

IDENTIFYING AND ANALYZING SUPPLIER COMPLIANCE RISKS -BEYOND QRM AND GMP

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Agenda

Risk Identification and Segmentation

Risk Assessment and Reporting

Remediation & Monitoring of Suppliers



How to manage integrity and compliance risks in suppliers

Establish

Identification of compliance obligations

and evaluating compliance risks



MANAGE

identified risks through effective integrity products and services to maintain and improve integrity



MANAGE AND IMPROVE your ongoing integrity programme

Integrity Crisis

Conducting

Investigations

Management of

Improve

PREPARE

and predict where supplier integrity and compliance risks will happen within your company and with those you deal with



Develop

Implement

UNDERSTAND your suppliers and their culture

(3)

Tolerance Reviews Process Mapping Culture Assessments

IntegrityCircles®

Compliance

Roundtable

UNDERSTAND your supplier integrity risks



Planning to address compliance risks and

to achieve objectives

Due Diligence

Risk Categorisation



UNDERSTAND country and industry predictions

integraRating* | Compliance Focus Analysis

Compliance Intelligence



ASSESS your suppliers to build an effective integrity framework





MONITOR

potential risks in your suppliers to ensure ongoing integrity



TRACK AND MONITOR your suppliers daily with continuous integrity monitoring





Monitoring Solutions



IntegraSure* integrity Audits







Due Diligence



Performance evaluation and compliance reporting

Compliance function

Evaluate

(111)

Maintain

control of compliance risks

IDENTIFY integrity

integraWatch*| Compliance Screening

risks in your suppliers

IMPLEMENT

by assessing and identifying potential risks in your suppliers to make informed decisions



ESTIMATE AND ALLOCATE resources



Resourcing and





PREDICT risks through transaction analysis



PIMM™ Methodology

for INTEGRITY AND COMPLIANCE RISK MANAGEMENT™

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TRAIN your suppliers











ComplianceDesktop*



ComplianceDesktop* User Training







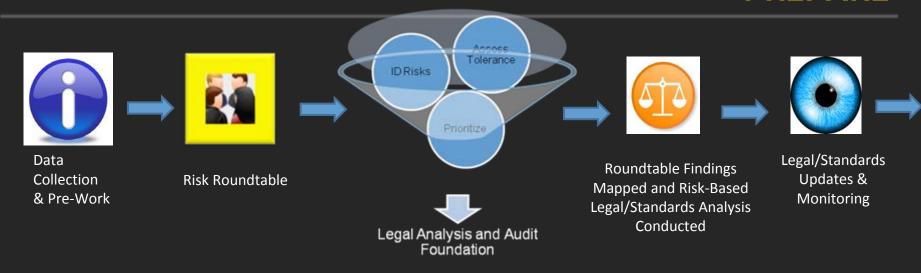


IntegraCheck* |





Compliance Programme: PREPARE



Most Companies have neither the time nor resources to assess all risks in depth – more likely to score and prioritize on available business model, country, enforcement, reputational, and industry data, among others.

One Approach:
Risk Impact Score x Effectiveness of Controls Score

Risk Prioritization Ranking



Compliance: Risk Roundtable Topics

Common Legal/Compliance Issues:

- ➤ Environmental, Health, Safety
- ➤ Labour Rights/Standards
- ➤ Human Rights/Trafficking
- ➤ Corruption and Bribery
- ➤ Export Control/Customs
- ➤War zone
- >Fraud/kickbacks
- ➤IP Violations
- ➤ Antitrust/Competition Law
- ➤ Conflict Minerals

Business Issues:

- **≻**Quality
- ➤ Single Source Dependency
- ➤ Production Capacity
- ➤ Lack of business transparency
- ➤ Transport and logistics
- ➤ Personnel/management turnover

Strategic Supplier Characteristics by: geography, (how many does each supplier have and in what provinces), type and description (multiple functions), number of employees (full and part time), strategic importance to supply chain and others

Stakeholders: provide details on perceived and actual compliance and business risks presented by these suppliers (depending on number, go through each, if warranted)

Compliance Risk
Classification and
Prioritization and
Company Risk Appetite
Assessment

Supplier buy-in and change management planning



Compliance Programme: From PREPARE TO IMPLEMENT







Build and implement Supplier Change Management Strategy







Initiate IntegraCheck® Due Diligence Reports or Bespoke Due Diligence, depending on outcome of Supplier Risk Roundtable

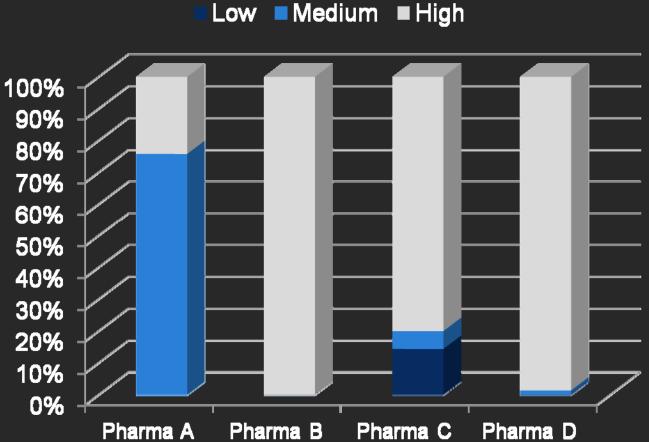
<u>Audit Plans</u>: are tailored to the prioritized risks presented by individual Suppliers based on country/province, enforcement of local/international laws, legal/financial/reputational exposure to Company based on possible breaches, pre-existing infrastructure to support compliance, number of employees, importance of party to Company supply chain, history of past compliance issues, and other factors.

