



Assessing Compliance Priorities: Considerations for Conducting an Effective and Collaborative Compliance Risk Assessment

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Opening Disclaimer

The views expressed by all of us are merely personal opinions. They do not necessarily reflect the views of our current or past employers.

Nothing we say should be considered legal advice.



Why Conduct a Compliance Risk Assessment?



Always better to be proactive vs. reactive



Identifies compliance risks



Allows for prioritization of risk areas



Evaluates the effectiveness of existing compliance program/framework



Identifies gaps in compliance



Facilitates allocation of resources



Government recognition (“credit”) in the event of investigation


Major Risk and Enforcement Areas for Life Sciences Companies

FDA

Kickbacks

False Claims

Privacy



7 Elements of an Effective Compliance Program (2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers)

- Designated compliance officer and compliance committee; senior management involvement
- Written policies and procedures
- Training
- Open communication; raising concerns/issues
- Response to compliance concerns/corrective action
- Enforcement of written policies/standards
- Internal audits/monitoring

DOJ Guidance for Evaluating Corporate Compliance Programs (updated 3/23)

➤ DOJ's expectation

- To assess the effectiveness of a company's compliance program, DOJ will consider three "fundamental questions"
 - *Is the company's compliance program well designed? ***
 - *Is the program being applied earnestly and in good faith? Is it adequately resourced and empowered to function effectively ?*
 - *Does the company's compliance program work in practice?*

*** more about this later*

"Even a well-designed compliance program may be unsuccessful in practice if implementation is lax, under-resourced, or otherwise ineffective. Prosecutors are instructed to probe specifically whether a compliance program is a 'paper program' or one implemented, resourced, reviewed, and revised, as appropriate, in an effective manner."

30,000 Foot View . . .

➤ Questions to ask:

- Are we considering the right risks?
- Are/how are we limiting risks?
- Are we mitigating risks/preventing them from reoccurring?



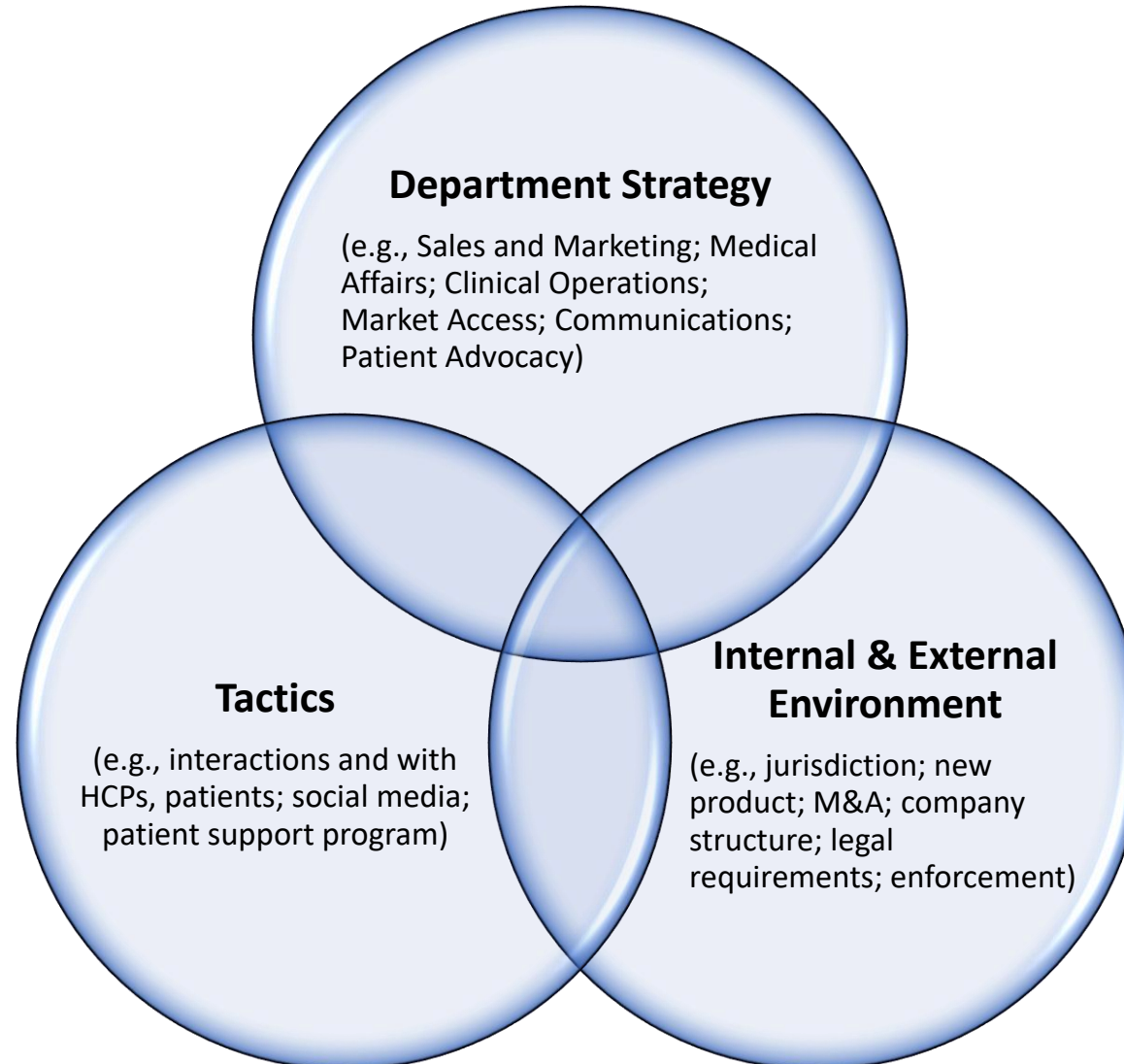
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Planning for a Risk Assessment

- Identify areas to be addressed
 - Enterprise compliance risk or focused risk areas (i.e., HCP engagement, Transparency/Sunshine, Privacy etc.)
- Consider methodology & approach
 - Document review
 - Interviews with stakeholders
 - Consideration of past identified risk areas/history of compliance violations
 - Budget and resource considerations/need buy-in from senior leadership/project manager (need one “point person”)
- What is your deliverable and how/who/where will it be shared?

