

Field-Based Monitoring: Mitigating Risk, Maximizing Success

■ By Wendy Heckelman, Ph.D.

This process allows a keen eye to be kept on desired skills and competencies.



Field-based monitoring is generally used by compliance departments to verify and ensure field behavior and activities are compliant with company standards. It is important to note that field-based monitoring can also provide tremendous value when integrated into everyday coaching of the sales field force.

Field-based monitoring can provide tremendous value when integrated into everyday coaching.

Compliance Field-Based Monitoring

All life sciences companies with commercial operations should perform field-based monitoring to ensure conduct and activities are compliant. A solid field-based monitoring program helps by placing the focus on areas of higher compliance risks, such as interactions with healthcare professionals and promptly addressing any potential issues. Field-based monitoring should be implemented due to recent Corporate Integrity Agreements (CIAs) issued for sales and marketing misconduct by the U.S. government. Field-based monitoring has been labeled as a key requirement in these CIAs. Mary Riordan, with the Office of the Inspector General, and other government

officials have stated that field-based monitoring is a minimum standard for effective compliance programs.

Maximizing Commercial Value

Field-based monitoring can be used to assess commercial operations and behavior, thereby providing more direct benefits to the business. The use of this process allows a keen eye to be kept on desired skills and competencies, such as customer focus and teamwork. By integrating field-based monitoring into the organization's marketing and sales functions, there is assurance that alignment on messaging and communications will be delivered to the field. Broadening the scope of traditional monitoring beyond areas of compliance enables the commercial organization to use field-based monitoring efforts to their advantage, thus providing greater benefit to the overall business.

Recommendations:

- **Concentrate monitoring resources, however limited, on areas with the greatest risk.** Perform an analysis of all sales and marketing activities to prioritize what is most likely to cause repercussions for the company. Also, pay attention and stay current on new trends in investigation and enforcement
- **Ensure field-based monitoring efforts meet the monitoring requirements of recent CIAs.** As noted above, these requirements should be considered a minimum standard for compliance programs

- **Inspect what you expect across the sales cycle.** Perform a regular review of what is being monitored. Determine if specific behavioral expectations for business planning, sales messaging, healthcare professional interactions and follow-up activities have been set. Monitoring can help position and reinforce behavioral expectations when examples are provided that include what can and cannot be done across the sales cycle.
- **Monitor data and behavior.** Other sources of data that provide information on customer interaction should be monitored regularly, i.e., call notes, requests for information and interaction with physician-owned distributorships (for anti-kickback violations). These data sources are increasingly used by the government during investigations and provide a more complete picture of field activities.
- **Broaden the focus of monitoring to benefit the business.** Going above and beyond the focus on criteria for traditional compliance monitoring will give the commercial organization additional and useful data. This will determine if there is alignment between corporate goals, performance management and monitoring criteria. Consider including desired competencies and skills.

- **Ensure effective reporting and follow-up procedures are in place.** Reporting should be designed to monitor trends and enable rapid response to potential compliance issues. Additionally, automated follow-up procedures will help close the loop on identified issues, reduce the workload, and limit the risk of manual steps.

In Conclusion

In summary, field-based monitoring is a critical tool/process used to reduce compliance risks. However, it also provides an organization with the opportunity to reinforce behavioral expectations across the sales cycle and is beneficial to the overall business.

Through broadening monitoring criteria and implementation efforts, a guaranteed result will be a more fully integrated and successful commercial operation. ■

Dr. Wendy Heckelman is president and founder of WLH Consulting, Inc. Email Wendy at wendy@wlhconsulting.com.

