

The National Disclosure Summit

*The Leading Forum on Disclosure, Transparency and
Aggregate Spend for Drug, Device and Biotech Companies*

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A Hybrid
Conference
and Internet
Event

GHC LIFE
SCIENCES
Global Health Care, LLC

Global Challenge: Conducting Background Checks

7 February, 2014

Agenda

Introductions

Background checks: relevance and framework

Practical example: implementing background checks at Grünenthal

Questions and answers

Introductions

Ronny Arijs



Vice President Global Sustainability and Chief Compliance Officer – Grünenthal Pharma

(Since March 2010)

- In charge of the broad spectrum of Compliance matters such as:
 - globalization of the compliance system and programs,
 - standardization of policies and guidelines,
 - building compliance culture and business integrity
- Strong focus on compliance risk management and global transparency especially on HCP interactions.
- Based in Grünenthal's headquarter in Aachen, Germany.

GE Healthcare

(Feb 1991 – Feb 2010)

- Senior Compliance manager for Europe, Middle East & Africa region, supporting the Asian compliance team and driving global compliance projects
- Multiple senior manager positions in the fields of finance, operations, sales 3rd party management, country/general management.

Economics and Business administration/Finance,
Brussels - Belgium

Geert van Gansewinkel



Managing Director Europe – Polaris

- P&L responsibility for European business
- Responsible for sales and delivery

Principal - The Boston Consulting Group

- Strategy: Corporate and IT strategy, organization design, PMI
- Transformation: process re-design, business improvement, change management
- Sectors: pharma, telecoms, technology, financial services, consumer goods

Consultant - Accenture

- Systems implementation
- Process Design
- Business deployment

MBA, IESE. Barcelona, Spain

MSc, International Business, University of Maastricht

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Why Is This A Relevant Topic To Discuss?

Why relevant?

Life Sciences companies typically work with large number of third parties

- HCP's/ HCO's
- Sales 3rd parties
- Vendors/ suppliers

The behavior of third parties can have significant impact in multiple ways

- Third parties act – formally or implied – on behalf of you
- Non-compliance can lead to prosecution or reputational damage

To prevent negative impact, need structured methodology to assess and act on risks

- Covering multiple areas of risk: Improper payment, bribery, data privacy, fair employment, etc.

Example: Anti-bribery regulations having effect on business decisions

Anti-Bribery Regulations are Making a Bigger Impact on Business Decisions

[\(The FCPA Blog, 8 April 2013\)](#)

In Brief: Anti-corruption regulations are having a larger effect on business decisions, one global survey of compliance officers found. Among the results:

- 71% of companies stopped or delayed working with another party over the potential to breach bribery regulations (almost 20% more than in 2009)
- 55% of respondents said worry about violations slowed or stopped entry into emerging markets (almost 15% more than in 2009)
- 56% of respondents said the scrutiny has improved relations with business partners

The Risk Is Not Hypothetical

Example: ProPublica Study Revealed Significant Risk In Current Practices

ProPublica

Analysis of publicly disclosed payment information

Payments to HCP's for acting on behalf of companies in speaker programs

Data covered 7 large pharmaceutical companies

Reporting period: 2009 and 2010, with some data from 2011

Key Findings

Sanctions against more than 250 speakers including some of the highest paid

- Misconduct included: inappropriately prescribing drugs, providing poor care or having sex with patients)

Some doctors had lost their licenses

88 speakers from one company who had been sanctioned and 4 who had received FDA warnings

5 of the 7 companies acknowledged that they did not routinely check state board websites for discipline against doctors

- Relying solely on self-reporting and checks of federal databases

HCP Checks Can Be Run On Different Levels of Scrutiny

Companies To Decide What Level Of Scrutiny To Apply

Background Checks Potential Levels

Sanction Information	Database screen for sanctions <ul style="list-style-type: none">• e.g. warnings, reprimands, exclusions, debarments• e.g. OIG, General Services Administration• Federal Level, State Level
Education Verification	Check standing and dates of licenses and certifications with relevant agencies
Prof. License Verification	Check standing and dates of licenses and certifications as well as standing with regulatory bodies
Additional Checks	Additional checks, including: <ul style="list-style-type: none">• Full identity check• Criminal search• Sex offender search

