Insight Brief

DISTINGUISH YOURSELF WITH RISK-BASED SUPPLIER INSPECTIONS

ROXANE NAPOLI, Associate Director, Product Marketing, Quality Compliance Solutions, IQVIA

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INTRODUCTION

The life sciences industry is increasingly leveraging external suppliers as companies strive to become more flexible and nimble in meeting market needs. However, in most situations, this model does not relieve a company's compliance liability or risk.

Optimization of supplier quality management processes can provide companies with room to differentiate themselves from their competitors and gain advantages in the industry. However, optimization cannot not happen without regard for potential risks inherent within complex supply chains or ever-evolving regulatory requirements.

The key is to circumvent potentially adverse situations before they become realities. By minimizing supplier-related risk, you can maximize compliance and quality improvement activities, thereby growing customer trust and brand loyalty. This can ultimately increase your organization's bottom line.

RISK-BASED INSPECTION APPROACH

You are probably conducting incoming inspections already. Taking a risk-based approach to these inspections will reduce chances of performing unnecessary inspections, and free time and resources to focus on items that require additional inspection. For example, implementing a risk-based sampling system (based on the criticality of risk identified in your risk files) helps you spend less time and money inspecting high-quality raw materials when you are confident that they meet or exceed quality standards. This also gives you the ability to pinpoint low-performing raw materials and suppliers based on their inspection state.

As part of this process, a typical risk-based inspection program will include a sampling system. This consists of a sampling plan, skip lot schedule, and inspection state switching rules. If you're thinking about implementing a sampling system for incoming inspection, these three components can provide the structure you need to get started:

Three Components of Risk-based Inspection

Sampling Plan & AQL
Manage inspection quantity

Skip Lot Schedule
Control inspection frequency

Switching Rules
Performance-based change

SAMPLING PLAN AND AQL

Sampling plans help to define your sample size or the number of items to be inspected from each lot of incoming material. When you choose a sampling plan, such as the commonly used ANSI/ASQ Z1.4, you set a baseline level for the percentage of defects you're willing to tolerate for each measured characteristic. The percentage may be zero percent, which means 100 percent inspection for your most critical product characteristics. For less critical characteristics, you may choose a different percentage to measure (typically between 2.5-4.0 percent).

> *Typically, the lower the AQL, the higher the sample size you'll need to ensure statistical confidence in a material's quality.*

This level is called your Acceptance Quality Level, or AQL. Based on your AQL, the sampling plan defines how many items to inspect for a given lot size. Typically, the lower the AQL, the higher the sample size you'll need to ensure statistical confidence in a material's quality. The incoming inspection sampling plan also defines how many defects are allowed for the lot to still pass inspection.
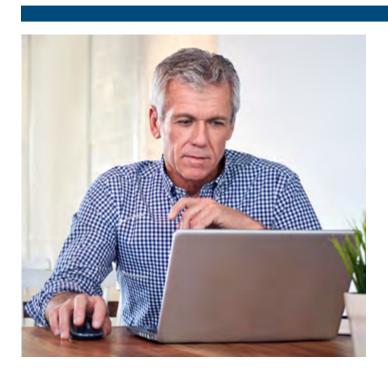
SKIP LOT SCHEDULE

A skip lot schedule details how many lots need to be inspected out of the total number of lots that you receive. Just like the sampling plan, your skip lot schedule can vary based on past supplier performance or based on a material's risk. You may decide to vary the inspection schedule for certain raw materials, while you may have other materials that need no incoming inspection at all.

SWITCHING RULES

Switching rules are a third component of risk-based incoming inspection. These rules take ongoing inspection results into consideration and tell you how your sample size and skip lot schedule should change as a result. For sampling systems like ANSI/ASQ Z1.4, switching rules govern changes between the following states:

- Normal –The baseline for sample size and number of lots to be inspected

- Reduced – Fewer lots are inspected and fewer samples are taken for each lot. This state is reached based on good results in previous incoming inspections.

- Tightened – More lots are inspected and more samples are taken for each lot. This state is reached based on poor results in previous incoming inspections.

Switching rules are also based on a statistical plan that modifies the inspection schedule while maintaining confidence that incoming quality will remain high. For this reason, you should try and stick with an industry-standard plan rather than creating your own skip lot schedule.

CHALLENGES IN RISK-BASED INSPECTION

Sampling systems may be difficult to track in a risk-based inspection environment. Industry standard sampling tables can be detailed and complex. Manual inspection management processes can make it challenging to understand each material's quality performance over time. These factors may make it difficult to determine sample size, skip lot frequency, and switching schedules for an organization's many suppliers and raw materials.

Fortunately, electronic inspection management solutions can automate these risk-based inspection processes. Organizations should leverage supplier quality management automation which combines industry-standard sampling systems with your ongoing supplier performance data to notify your team when an inspection is needed. You can have all the benefits of risk-based inspection without the administrative and statistical headaches.

SAMPLING SYSTEMS AND COMPLIANCE

In the life sciences industry, compliance should be at the forefront of every incoming quality decision. Remember to consider the compliance aspects of your sampling choices.

Sampling systems should only be implemented if you have confidence in a supplier's previous quality performance.

It is critical that you clearly document and statistically validate the sampling system that you use. It is also important to note that sampling systems should only be implemented if you have confidence in a supplier's previous quality performance. Be sure that you've documented any audits, inspections, nonconformance history, or other records in support of this decision within your quality management system.

CONCLUSION

When you're working with a large network of suppliers, it can be difficult to understand which suppliers need more attention from your team. Adopting a risk-based incoming inspection process will help identify and improve suppliers with poor performance, while providing the confidence you need to forego inspection for consistent, high-quality suppliers. An automated software solution such as IQVIA™ SmartSolve® EQMS can automatically track supplier quality history and use it to determine the appropriate inspection interval for each supplier.

To learn more about how IQVIA can assist your company with continuously improving your quality and compliance, visit us at: iqvia.com/qualitycompliance

ABOUT THE AUTHOR

ROXANE NAPOLI, Associate Director, Product Marketing, Quality Compliance Solutions, IQVIA

As Associate Director of Product Marketing for Quality Compliance Solutions, Roxane Napoli is responsible for the Go-to-Market process for IQVIA™ SmartSolve® EQMS, Quality Compliance Consulting, and related Technology Implementation Services.

Roxane holds a Master of Business Administration and a Bachelor of Science in Physics from the University of South Florida.

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CONTACT US

iqvia.com/contactus

LOCATION

4820 Emperor Boulevard

Durham, NC 27703

United States

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