THIRD-PARTY VENDORS AND STRATEGIC PARTNERS

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The information presented and discussed represents the opinions of the authors/presenters and, although descriptive of general activities, do not necessarily reflect the views of either Genentech or Huron Consulting Group.

Track Objectives

- To review the issues involved in working with third- party vendors, consultants and other strategic partners in the development and execution of business activities
- To provide practical ideas, tools and techniques to work with external partners to ensure prevention, detection and correction of compliance risks
- The scope of third parties: agencies, consultants, meeting planners, medical writers, strategy partners, CROs and others

Why This Topic Is Important:

- Third-party vendors and strategic partners:
 - Are <u>present</u> in almost every aspect of a company's business
 - Are an <u>extension</u> of your business, and sometimes of your identity – often indistinguishable to the casual observer
 - Are <u>acting</u> on your behalf
 - Can help your company manage <u>risk</u>...but they can also put your company at risk

The Landscape



A Few Realities:

- Variable vendor management capabilities:
 Procuring, on-boarding, managing
- People experience and turnover rate: Yours and third-parties'
- Competitive pressures: To act rapidly, to out-do
- Ever evolving requirements:
 - Federal & state laws, Industry codes, institutional policies
 - Disclosure & transparency

Polling Question (Ask Yourself...)

- Do you regularly train third-party vendors, agencies, etc. as part of your compliance training program?
 - Regularly (at least once per year)
 - B. Occasionally proactive (e.g. at on-boarding)
 - Reactively: As part of audit corrective plans,
 CIAs, etc.
 - Never or almost never

Some Critical Questions:

- For what reason are you hiring them?
- What are your and their expectations?
- What should be in the contracts and agreements?
- Who is actually going to be doing the work?
- Whose policies and guidelines should apply?
- Should you have to train the third-party? How much? How often?
- How will you ensure management/supervision & accountability?

Some Critical Questions:

- Are there privacy and confidentiality protections?
- How will you handle privileged communications?
- When & how will you do performance evaluations?
- How will corrective actions be implemented?
- What are the consequences of non-compliance?

Some Ways To Mitigate Risk:

- Have clear and comprehensive agreements with duties/obligations and representations/warranties spelled out
- Limit number of vendors/partners -> better ability to monitor and manage
- Conduct pilots before fully committing
- Seek long-term partnerships / limit vendor turnover
- Ensure vendors have standards of conduct, policies, SOPs
- Have clear data & records expectations: timeliness, data integrity, retention

Some Ways To Mitigate Risk:

- Implement initial and ongoing training: "Vendor day", testing
- Have a regular communication and issueresolution plan
- Conduct appropriate monitoring and auditing
- Conduct regular business performance evaluations (two-way)
- Ensure roles and responsibilities are clearly defined: Who does what; who is accountable for what
- Consider sub-certification and assurances (like SOX): Formal and/or informal

10

EFFECTIVE PARTNERSHIP, CONTRACTS AND AGREEMENTS: GOOD FOR BUSINESS, GOOD FOR COMPLIANCE

Our Sessions For Today

Due Diligence Monitoring and Auditing of Third-Party Vendors

- Diana Borges, Compliance Manager, Teva North America
- Brian Dahl, Director of Compliance, Teva Pharmaceuticals
- Michele Girdharry, Manager, Huron Consulting Group
- Paul Silver, Managing Director, Huron Consulting Group

Robust Agreements and Vendor Training: When, Where and How

- Janis Crum, Esq., Associate Director of Auditing, Genentech
- Mark DeWyngaert, PhD, Managing Director, Huron Consulting Group
- Ned Kelly, MD, Vice President, Pharmacovigilance, Quintiles