<u>Supplier Change Management:</u> this step is absolutely critical and often overlooked. Consensus building through a variety of media and resources, depending on country and nature of pre-existing relationships (may take form of written communications, face-to-face strategic supplier forums (using interactive polling to demonstrate value of compliance programmes to suppliers, executive-to-executive business and compliance planning, etc.

<u>Due Diligence</u> should be performed before a site visit-based audit takes place so that the audit team is well-versed in past compliance issues history and in current company make-up and management.



Pharmaceutical Industry Sampling: FY13/14 DD Case Types Ordered







Compliance Program: IMPLEMENT





















Records Inspection

Executive Interviews

Focus Group Sessions

Site Inspection(s)

Create Report

Anti-Corruption: Audit Review Samples

- •Review of inspection/clearance/safety records:
- •Critical use of subcontractors: examine workflows and payments
- •Freight, shipping, customs agents records
- •Government officials: gifts, travel, entertainment
- •Slush funds, undesignated office or supplier funds
- •The "other" set of records
- Investment and capital funding review
- Fear of speaking up/retaliation (Focus Groups)



Consolidated Dashboard



Single Dashboard: Metrics on All Risks

Reporting

Auditing

Investigatio n Policy & Process Change





Compliance Programme: IMPLEMENT



Dashboard &
Benchmark Identified
Risks to Examine
Trends and Set Up KPIs
for Programme
Success



IntegraRating®
To assess where
compliance
investment
will yield best results



Meetings to review report results with individual Suppliers and review remediations





Face-to-face, case study based Company Audit Team Training followed by Audit Team Shadowing on Followups with Suppliers



Anti-Corruption Compliance Programme:

- •Typical areas for improvement/KPI Set Up:
 - Supplier's own third party management
 - Engagement with govt officials (e.g., inspections)
 - Conflicts of interest (PEPs and SOEs)
 - · Gifts, travel entertainment and fund tracking
 - Communications and training re: anti-corruption
 - Employee compliance reporting: speak up!
 - Monitoring of anti-corruption programme
- •Using country-based and forthcoming ISO hallmarks



Compliance Programme: MONITOR & MANAGE



Conduct follow-up on remediation work with individual suppliers

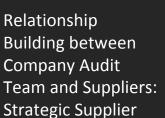








Building between Company Audit Team and Suppliers: Strategic Supplier Forum





Hand off to Business

for Monitoring



Benchmark Suppliers for Compliance and **Enhance Overall Programme Strategy** and KPIs



Year 2: Team Audits with cross-check of findings and recommendations by Legal/Compliance





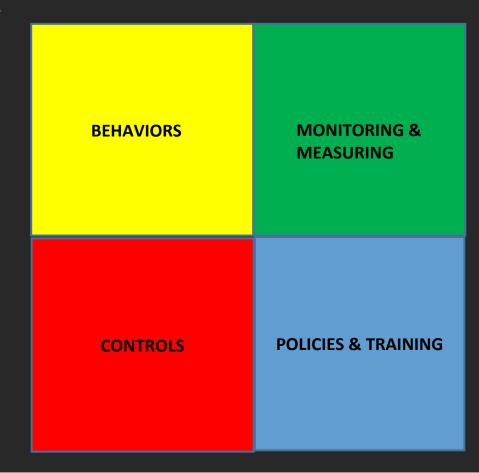
New/changed laws/standards or changed business conditions



What Kinds of Risk Mitigation May Work Best?

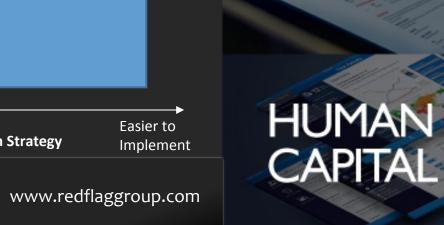
Tougher Landscape

Compliance Landscape (Country and Industry)



Ease of Implementation of Risk Mitigation Strategy





SALES

SUPPLIER

CUSTOMER

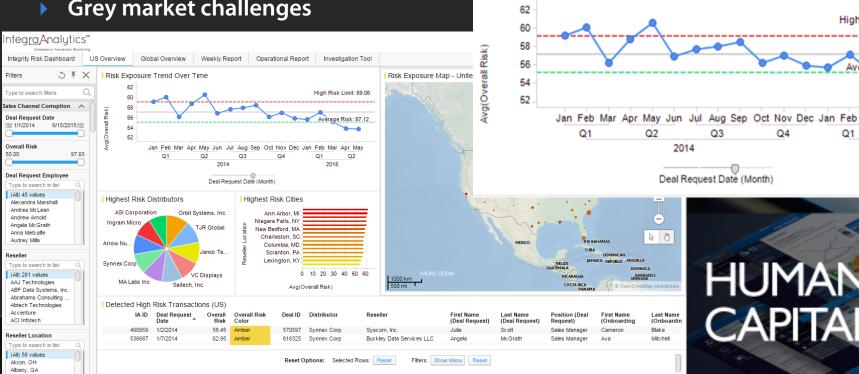
Transactional Monitoring

Using real-time data on payments, supplier, procurement and HR data bases, etc. to detect, flag and alert the company to high risk transactions for issues management regarding:

Supply chain kickbacks

Distribution channel bribery

Grey market challenges







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