*Live Auditing*

# Live Auditing is Here to Stay. The Question is How to do it?

***A pragmatic approach for planning and conducting live field auditing***

**By Dan Koerner and Jon Wilkenfeld**

The debate over live auditing is over. It's clear that live auditing is necessary and here to stay. The number of required live audits in corporate integrity agreements (CIA) has increased dramatically in the last twelve months. The four latest CIAs expanded the required amount of field force monitoring ranging from 30-75 ride-alongs compared to the 10-30 range included in CIAs back in 2007-08. Meanwhile, three of the last four CIAs – Pfizer and AstraZeneca – require a minimum of 200 speaker program audits. *(See table, next page, for a list of CIA live auditing provisions.)* If these recent CIA provisions are any indication, the Office of Inspector General (OIG) has sent a strong signal that live auditing should be considered an essential tool for compliance departments.

## PhRMA Code Requirements

The PhRMA Code states that *"...companies should periodically monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines."*

The OIG's focus on live speaker program reviews may have stemmed from the above provision in the 2009 revised version of the PhRMA Code. Monitoring also helps to ensure compliance with other PhRMA Code guidelines. Additionally, several state laws mandate adherence to the PhRMA Code or include their own audit provisions.

There are numerous additional benefits in conducting a formalized yearly review of the field force. Reviews help to provide the Compliance office with a better understanding of daily sales activities and assist in identifying key areas for enhancing policies, procedures, communications, and training. Monitoring also allows companies to internally identify noncompliant (or potentially noncompliant) activities and implement corrective and preventive actions (CAPA) to fix and prevent future occurrences.

## Auditing vs. monitoring

Many companies make a distinction between auditing and monitoring activities. While the terms may differ from company to company, the basic principle is the same: Review the activities of the field force to ensure compliance with federal regulations and company policies. For the purposes of this article, the term "audit" describes the process of reviewing field force activities, regardless of whether the review is conducted by those reporting through the sales or marketing functions, compliance, legal, or internal audit or external providers on behalf of any of these groups.

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## Scoping the Audit

There are no concrete guidelines for determining the precise number of audits to conduct, nor is there a guidebook on who, what, or when to audit. Most often, the key questions that drive audit planning are: How much budget do we have and what are our greatest risks? It may be wise to develop a long term audit plan over a period of three or five years to help balance resources and risk. The following are several practical steps for developing a live audit plan.

**Select the audit team.** Whether a company selects internal or external auditors (or a combination of both), the most important consideration is that the auditors have an understanding of compliance issues, product-specific risks, medical terminology, and a general understanding of the product(s) being audited. The audit team should have a clear project leader but successful audits can be completed using a diverse team of auditors, depending upon the company's available resources. Additionally, it is helpful to appoint a project manager to help coordinate the logistics.

**Assess the budget.** It can be very costly to conduct live audits given the resources and travel expense involved. Setting the budget in advance will help to determine the audit scope and breadth to best maximize audit dollars.

**Identify the reach.** Beyond identifying the total number of audits, it is important to define the scope of the audit by considering the organization's risk exposure and the appropriate mix of audits. Listed below are some key considerations:

- What products present the highest risk to the organization?
- Has a specific territory or region been the target of multiple investigations?
- What audits have been previously conducted or have already been planned for the future?

Depending upon the answers to these questions, it may make sense to focus auditing resources across the country focused on many products, or in an identified region for an identified product or somewhere in between.

**Define the Protocol.** Companies should go one step further and take a broader view of their potential risk in addition to focusing on the most common risk areas (e.g. off-label promotion, fair balance, etc.). This may include a review of previous audit findings and internal investigations to help identify areas that may be of particular concern. Reviewing recent settlements and current government investigations may help to assess trends within the industry, which should be considered in determining additional risks. Another consideration may be checking the effectiveness of recent training or compliance with new or revised policies and procedures (e.g. meal limits). Other questions to consider include:

- What violations have the highest rates of occurrence in the investigations process?
- Were CAPAs that were previously implemented effective in addressing the issue observed?

## Development of Audit Materials

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Preparation is one of the single most important elements of audit planning. Creating formalized training and audit materials such as product information guides, Frequently Asked Questions (FAQs), and audit observation sheets help to ensure auditors stay on track and keep within the scope of the audit. In order to be successful, the audit team must have a clear view of what is in scope for the audit. It is important to develop an audit protocol which clearly explains the specific parameters being audited as well as how the auditor should handle potential situations that may come up during the course of the audit.

