

# MITIGATING COMPLIANCE RISKS ACROSS THE SALES EXECUTION CYCLE

Wendy Heckelman\*



U.S. Government regulators are focusing on a wider range of sales practices in their investigations of biopharmaceutical companies<sup>1</sup>. This point was explicitly made by OIG Senior Attorney, Mary Riordan at last year's Pharmaceutical Regulatory and Compliance Congress in Washington, D.C. In her talk on the OIG's enforcement priorities for the coming year, she stated that companies should be looking at all aspects of interactions with customers and use "creative effective auditing" of different sources of data (such as communications and call notes) to get a more complete picture of their company's activities. Thus, companies need to identify and mitigate risks across the full range of sales' job functions, not just when they are out in the field working with health care practitioners (HCPs) or health care organizations (HCOs). This article provides recommendations to help compliance and sales leaders develop an effective risk mitigation strategy across what we call, the "sales execution cycle."

## ■ The Sales Execution Cycle

To get an accurate portrayal of sales professionals' activities, think of a cycle of execution that runs from planning to implementation, and then to follow-

up and recalibration (see Figure 1, on the next page). Planning involves the creation of business plans, including target identification and determining future actions needed to reach sales goals.

\* Wendy Heckelman, PhD, President and Founder of WLH Consulting, Inc.

1 This article focuses on US regulatory and legal requirements, so all references to the government and to government officials refer to the US government. The recommendations have global relevance, however, because similar requirements exist across countries and jurisdictions.

## MITIGATING COMPLIANCE RISKS ACROSS THE SALES EXECUTION CYCLE



Figure 1.

Implementation is the actual execution of those planned activities. Follow-up and recalibration include the tracking of sales activities, reporting, and closing the loop on performance or compliance related issues.

An effective risk mitigation strategy considers activities across the sales execution cycle. Start by determining key risk areas for your company with a risk assessment that looks at both policies and behaviors. Looking across the cycle, review your compliance policies to ensure that they are clear and provide sufficient guidance to enable (not paralyze) the field to effectively conduct business activities. Next, also across the cycle, look for any gaps between policies and actual organizational behavior.

To guide your efforts, we have created recommendations for each stage of the sales execution cycle. These include best practice recommendations for training, monitoring, and documentation. Use these recommendations to ensure that you have a sufficiently broad lens to examine and address areas of risk.

### Planning

During business planning, a sales organization chooses sales activities performance to drive desired results. At a minimum, these planned activities must be consistent with all regulations and guidelines that govern sales behavior<sup>2</sup>. To provide a few obvious examples, there should never be a plan for having off-label discussions with healthcare providers or to use Speaker Programs to increase access to healthcare organizations. Also, all identified targets (and their patient populations) must be consistent with the product label and indication.

Make sure the entire sales organization is not only trained to develop compliant business plans, but also to properly document planned activities. For example, compliant business plans must be documented in an unambiguous fashion to avoid misinterpretation. Sales professionals should understand that during an investigation documents may be subpoenaed and read out of context by potentially “unfriendly” audiences. For instance, no statement in a business

2 These include external laws and regulations including the False Claims Act, FDA Regulations, OIG Regulations, external guidances such as the PhRMA Code, and internal company policies.

## MITIGATING COMPLIANCE RISKS ACROSS THE SALES EXECUTION CYCLE

plan should give the impression that the company is putting profit or gain in front of patient health considerations.

Regular internal reviews of all business planning documents should also be conducted with immediate feedback given on any areas of potential concern.

### **Implementation**

Start your examination of the implementation stage of the sales execution cycle with what sales professionals are trained to do. All sales training should communicate and reinforce clear behavioral expectations for driving revenue growth within compliance guidelines. When behavioral examples are identified and provided at the product level they are also more practical, which makes it easier for sales professionals to apply them to their daily activities. This focus on both compliance and sales performance also facilitates cross-functional collaborations between sales and compliance leaders and helps

compliance become part of how good business is done.

Training on sales execution should also incorporate learning best practices. These include a focus on behavioral skills (what you *do and don't* want to see), enabling practice and feedback, and ensuring reinforcement for desired behaviors<sup>3</sup>. For example, you may not be reinforcing compliant behavior if your incentives are giving the message to “sell at any cost.”

