

Finding the Golden Nuggets - OIG-HCCA Recommendations for Smaller Life Science Companies

by Carla-Marie Ulerie, Eric Davis, and Jon Wilkenfeld¹

Abstract: Recently the OIG and the HCCA published a resource guide with recommendations for determining if a compliance program is effective. Since small to mid-sized pharma and medical device companies typically operate with limited compliance staff and financial resources, we identified recommendations that were relatively easy or low cost to implement but were rarely adopted. Based on our review we have determined the “golden nuggets” from that guide.

The Department of Health and Human Services, Office of Inspector General (“OIG”) and the Health Care Compliance Association (“HCCA”) published a Resource Guide to provide a “large number of ideas for measuring the various elements of a compliance program.”² The 15,000-word document is based on the OIG’s “Seven Elements” and includes a landscape of recommendations for a wide range of organizations. The Resource Guide encompasses everything from fundamental principles well known to most experienced compliance professionals to some novel ideas worth exploring.

To help busy compliance professionals make the most of the Resource Guide, we sifted through the guidance and distilled the most critical “golden nuggets” for small to mid-sized life sciences companies to consider during the building or maintenance phases of developing a compliance program. We presented the top recommendations discussed below at CBI’s Pharmaceutical Compliance Congress.

Scope and Methodology

Since smaller pharma and medical device companies typically operate with limited compliance staff and financial resources, we identified recommendations that were relatively easy or low cost to implement but were rarely adopted. We intentionally omitted basic compliance program elements such as Code of Conduct, hotline, and risk assessments, because while critical, we presumed these to be well-known concepts. These well-known building blocks of a compliance program need to be completed before undertaking more advanced objectives.

For reference, the numbers in parentheses following various recommendations refer to a specific section within the Resource Guide.³

Building a Compliance Program – Six Golden Nuggets

When a smaller company begins the substantial undertaking of building a compliance program, we determined that there were six (6) essential considerations or “golden nuggets.”

1. Human Resources Integration

Intertwining compliance with Human Resources (“HR”) was identified as a key aspect of demonstrating an effective compliance program. We agree that one of the most important roles of the compliance officer is to partner and collaborate with their counterpart in HR. A unified message leads to greater adherence to core principles. We also acknowledge that achieving this “ideal state” can be challenging and requires both transparency and patience.

To help create a unified message, the Resource Guide recommends including compliance terminology in job descriptions (4.36, 6.33, 6.34). Once documented, tie compliance objectives to the performance review process, including employee recognition, bonuses, and

promotions (2.48, 2.54). Along the same lines, companies should be recognizing employees' positive compliance efforts in non-monetary ways such as newsletters or website announcements (6.20). To facilitate employees' understanding of compliance goals from the outset, the Resource Guide recommends that employees receive orientation on the code of conduct and compliance policies within 30 days of hire (1.46) and look to further embed compliance into onboarding activities. Finally, exit interviews are opportunities to request information regarding compliance concerns from departing employees (2.63).

2. Accessibility and Writing for Clarity

Many compliance policies contain lengthy legal language. While the resulting policies may cover everything required by the various regulatory bodies, frequently they do not resonate with employees who do not have a legal background. While much is delivered, little has been communicated.

The HCCA and OIG recommend a Flesh-Kincaid "10th Grade" reading level.⁴ This standard may be tough to achieve given the nature of some policy documents, so we would recommend aiming for a 12th-grade level, which is still categorized as "fairly difficult to read" according to the Flesh-Kincaid scale. In our experience, we've found that many policies are written above a 15th-grade level. As the reading level increases, comprehension declines. We recommend companies at least understand the readability of their policies. Microsoft Word can provide information on the Flesh-Kincaid rating of a document by selecting "show readability statistics" under the proofing options.

Companies may also want to consider recommendations pertaining to American Disabilities Act compliance (4.16), translation into foreign languages (1.22), and the ability to access the policies, when needed (1.5). Overall, the message is simple – make sure that employees know where to find your documents and when they do, they understand what they've read and know where to ask further questions.