Understanding the Business



Assessing your Current State (of compliance)

How is Compliance viewed by the organization?

Do you have a compliance program structure in place?

Do you have a Code of Ethics?

Do you have policies/procedures?

Has training been done at all levels (including the Board level & Senior Management)?

Are employees aware of the rules?

Do employees understand the rules?

Do you have review committees?

DOJ Risk Assessment Analysis

“Prosecutors should also consider ‘[t]he effectiveness of the company’s risk assessment and the manner in which the company’s compliance program has been tailored based on that risk assessment’ and whether its criteria are ‘periodically updated.’”

Risk Management Process

- *What methodology/metrics has company used to identify, detect and address risks?*

Risk-Tailored Resource Allocation

- *Does company devote the appropriate amount of time to the correct risk areas?*

Updates and Revisions

- *Is the risk assessment current/subject to periodic review? Is it just a snapshot in time? Has the review led to updates in policies, procedures and controls?*

Lessons Learned

- *Does the company have a process for tracking lessons learned from its own issues or from other companies’?*

Developing a Compliance Risk Matrix

Identify risks

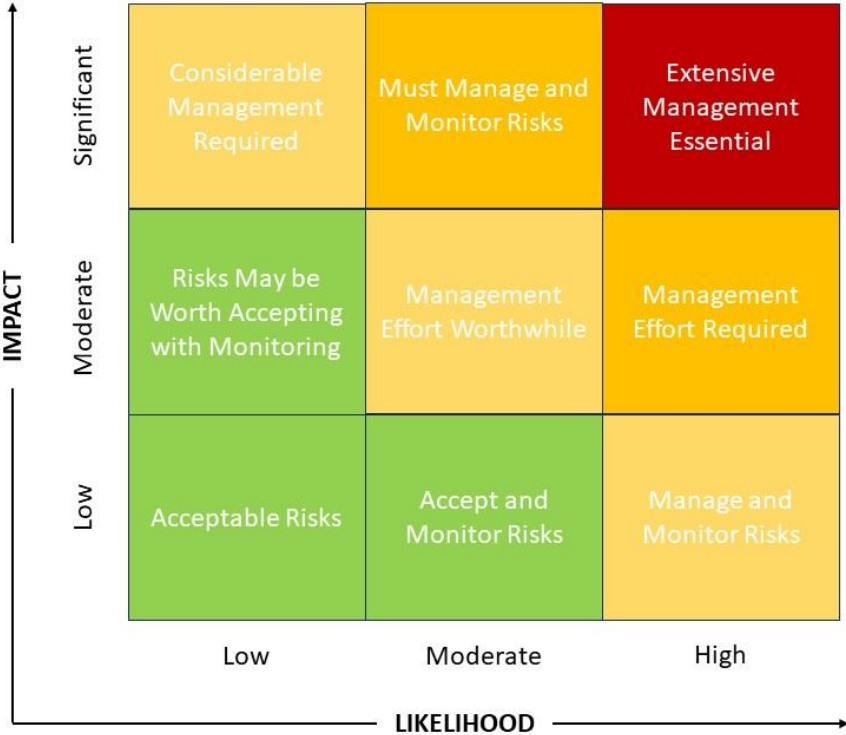
Prioritize and measure risk based on:
-Probability of occurrence
-Severity of Impact

Evaluate/Confirm appropriate controls or strategies to minimize the risk

The structure of your company will likely drive your risk profile

Use as a tool in the decision-making process

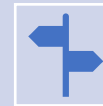
RISK ASSESSMENT



Developing Priorities and Timelines



How will the “results” of the risk assessment be communicated within the company?



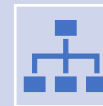
What will the company do to manage the risk(s) (policies, training, monitoring, etc.)?



What resources does the company have to manage the risk?



When will implementation take place?



What role will everyone play?

Hypothetical #1

You are a compliance attorney at a growing company that is about 10 months away from receiving FDA approval of its first product. You are responsible for leading the build of the company's compliance program and you think that it would be prudent to conduct a company-wide healthcare compliance risk assessment to assess the company's current and future potential risks and evaluate its needs.

- **What (additional) considerations, if any, are necessary to contemplate as the company approaches commercialization?**
- **How would you begin the risk assessment process?**

Hypothetical #2

Your company, which is subject to transparency reporting and disclosure requirements, has just acquired another company what is also subject to these requirements. As you look to integrate operations you have determined that it would be helpful to conduct a transparency risk assessment to assess each company's compliance approach with these requirements.

- **How would you approach this risk assessment?**
- **Which individuals at your company do you think you will need to get onboard, or buy-in from to be able to effectively conduct this assessment?**

Potential Benefits of doing a Compliance Assessment



Compliance efforts become more effective



Reduce Legal/Compliance Risk



Save \$\$\$ (Legal fees, penalties, settlement costs)



Improve Reputation



Improve company culture



Manage and mitigate existing and new risk areas



WILL HELP YOU SLEEP AT NIGHT

Questions/Ideas?