Ensure training is updated regularly to maintain relevance with the latest trends in government investigations. These trends currently include looking for subtle off-label selling behaviors, such as targeting inappropriate patient populations, and more nuanced false claims, such as making unsubstantiated claims of economic superiority over other products<sup>4</sup>.

Next, connect your training and monitoring programs so you “inspect what you expect.” Your monitoring

---

3 Ajzen, I. (1991). The Theory of Planned Behavior; Bandura, A. (1977). Social Learning Theory; Baldwin, T.T. & Ford, J.K. (1988). Transfer of Training; Gagne, R. & Driscoll, M. (1988). Essentials of Learning for Instruction.

4 Bloom, S. (2012, May 29). Veteran Prosecutor puts Spotlight on Managed Care Payor Relationships. *Rx Compliance Report*, XI(2), pp. 14-16.

## MITIGATING COMPLIANCE RISKS ACROSS THE SALES EXECUTION CYCLE

program for field behavior should include the usual suspects that have previously gotten companies into trouble. That is, monitor healthcare provider interactions, requests for off-label information, requests for funding, and sample distribution. However, keep your monitoring program current by heeding Riordan's advice (above) and ensure you examine all types of interactions with health care providers and organizations because the government is starting to pay more attention to the latter, e.g., interactions with payors, P&T committee members, and physician-owned distributorships for potential anti-kickback violations. In addition, monitor data that could "connect the dots" or reveal trends in field behavior, e.g., undue numbers or irregular patterns of HCP requests for medical information or adverse events. Monitoring should also include verification that appropriate, approved sales and marketing materials are being used for the right audiences. Most companies already strictly prohibit the altering of

internally approved marketing materials; however, where field professionals call on multiple types of HCPs, are they using the appropriate materials prepared for each type?

There is an additional benefit to expanding the scope of your existing monitoring program. Regular and broad monitoring can make your entire compliance program more effective because it reinforces the notion that compliant behavior is an ongoing expectation. As stated above, it becomes integral to the way that good business is done.

Finally, as for business planning above, the sales organization needs good documentation practices for recording field behavior (call notes, emails, etc). Documentation training should clearly convey what can and cannot be recorded and where. Monitoring of documents should include a review process for emails and call notes, especially if they include free text. Some companies<sup>5</sup> have managers review call notes and have systems perform word searches to identify potential issues.

---

5 Weinstein, B. (2012, August 24). Veteran Compliance Officer Outlines Key Ingredients for Effectively Engaging the Business. *Rx Compliance Report, XI(8)*, pp. 12-15.

## MITIGATING COMPLIANCE RISKS ACROSS THE SALES EXECUTION CYCLE

### **Follow-Up and Recalibration**

Good follow-up and recalibration efforts are a critical component of an effective compliance program because they demonstrate a commitment to reinforcing compliant behavior, both internally and externally. Sales managers should play an important role in these efforts. In most companies, managers already conduct field rides to monitor activities and give feedback on sales performance. Expanding their role to include monitoring of compliant activities across the sales cycle, e.g., reviewing business plan documents and other organizational behavior, has multiple advantages. These include reinforcing the notion that compliance is integral to good business and making managers part of the larger compliance team. Of course, additional audits should also be conducted, e.g., by compliance or third-party auditors to verify managers' findings using an "external" perspective. To help managers with these additional monitoring responsibilities, they need to be trained on proper monitoring,

coaching, and feedback procedures, as well as how to properly document these activities. When managers' monitoring, coaching, and feedback reports are fully completed and show follow-through on recommendations regarding any potential compliance issues, the company demonstrates a proactive stance towards addressing compliance issues.

Companies should not fear documenting their follow-up on compliance issues. In fact, recent settlements and CIAs have shown that the government treats companies more favorably if they find the company had already discovered unfavorable practices and was working to proactively address them. For example, instead of having to comply with burdensome externally imposed requirements in a very tight timeframe, companies have been allowed to continue with existing proactive procedures they already had in place<sup>6</sup>.

Make sure there are closed loop procedures in place for following up on all potential issues identified through monitoring so that nothing falls through

---

6 Kelton, E., Kenney, B., & White, M. J. (2012, August). GSK's \$3 Billion settlement marks largest healthcare fraud resolution in history, *Rx Compliance Report*, XI(6), pp. 1-8.