3. Annual Employee Survey

To help determine whether a compliance program is working, companies can solicit employee feedback on compliance initiatives. We agree with the Resource Guide that surveying employees proves valuable. Short surveys can be conducted annually using low-cost,

anonymous online tools. And perhaps more importantly, the results can be tracked and analyzed over time, to better understand the compliance program's progress and effectiveness across years.

Of the many questions offered in the Resource Guide, we identified two main categories – to gain feedback on the implementation of the program, and assess the perception of the compliance culture.

Companies should ask whether employees believe:

- Compliance documents and communications are accessible and understandable (1.1, 1.4, 4.16)
- Policies help them do their jobs effectively (1.23).
- Training is appropriate for their position (4.21) and effective (4.17, 4.40)
- Risk assessments identify the significant risks (5.34)?
- Whether established controls help prevent compliance violations (6.17).

When evaluating the perception of an organization's compliance culture, the HCCA and OIG suggest several useful questions like asking about the roles of the compliance officer and compliance team, the approachability of compliance staff (4.41), and the general sentiment towards compliance staff as either solution facilitators or a police force (2.31). There could also be questions about the general compliance culture (4.46), impact of the compliance department (2.41), the existence and awareness of compliance reporting channels (5.11, 5.17), experience with retaliation (5.76), and trust in the system (5.3).

4. Independent Compliance Officer

Companies in the process of building their compliance programs should look for ways to empower the Compliance Officer. The HCCA and OIG recommend that the Board should review and approve the compliance workplan and budget (2.6). The Compliance Officer should then have the freedom to operate within the approved budget to address areas of risk. The Compliance Officer should be able to submit material directly to the Board without CEO approval (2.27). Having the Board approve the compliance budget and workplan not only provides high-level buy-in but also helps the Compliance Officer maintain independence. The Compliance Officer should also be part of key corporate initiatives such as the strategic planning process and due diligence of acquisitions (2.22).

While all of these recommendations are sound, we note that this is an area where many companies struggle. Issues of control and responsibility are often the most difficult ones to traverse in the corporate arena.

5. Appropriate Location and Compensation for Compliance

In line with the HCCA and OIG, we support a compliance function that places compliance personnel on equal footing with other business functions (2.27, 2.38). Far too often, companies locate compliance professionals apart from other business functions or at too low a level within the organization to really affect outcomes. The Resource Guide recommends that senior teams sit together (2.27). Prosecutors have commented that they consider the physical location and organizational status of compliance when assessing the effectiveness of a compliance program as part of an investigation.

Compliance teams should also be compensated and receive promotions in a similar manner as other General and Administrative functions such as Human Resources, Finance, or Legal. Relegating compliance personnel to the basement, paying them less than other corporate functions, and not granting them senior titles all reflect negatively on the existence of a bona fide program.

6. Document Retention

Compliance Officers understand that maintaining records is a required element of the job. The Resource Guide identified a few additional types of documents that, if retained, would aid in tracking and evaluating the effectiveness of a compliance program as it develops. These include:

- Efforts to maintain the skills and competencies of compliance staff (4.43)
- Documents displaying compliance staff knowledge of regulatory and legal changes (2.57)
- Informal presentations (4.26, 4.31)
- Employee and Compliance Committee engagement (2.17, 4.38)

Additionally, Compliance Officers should retain all presentations delivered to the Board of Directors (Board), including meeting minutes (1.11). In that way, organizations may clearly track plans that received Board oversight and approval, as well as conclusively demonstrate Board engagement.

Maintaining a Compliance Program – Four Additional Golden Nuggets

As we have experienced, compliance is not a once-and-done program. An effective program takes continuous dedication and effort. Here too, the Resource Guide has golden nuggets worth mining.