**Table 1: Recent CIA Live Auditing Requirements**

| Company | Settlement Date | Minimum Number of Field Ride-Alongs | Number of Speaker Programs |
|---|---|---|---|
| Ortho-McNeill-Janssen | 4/28/10 | 30 | 40 live audits |
| Astra-Zeneca | 4/27/10 | 75 | 250 live audits |
| Pfizer | 8/31/09 | 60 | 200 live audits |
| Lilly | 1/14/09 | 50 | N/A |
| Cephalon | 9/29/08 | 30 | N/A |
| Otsuka | 3/25/08 | 10 | N/A |
| BMS | 9/26/07 | 30 | N/A |
| Jazz | 7/13/07 | 10 | N/A |
| Allergan | 9/1/10 | 30 | 75 live audits |

**Educate the Audit Team.** The audit team needs to be well-versed not only on their role and the company's compliance policies but also the science behind the products. Each product in a company's portfolio is unique with specific approved indications, known adverse events, precautions, and off-label risks. Approved promotional claims, materials, and educational items are constantly

changing. It can be next to impossible to keep up! Work with Medical, Legal, Regulatory, and other departments as necessary to obtain the most current information about the company's promoted products.

It is essential that the audit team receives the necessary training and materials to prepare them for the tasks ahead. A formal training program designed for the audit team should include information related to:

- Scientific information about the product(s)
- The scope and protocol of the audit
- Appropriate interactions with sales representatives
- Responses to questions from the representatives, doctors, and other individuals
- Appropriate behavior of the auditors (e.g. how to handle introductions, when to step in, whether or not it is appropriate to have an alcoholic beverage at a dinner program, etc.)
- Formalization of the observations

## Communication

**Set the Tone.** Add credibility and seriousness to the audit by setting the tone at the top. A message from the CEO or Senior Management will help to convey the importance and purpose of the audit and help ensure cooperation. It is also important to develop a broad-based communication plan that includes how and when the representative and his or her manager will be informed of the audit and how information will be communicated after the audit.

**Put the Sales Representative at Ease.** Before beginning the audit, the auditor should explain to the representative the purpose of the audit to help assure them that they are not being individually targeted. It may be helpful to focus the conversation on the audit as a company compliance initiative.

## Audit Results

Standardization of audit information helps to ensure consistency and provide guidance to future auditors. However, standardizing information can be difficult given the different situations that auditors may encounter. The audit team should hold regular status meetings as a forum to discuss concerns and initiate any changes that may need to be implemented into the current audit process. Status meetings also allow the auditors to express areas of concern that are considered out-of-scope. Out-of-scope observations are important because they may help shape future audit initiatives.

**Observations vs. Findings.** It may be helpful to categorize the results from the audit into "Observations" and "Findings" to better understand potential violations.

- Audit Observations – initial results that may have the potential to violate policy or law
- Audit Findings – confirmed violations of policy or law

## Five Helpful Hints

1. **Stay within scope.** Observations that fall out of scope may be incorporated into future audits. This does not mean that egregious behavior should be ignored, but rather handled outside of the formal audit. For example, if adherence to HR policies is out of scope and a violation is observed during a ride-along, it should be reported via the appropriate channels but not included within the finalized audit report.

2. **Make use of the available resources.** Auditing field forces that border the geographic vicinity of other field forces helps to reduce travel time and cost. When auditing multiple types of programs (e.g. ride-alongs and speaker programs), plan ride-alongs that are within driving distance of a speaker program for the same/next day.

3. **Develop protocols for handling cancellations and vacations.** Solidify a procedure for back-up auditors and representatives in case of vacation, sickness or emergencies.

4. **Limit the number of auditors.** Limiting the number of auditors will help to provide consistency of the observations and findings.

5. **Set a timeframe for follow-up with representatives and managers.** Provide notification to the parties involved on the progress and results from the audit within the communicated timeline.

Observations may result in the revision of policies, materials, or training to clarify the topic in question, whereas findings may be potentially used for follow-up investigations and disciplinary actions. Both observations and findings should be used for scoping future audits and should be incorporated into the audit plan for the following year(s).

**The Audit Report.** Once the audit is complete, it is important to put together a plan for follow-up actions. One way to think about this is to use a CAPA framework. The first step is to focus on the corrective action, which is an immediate response to the observed legal or policy violation. For instance, the audit team may refer a representative's conduct to the company's internal investigation process or may determine that follow-up communication be sent to the doctor correcting a false or misleading statement made by the representative. Each of these completed corrective actions should be documented in the audit report.

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The audit report should also look to uncover the root cause of the violation as part of the preventative action process. While companies may choose to handle this in different ways, one approach is to have the audit team hypothesize potential root causes and request that the audited function look to confirm the underlying cause. With this approach, the audit team may issue a recommendation such as "investigate training and communication regarding a specific claim."

Another way is to have the audit team research the root cause and develop specific recommendations to limit the likelihood of future occurrences such as "edit the fair balance policy" or "restate the messaging in the new hire training course." Regardless of the approach used, it is important to assign clear roles and responsibilities of who will be accountable for making sure the identified corrections are implemented.

At the end of the day, the most important thing is that there is follow-up on all of the findings from the audit to reduce the risk of the misconduct occurring again in the future. ■

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*For more information, visit www.potomacriverpartners.com or contact Jon Wilkenfeld at jwilkenfeld@potomacriverpartners.com.*