### MITIGATING COMPLIANCE RISKS ACROSS THE SALES EXECUTION CYCLE

the cracks. These should include following up and addressing internal whistleblower concerns before they are taken outside (whistleblowers almost always report internally first<sup>7</sup>). The costs of not addressing these procedures continues to rise for companies and individuals, e.g. the recent GSK CIA provision that can recoup bonus compensation for executives or their subordinates for “significant misconduct” on their part or on the part of others<sup>8</sup>.

A critical part of the closed loop procedures are proper documentation of all actions taken and final resolutions. Don’t forget to record that final coaching session or audit report showing that the issue had been resolved.

Create timely and complete reports on the findings from monitoring efforts and follow-up actions. Bring together behavioral and data monitoring results to provide a more complete picture of how sales execution is actually occurring, per Riordan’s recommendations above.

Distribute these reports to all individuals with “signing authority” in the company to enable them to certify with confidence that compliant behavior is occurring in the organization. This also enables individuals throughout the organization to take personal responsibility for compliant behavior by monitoring and acting on any potential compliance risks.

You should also conduct periodic risk re-assessments using the data from internal monitoring as well as trends in government investigations and the most recent CIAs. For example, GSK’s most recent CIA<sup>9</sup> requires the company to continue a self-initiated change in their compensation model where sales representatives’ incentives are no longer tied to the prescriptions that physicians write. Companies should carefully consider the risks of not proactively changing their incentive compensation model. At the very least, compliance input should be sought for any new changes in sales representatives’ incentives.

---

7 Slade, S. (2012, February, 29). Facilitating Disclosure and Prohibiting Retaliation: Perspective of a *Qui Tam* Plaintiffs’ Council, *Rx Compliance Report*, XI(1), pp. 12-14.

8 [http://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline\\_LLC\\_06282012.pdf](http://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline_LLC_06282012.pdf)

9 [http://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline\\_LLC\\_06282012.pdf](http://oig.hhs.gov/fraud/cia/agreements/GlaxoSmithKline_LLC_06282012.pdf)

## MITIGATING COMPLIANCE RISKS ACROSS THE SALES EXECUTION CYCLE

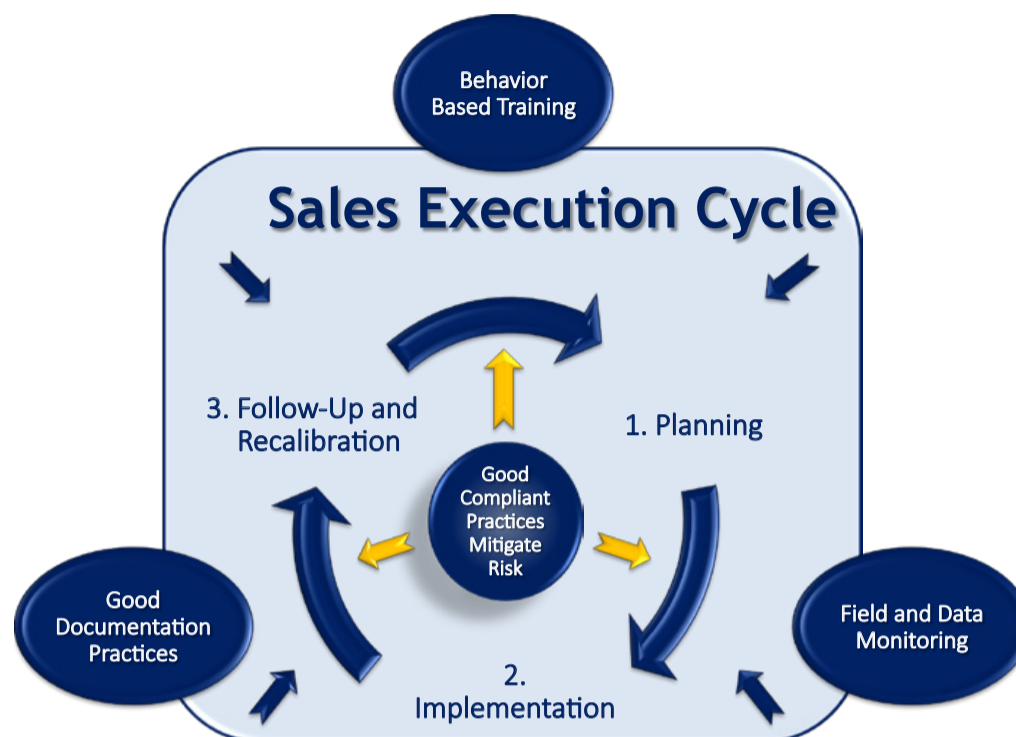


Figure 2.