1. Enhanced Governance

Once the building mechanisms are in place, the organization must continue to refine its compliance program. The Resource Guide notes the importance of tying the budget, compliance plan and staffing levels based on the level and types of risk (2.7, 2.8, 2.35). The company must also monitor regulatory changes to make sure new laws, guidance, and risks are covered (2.57, 2.58). Organizations also need to hold leadership accountable and ensure they are engaged and add value (2.15, 2.9, 2.17, 6.24), not just holding spots on committees. The Resource Guide recommends Compliance should evaluate senior executives' behavior, especially when the executive is considered for promotion (6.33).

2. Compliance Interviews

Compliance personnel should actively engage with other business functions as they maintain the company's compliance program. The HCCA and OIG recommend moving beyond surveys and suggest interviewing employees. One recommended area is to test whether employees understand company policies (1.21), although we recommend expanding this to cover all compliance communications, including training. The HCCA and OIG also discuss the value in performing exit interviews with vendors (3.24). Third parties offer a fresh perspective and have the freedom to be more candid. This new perspective is invaluable where, in the age of the whistleblower, what you don't know can hurt you.

3. Robust Corrective and Preventive Action Process

We believe an effective corrective and preventive action ("CAPA") process, that goes beyond quality and which is directed by management (5.57, 5.66) is crucial to an effective compliance program. Documenting violations, investigating, retraining (4.10) or delivering other disciplinary action is essential to maintain a program's credibility. The Resource Guide recommends developing dashboards for the Compliance Committee and Board of

violations and corrective action taken (6.22, 7.40). Using dashboards helps close the compliance loop from planning through identification to investigation and follow up.

4. Document Auditing

The OIG and HCCA recommend an organizational audit of various items, not always included in traditional life science company audit plans, including:

- Board Minutes (1.11)
- Compliance Committee attendance records (2.12)
- Accessibility of policies (1.1)
- Disciplinary records (2.51)
- Job descriptions (3.6)
- Training records, including third-parties (e.g., Vendors) (3.33)
- Exclusion checks (3.21, 3.37) and
- Implementation of CAPAs (5.37)

Most of these areas tie directly into topics covered earlier in this article. For example, mature compliance programs should review job descriptions to test the lasting impact of “HR Integration” and click on links to policy documents to make sure they are still accessible. Similarly, if the program is truly effective, an audit of Board minutes would show approval of the compliance budget by the Board

and a review of CAPAs would show that management consistently implements recommendations identified by previous audits. In other words, don’t forget to test that what you implemented during the “Building a Compliance Program” phase still works as the company matures.

Conclusion

We recognize that building and maintaining an effective compliance program can be particularly challenging for smaller life sciences companies expected to “do more with less.” We aim to help companies strengthen their compliance program in practical ways that add value without burdensome cost. The Resource Guide provides practical advice in several areas for companies looking for simple, practical ways to get the most out of their compliance program.

References

- 1 Ms. Ulerie and Mr. Davis are a Manager and Analyst respectively with Potomac River Partners. Mr. Wilkenfeld is the company President.
- 2 See HCCA-OIG Compliance Effectiveness Roundtable, Roundtable Meeting: January 17, 2017, Washington DC. *Measuring Compliance Program Effectiveness – A Resource Guide*, at 1 (Jan. 2017).
- 3 A cross-listing of these topics can also be accessed on the Potomac River Partners webpage (<https://potomacrivpartners.com/potomac-thinking/publications/>).
- 4 *The Flesh-Kincaid Grade Level Formula is a readability test designed to indicate how difficult a passage in English is to understand, where the score is presented as a U.S. grade level. The prior sentence scores a 16.2.*



PotomacRiver
PARTNERS

703.430.5944

www.potomacrivpartners.com

Carla-Marie Ulerie

cmulerie@potomacrivpartners.com

Eric Davis

edavis@potomacrivpartners.com

Jon Wilkenfeld

jwilkenfeld@potomacrivpartners.com

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