

# Preparing for an Inspection of Information Integrity

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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 my clients, I 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 (IT/ICT), your regulatory compliance team and your legal department involved.

As simple as this sounds, I 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. I 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.

## 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-unks” 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:

1. Ensuring you have data and accountability transparency; and

2. 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. Trace the documented proof of patient safety and product efficacy through various levels of management (for accountability) and computer systems (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 information's lifecycle, who in your organization is accountable for its integrity.

## Final Thoughts

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 to constantly assess 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. You may also want to have the outside expert to conduct an information integrity audit preparation best practices workshop .

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?*

More recommendations and compliance strategies are on the Cerulean website ([www.ceruleanllc.com](http://www.ceruleanllc.com)).

## About the Author

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