Share all additional information about identified risks throughout the organization to ensure a coordinated, proactive stance and prevent compliance violations. For example, ensure any instructions or warning letters from the FDA are communicated throughout the organization (especially between marketing and sales).

Finally, use the results of your risk assessments and monitoring efforts to recalibrate your compliance program. Do your policies need to be clarified or updated? Are your training programs effective? Are monitoring, follow-up, and reporting procedures giving you the information you need and enabling you to respond quickly and effectively to mitigate risks?

### Connecting the Stages of the Sales Execution Cycle

Behavior based training, field and data

monitoring, and good documentation practices are essential components that connect the stages of this cycle together and reinforce a culture of compliance throughout the sales organization (see Figure 2). As defined in the paragraphs above, these additional components play an important role in risk mitigation throughout the three stages of the sales execution cycle. Other best practices for training, monitoring, and documentation include:

- Cascading learning from the top. When senior leaders deliver or co-facilitate training to managers it helps them walk the talk and reinforces the desired culture change. It also has the added bonus of helping address compliance violations that occur at different levels of the organization (not all violations occur in the field<sup>10</sup>).

10 Compliance and Ethics Leadership Council (2006). Key Findings of Compliance Failure Analysis. Corporate Executive Board. [www.celc.executiveboard.com](http://www.celc.executiveboard.com)

## MITIGATING COMPLIANCE RISKS ACROSS THE SALES EXECUTION CYCLE

- Keeping all business writing clear and factual to ensure it cannot be used against the company at a later date. For example, avoid the expression of opinions and/or emotion in all business plans, activity documentation, and colleague appraisals.
- Involving managers in regular monitoring and feedback of direct reports, at all stages of the cycle, to reinforce local ownership of responsibility for compliant behavior. Involve all managers, including senior leaders in this practice to further reinforce behavioral expectations (i.e., from the top-down).
- An effective risk mitigation strategy for pharmaceutical sales organizations considers activities across the sales execution cycle, not just when representatives are in the field
- Ensure there are policies that are clear and enable (not paralyze) effective actions, then look for gaps between policies and activities at each stage of the cycle
- Ensure that business plans are created in a compliant fashion and that target lists are consistent with product indications
- Provide compliant documentation training that includes what good business plan language looks like and what sales activities can be documented and where
- Create and communicate clear behavioral expectations with leader-led learning cascades to reinforce a culture of compliance at all levels of the organization
- Involve managers in field monitoring efforts to enhance local ownership of compliance

### **Key Takeaways**

Your compliance efforts should have a broad enough lens to address all potential areas of risk and encourage active field participation and ownership to make compliance an integral part of how good business is done.



## MITIGATING COMPLIANCE RISKS ACROSS THE SALES EXECUTION CYCLE

- Expand your monitoring to include all types of interactions with health care providers and organizations, as well as data that could reveal trends in field behavior
- Create procedures that close the loop and document all actions taken to follow-up on potential compliance issues

Applying these practices with help ensure your organization is compliant across the cycle of sales execution. ■

---

Dr. **Wendy Heckelman**, President and Founder of WLH Consulting, Inc. has over 20 years of experience working with Fortune 100 clients in the areas of pharmaceuticals, animal health care, consumer health care, biotech, and others. WLH Consulting, Inc. has worked with biopharmaceutical sales organizations on all stages of the Cycle of Execution. Please feel free to contact Dr. Wendy Heckelman to learn more about how to create a culture for compliant sales practices in your organization. Call 954-385-0770 or email at [wendy@wlhconsulting.com](mailto:wendy@wlhconsulting.com).

---