

cerulean's
SMARTER COMPLIANCE™ 

Competitive knowledge and know-how for senior executives and governance boards

SUMMARY

Addressing information integrity; using a strategic vendor matrix to grow your business; meeting tips; preparing your people — not just your facility — for an audit; writing to learn and our calendar of upcoming events.

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Information Integrity

Last year, 95% of all regulatory enforcement focused on one topic: the integrity—or lack thereof—of a company’s information. What are the steps to prepare for an inspection of information integrity?

With our clients we recommend a practical approach using four key themes:

1. Clarity of accountabilities
2. Clarity of expectations
3. Simplicity of risk control
4. Transparency of knowledge

Clarity of Accountabilities

As a company leader, you are in charge of setting out the accountabilities of each department within your firm. Set down these accountabilities in writing. These do not need to be detailed job descriptions, etc., but rather, brief statements on who is accountable for what aspects of capturing, maintaining and archiving information.

At a minimum, you will want your information technology group, your regula-

tory compliance team and your legal department involved.

As simple as this sounds, we have repeatedly found that companies struggle with their operational aspects. Continue to check-in with your teams to ensure mutual agreement on accountabilities and expectations.

Clarity of Expectations

Hand in hand with an understanding of accountability, you—with your teams—need to lay out expectations for your company’s level of confidence when it comes to data quality. We recommend you adopt, *at minimum*, the same standards of confidence you expect from your product, whether that’s 95% accuracy and reliability, 98% accuracy and reliability, etc.

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Strategic Vendor Selection

With the exception of start-ups, most businesses have a vendor qualification process. Ironically, what nearly all of these businesses do not have, is a strategic process to verify that the supplier is a “good fit” for the business and its strategic goals. Given the industry average cost of a qualification—\$5,000—8,000 (USD)—consider first developing a system that will determine if any potential

vendor, supplier, consultant, etc. is a good match for you and your business objectives.

To do this, utilize our **Strategy-Impact Matrix™**.

Step One: Prioritize Strategies

First, sit down with the rest of your team and lay out a prioritized list of

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Information Integrity

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Simplicity of Risk Control

The challenge here is not to “dumb down” your firm’s risk management methods, but rather to identify those elements applicable to each group’s set of information accountabilities. Each of your teams (and their individual members) should know enough to recognize a potential risk when an unknown unknown (or “unk-unk” as they are called in product development) arises. At that point, your documented risk assessment and control policies start.

Transparency of Knowledge

There are two challenges with this strategy: first, ensuring you have data and accountability transparency; and second, ensuring that each of member of your company has the know-how to recognize and tackle new situations as your business evolves.

Data and accountability transparency can be addressed by combining the concepts of flowcharts and organizational charts, tracing the proof of patient safety and product efficacy through various levels of management and personnel (for accountability) and through system levels for data. Then, correlate the two charts so that you can draw the relationships between them; the goal is to identify, at any time in the infor-

mation’s life, who in your organization is accountable for it.

Ensuring your teams have the know-how to recognize and tackle new situations as your business and marketplace evolve is a long-term commitment that comes with maintaining information’s long lifespan. Tactics to handle this will depend upon each group’s accountability, but several principles apply. Training may be an obvious one, but so is continued awareness of industry trends and best practices.

If you are running lean and cannot devote the time constantly assessing industry trends and best practices, consider asking a third-party for a summary document of items that might be applicable to your company and the information you guard.

For companies whose entry of new products into the regulated marketplace hinges upon a review of information proving product safety and efficacy, data integrity is the quiet elephant lurking in the corner.

Are you ready?

For more insights and advice, see the Cerulean website.
 (www.ceruleanllc.com)

“The challenge is to ensure you have information and accountability transparency.”

Competitive Tactics: Running an Effective Meeting

Practical tips to put in use today

Improve your company’s meeting effectiveness by:

- *Closing the meeting with a clear summary and action plan.* By reviewing the meeting, and then setting out the follow-ups, you make sure good ideas and necessary action items are not forgotten.
- *Carving out micro-meetings.* Set aside 10-minute segments during your day to discuss specific items—new product launches, weekly reports, etc.—with the specific people or small groups involved. Doing this before a larger meeting will allow you to modify the agenda of the larger meeting should anything pressing come up as a result of the micro-meeting.
- *Providing meeting guidance.* Lay out rules that cover the basics: when to call meetings (versus when other approaches will work just as well), how to prepare an agenda, how to encourage participation, and how to resolve differences.