Potential Criteria For Deciding What Level Of Scrutiny to apply

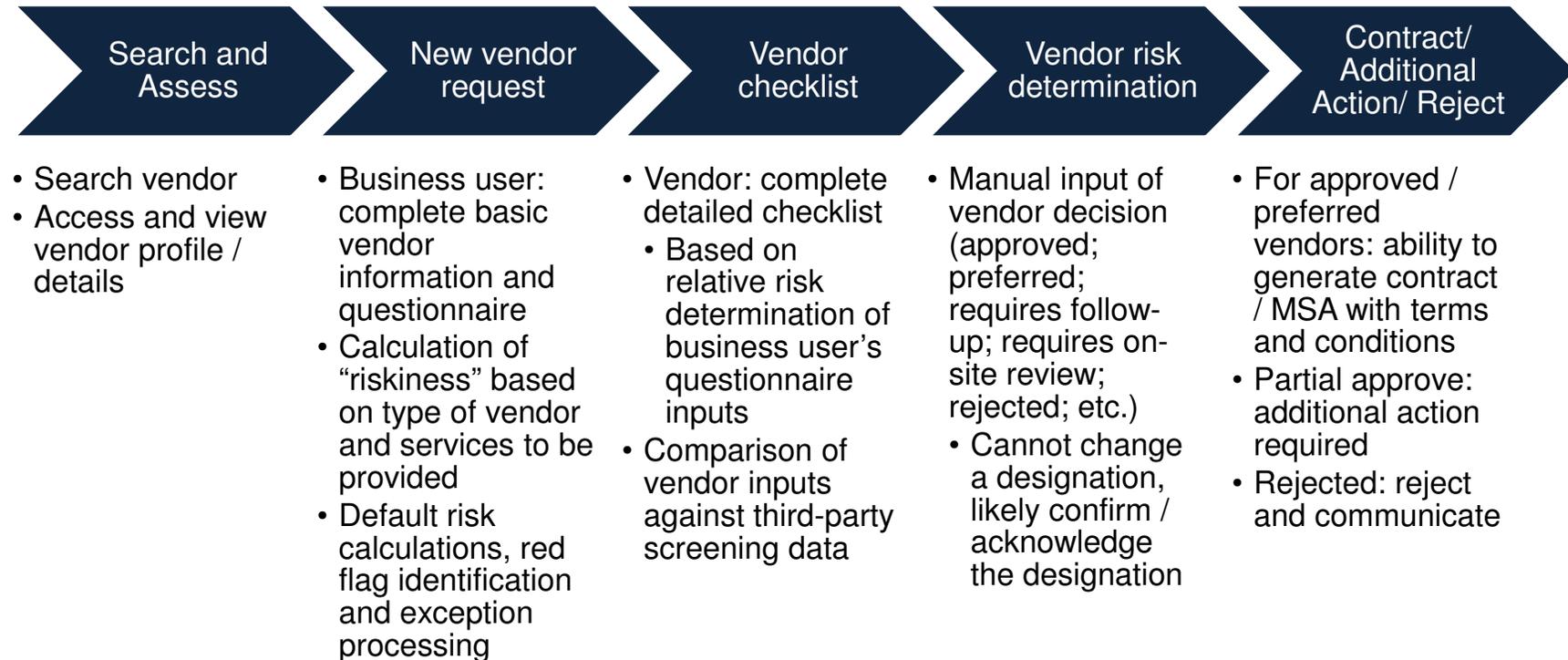
Frequency	Number of interactions between HCP and company
Value	Value associated with collaboration
Exposure	Type of engagement, e.g. purely internal consulting assignment vs external speaker program

Also For Non-HCP Third Parties, Need to Establish Clear Criteria For Assessing Risk

Criteria	Key Questions	Sample High Risk Qualifications
Country	What is the risk level of the involved country?	CPI (Corruption Perception Index 0<1.9)
Vendor Type	What is the type of the vendor?	Brokers, Consultants, CROs, Sales Agents
Value	What is the agreement value and is there a budget in place?	High \$/€ value contract, but no detailed budget in place
Government involvement	Is the vendor government owned or active in a country where SOEs are common?	Owned or controlled by government
Corporate Executive Affiliations	Are executives known to be affiliated with government or political party?	One or more executives have positions in government
Litigations	What is the involvement of the vendor in litigation (fraud, bribery, corruption)?	Involved in litigation and found guilty

To Ensure Consistency and Minimize Risk, Need to Install Structured Process For Assessing Third Party Risk

Illustrative



Follow Up Action Should Be Defined Based on Assessment Of Risk

Illustrative

Example: Weighted “Risk score” for each party

	Score	Weight (1,2,3)	Wscore (SxW)
1 Country	1	3	3
2 Type	2	2	4
3 Value	3	2	6
4 Government owned	1	1	2
5 Corp execs affiliations	1	1	2
6 Litigations	1	1	2

Total Risk WScore: **19**

Total WScore:
 10-15 = Low █
 15-25 = Medium █
 25-30 = High █

Follow up differentiated per type of vendor

Vendor type	Potential measure
High Risk	Perform detailed due diligence check, potentially reject contract
Moderate Risk	Perform high level compliance check, potentially include additional measures (e.g. NDA)
Low Risk	Perform high level compliance check
No Risk	No action required

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