

After the Implementation: Maintaining an Effective Compliance Program  
Risk Assessments and Auditing & Monitoring Strategies

Presented by: Jean Sands, Pharmaceutical and Life Sciences



---

---

---

---

---

---

---

---

Risk Assessments

- Conducting Risk Assessments

Risk Assessments and Auditing & Monitoring • After the Implementation: Maintaining an Effective Compliance Program

2

---

---

---

---

---

---

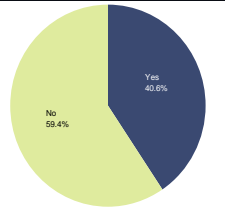
---

---

Percentage of companies that use compliance risk assessments to determine whether their monitoring programs are effective

(Respondents could only choose a single response)

Response	Frequency	Count
Yes	40.6%	13
No	59.4%	19
Valid Responses		32
Total Responses		32



Risk Assessments and Auditing & Monitoring • After the Implementation: Maintaining an Effective Compliance Program

6

---

---

---

---

---

---

---

---

### Conducting Risk Assessments

Conduct initial assessments in selected process areas, using interviews and process walkthroughs with key stakeholders to identify the current processes, risks, metrics and monitoring programs in place.

Consider identifying:

- The future process, metrics and monitoring needs for each stakeholder group;
- Assessing the existing infrastructure capacity (people, process, technology);
- Assessing data availability and data quality;
- Risk appetite and tolerance of the organization regarding the compliance risks associated with the selected activities; and,
- The capacity of the current incident management process to effectively manage the likely increase in the volume of issues to be resolved upon implementation of the monitoring program.

Risk Assessments and Auditing & Monitoring • After the Implementation: Maintaining an Effective Compliance Program

3

---

---

---

---

---

---

---

---

---

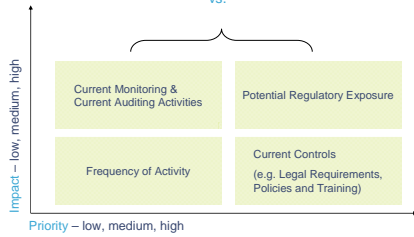
---

---

---

### Risk Maps

Review Areas (e.g. Educational Grants, Charitable Contributions) vs.



Risk Assessments and Auditing & Monitoring • After the Implementation: Maintaining an Effective Compliance Program

4

---

---

---

---

---

---

---

---

---

---

---

---

### Risk Assessment Table Potential review areas

Risk rating (Priority & Impact)	Description
e.g. Medium, High	Company-Conducted Product Training and Education
	Promotional Activities (Medical/Regulatory/Legal process and Dissemination of Promotional Information)
	Sales Promotional and other Activities (e.g. Educational Items and Meals)
	Dissemination of Medical Information
	Consulting Arrangements (e.g. Advisory Boards and Faculty)
	IP and Royalties
	Supporting Third Party Educational Conferences
	Speaker Programs
	Charitable Contributions and Donations
	Market Research
	Health Economics and Reimbursement Information
	Interactions with Government Officials
	Evaluation, Loan and Demonstration Products

Risk Assessments and Auditing & Monitoring • After the Implementation: Maintaining an Effective Compliance Program

5

---

---

---

---

---

---

---

---

---

---

---

---

**Auditing & Monitoring**

- Building an Auditing & Monitoring team
- Effective Auditing & Monitoring strategies

**"An effective compliance program should incorporate thorough monitoring of its implementation and an ongoing evaluation process"**  
 - OIG Compliance Guidance

Risk Assessments and Auditing & Monitoring • After the Implementation: Maintaining an Effective Compliance Program

---

---

---

---

---

---

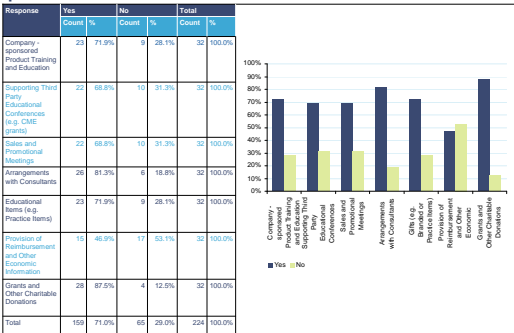
---

---

---

---

**Do you monitor the processes set in place for the following provisions of the AdvaMed code?**



Risk Assessments and Auditing & Monitoring • After the Implementation: Maintaining an Effective Compliance Program

---

---

---

---

---

---

---

---

---

---

**Commercial activities for Monitoring**

Typical compliance monitoring programs, include evaluating and enhancing monitoring processes, controls, and key performance indicators (KPIs) for the following commercial areas:

- Any relationship with healthcare professionals (HCPs) where value is exchanged.
- Engagement of HCPs for consulting, educational and / or other advisory arrangements.
- Exchange of scientific information (off-label promotion).
- Awarding or payment of educational, clinical, and/or investigator sponsored study research grants.
- Any component of the above-mentioned activities outsourced in whole/in part to a third party vendor.
- Reimbursement guidance and support.

Risk Assessments and Auditing & Monitoring • After the Implementation: Maintaining an Effective Compliance Program

---

---

---

---

---

---

---

---

---

---





**Effective Auditing & Monitoring strategies**  
**Better practices of leading companies**

- Develop and **implement specific disciplinary policies/procedures** which govern the resolution of compliance policy infractions
- Develop and **implement written policies/procedures for notifying the Board** (or a Committee thereof) of compliance related investigations or issues

---

---

---

---

---

---

---

---

**Better practices**  
**Summary**

- **Employ a disciplined approach to identifying and managing risk within your organization.**
  - Goal of managing risk **vs.** eliminating risk is appropriate
- **Embed risk and compliance monitoring throughout your organization.**
  - Independent audit function and partner that complements business needs and shifting compliance priorities
- **Implement sustainable remediation procedures.**
  - Highly ethical companies always document and act on deficiencies, no matter how seemingly insignificant
  - Look beyond mitigating a single incident, focus on integrating governance, risk and compliance throughout organization
- **Use technology to improve risk management and compliance capabilities.**

---

---

---

---

---

---

---

---

**Questions?**

<b>Peter Claude</b> Pharmaceutical and Life Sciences, Partner T: 415.498.5024 E: Peter.Claude@us.pwc.com	<b>Jean Sands</b> Pharmaceutical and Life Sciences, Manager T: 312.298.3026 E: Jean.Sands@us.pwc.com
--	--

---

---

---

---

---

---

---

---



---

---

---

---

---

---

---