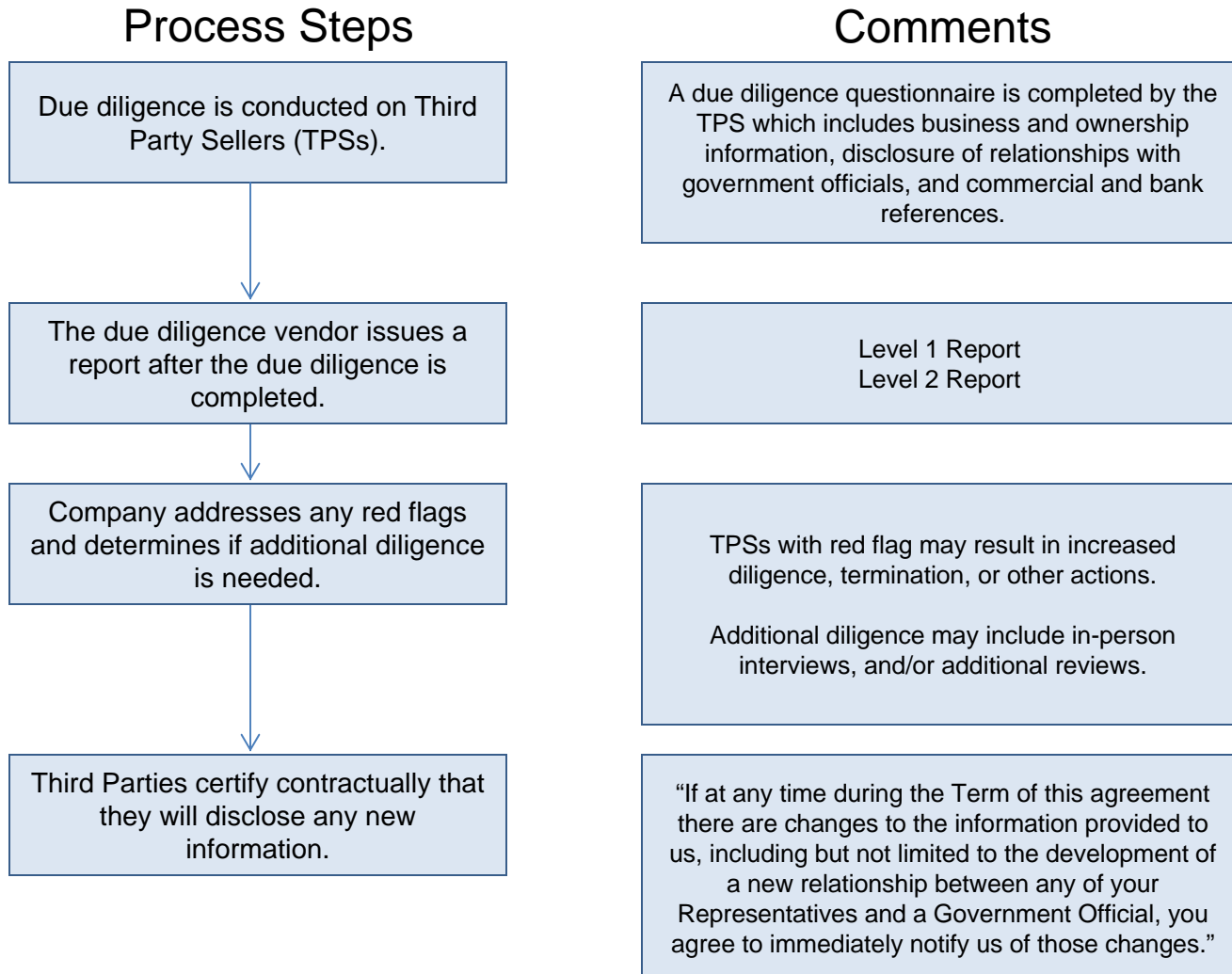
- Select third parties that uphold ethical and compliance standards similar to those at company
- Establish Contractual compliance obligations
- Train third party sellers (TPS) on applicable laws and company Code, and provide them with effective tools
- Conduct risk-based monitoring and auditing
- Respond quickly and effectively in the event of possible non-compliance

Key Components

- Due diligence
- Contracting
- Training
- Audit plan

Recognize that the management of relationships with third parties is a vital part of a compliance program.

Due Diligence Process (example)



Examples of Red Flags

- Rumors regarding unethical or suspicious conduct by an employee, marketing representative, consultant or other business partners
- Unnecessary third parties or multiple intermediaries
- Request for payment to a third party
- Requests for payment in a third country
- Business in a country where bribery is common
- Requests for payment in cash
- Requests for excessive commissions or other payments
- Political contributions
- Requests for reimbursement of expenses that are poorly documented
- Incomplete or inaccurate information in required disclosures
- Refusal to certify compliance

Contracting (example)

In-scope Third Party Sellers must execute a written agreement that includes their agreement to:

- Comply with applicable anticorruption laws, including but not limited to the U.S. Foreign Corrupt Practices Act and National anticorruption laws;
- Not offer, approve, pay or otherwise facilitate improper payments to HCPs or Government Officials;
- Conduct appropriate due diligence on any of their agents, resellers, partners, etc., and keep a detailed record of such checks;
- Provide, facilitate or undertake compliance training; and
- Notify Company of any known or suspected violations of applicable laws

Training (example)

Training Program

- On-line – translated in same languages as Code of Conduct. Principals have 60 days to complete
- Third Party Seller Principals are responsible for training their staff
- Live training provided wherever possible

- Live training delivered to select Third Party Seller
 - By compliance
 - By sales
 - By TPS principal

Audit Plan (example)

- Audits performed at least 6 months after the Compliance contract signed and on-line Compliance training completed
- Audits should look at data covering the period of 6 months prior to the audit
- Possible audit areas to cover:
 - Existence of a Compliance Program; HCP Consulting Payments;
 - Gifts to HCPs or Government Officials
 - Funding of HCP to Business Meetings and third party educational conferences
 - Grants and Donations connected to HCP or Government Officials
 - Completion of due diligence, existence of contractual language and training of sub-distributors
 - Political Donations
 - Protocols