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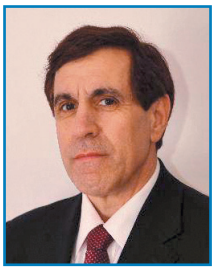
Compliance Notes

Connecting QbD, Knowledge Management, and Supplier Quality Management

Understanding overall supplier capability versus the critical-to-quality attributes of your product can reduce both risk and cost.

Supplier quality management (SQM) is, at its core, a compliance risk-mitigation strategy within the overarching strategy of quality risk management (QRM). I think sometimes, however, the emphasis becomes too focused on the compliance risk associated with the execution of the supplier quality-management program itself and we need to remind ourselves that one of the most fundamental compliance risks SQM is designed to mitigate is product failure. The effectiveness of SQM in mitigating the risk of product failure, however, is directly related to how well you understand the impact the material supplied has on product quality. Absent that, one could have an SQM program that is fully compliant in its execution and yet ineffective in preventing product failure.



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Application of quality-by-design (QbD) in product development and/or postdevelopment product/process characterization combined with effective knowledge management have proven to be a highly cost-effective approach to rigorously connect raw material characteristics to product critical quality attributes. Integrating these tools and tactics into your supplier quality-management system can appear a daunting task, but the payoff is well worth the effort. Not only will you be able to focus supplier management on the right issues, you won't squander your resources and those of your suppliers focusing on things unimportant to product quality.

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At one point in my career, I accepted a managerial rotation assignment in which I moved from manager of pharmaceutical manufacturing to lead the procurement

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group. As part of a review of overall sourcing strategy, my new team identified a supplier from whom we purchased a basic excipient as a potential target for negotiation or replacement because their cost seemed out of line. Dialog with the supplier revealed that the cost differential was being driven by our specification that the product be packaged in paper bags of an unusual size. Ironically, from my previous job, I knew that handling, opening, and loading those paper bags into granulators was not only time consuming, but we also ended up putting partial bags back into the warehouse because their weight wasn't an even multiple of our batch size. Having the supplier switch to providing the material in totes eliminated the purchase-cost differential and reduced our conversion cost. We had essentially been paying a supplier extra money to provide us with something we did not need.

So, what does this have to do with QbD, product knowledge, and supplier quality management? Having a supplier maintain tight control over a characteristic that isn't really important to the quality of your product often drives extra cost which they, naturally, pass on to you. Incoming quality control and supplier quality management efforts to ensure they meet the unnecessary specification add to the overall conversion cost. Worse, when achieving the specification is difficult for the supplier, compliance risk increases because, unnecessary or not, failure to meet the specification is a deviation.

Meanwhile, in the absence of process characterization rigorously linking raw-material characteristics to product quality, you risk under-specifying something whose negative impact you would gladly pay your supplier extra to avoid, and on which focusing supplier quality-management resources makes good business and compliance sense.

Consider the basic supplier quality-management consideration of multiple versus sole sourcing. A colleague recently reminded me of Deming's preference for sole sourcing. After all, the resultant variability of multiple suppliers can't be any less than the most variable among them, and the probability is that the composite variability will be greater than any of them alone. Meanwhile, the cost to manage each of them is incremental. When the risk of supply interruption is unacceptably high, however, the incremental supplier-management cost of qualifying another supplier is justified. Ironically, even when the secondary supplier is duly audited and qualified, when finally utilized, supply continuity is often jeopardized by unexpected deviations in product quality.

Even though the secondary supplier's product meets all the specifications, the centering or variability of some characteristic to which the process is sensitive isn't the same as that of the primary supplier and, therefore, isn't the same as what was used to develop and validate the process. Sometimes, it's a characteristic never previously identified as important and for which you currently don't even have a specification. Far more often, it's a specified characteristic whose variability has more impact on product quality than previously understood.

The risk of this quality deviation happening is higher in products developed using traditional three-batch validation. However, it can occur even in products developed using QbD, particularly when developed using raw material from only one supplier because suppliers are only shipping product within specifications and attempting to minimize variability. Consider a supplier who your supplier quality-management team has qualified against specifications. The supplier's natural process capability may result in the value of a critical-to-quality characteristic being centered to one side of the specification but within a narrow enough range that what it produced generally meets the specification. When it doesn't, it sells it to an alternate industry.

Often, suppliers are unwilling or even unable to produce material much outside their normal process capability. So, the product knowledge initially developed using a given supplier's material will often be narrower than what you need to push the limits of your design space. Over time, however, there will probably be instances in which you will receive lots inside your specification but outside your original design space, particularly as you seek to qualify second-

ary suppliers. Effective knowledge management will allow you to identify and integrate these lots into your design space and expand it.

The key message here is that for these risk-management strategies to effectively inform supplier quality management, product and process understanding can't be viewed as a once-and-done static event completed during initial product development. Rather it must dynamically evolve and grow over the entire course of a product's lifecycle. This growth is particularly important when it comes to supplier quality management because your supplier's processes, like yours, are subject to process variability and drift. Gathering and analyzing data on an *ad hoc* basis to characterize a process in reaction to product failures is sometimes unavoidable. More and more, however, the benchmark practice is to recognize and support the total lifecycle evolution of product and process knowledge through proactive development of knowledge-management systems designed to dynamically integrate raw material and product release testing data with data within manufacturing batch records.

The good news is that whether or not your product was developed using QbD, where it is in its lifecycle, or how sophisticated your current knowledge-management system, it's never too late to characterize processes and develop product and process knowledge you can leverage to mitigate risk and focus resources to maximize cost effectiveness in supplier quality management and in QRM overall. We have seen organizations quickly and significantly reduce risk and cost through process characterization in reaction to product failure. Proactive characterization and knowledge management is just as effective at reducing risk and costs far less because it isn't initiated by a product deviation crisis. Moreover, a knowledge-management system need not be a complex and expensive information systems undertaking. When the true value of integrating data already being generated is demonstrated through these *ad hoc* characterizations, organizations often identify simple ways to leverage what they learned on an on-going basis.

If you don't want to wait for product failure to catalyze action, an overall portfolio risk assessment will inform your priorities *vis-à-vis* which products you target first for characterization. This can be as simple as a review of product, process, and testing deviations to identify the products which give you the most trouble. Given the connection between SQM and product knowledge, a holistic approach that includes an understanding of overall supplier capability versus critical-to-quality attributes is the way to go. Along the way, your organization will not only gain product knowledge that can be leveraged to reduce both risk and cost, you will inevitably discover opportunities to connect and leverage information already being generated and begin to build the foundation of your knowledge-management system. ◆