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Implementing Risk Managed Supplier Quality

Insights from the Experts

A risk managed approach to the global supply chain is more important than ever for life science manufacturers. The process is often easier said than done. Four medical device quality leaders came together to share their experiences in implementing risk managed supplier quality, driving superior outcomes and leading change in their organizations.

It has been half a decade since ISO 14971 listed the device requirements for a risk management system. Since then, manufacturers have been struggling to implement this approach into the Quality Management System (QMS) and enhance supplier quality. As the industry continues to be challenged with supplier quality, Regulatory Compliance Associates, Inc. (RCA) brought together four industry leaders to discuss best practices. RCA is a consulting firm focused on quality and compliance within FDA-regulated industries.

The leaders who shared their thoughts in this paper include:

- **Matt Anderson,** Vice President, North America Quality for Merz, Inc
- **Angel Estrada,** Vice President of Quality and Regulatory Affairs for Zimmer Surgical.
- **Mark Iwicki,** Independent consultant in life science supplier quality
- **RCA Moderator Mike Miller,** Director of Program Management

RCA Moderator Miller:

What is changing in supplier quality?

Estrada: It is becoming more complex. We have all seen the globalization of the supply chain and the growth of outsourcing. For many of us, supplier quality used to mean managing raw components and now it can mean managing outsourced finished goods. Some suppliers own the entire production process and the device manufacturers are merely distributors who supply their label.

We used to focus on supplier qualification, incoming inspections and certifications of compliance. Now, with the vertical integration of suppliers, supplier quality has become much more complex and more regulated as the FDA now requires registration of Tier 1 suppliers.

RCA Moderator Miller:

How are device manufacturers responding to the challenges?

Anderson: A few years back when supply chain contamination within pharmaceuticals was making front page news, life science quality organizations

focused on the GMP elements such as audits, quality agreements and incoming inspections. These are all good things but did not always make a huge impact on the quality coming in the door.

Today, many manufacturers are using more of a risk managed approach to managing supplier quality. This approach addresses each supplier situation individually by evaluating the areas of greatest risk to the manufacturer, developing plans to mitigate this risk and focusing on areas which provide the greatest bang for the buck.

RCA Moderator Miller:

How do you see risk management playing out in your supply chain organizations?

Anderson: Many companies with a large supplier base are focused on compliance and trying to take care of everything. This results in diluting resources and missing what is most important. For example, many individuals felt the entire supply chain should be audited. For a large company to audit the entire vendor base, it could mean doing 50,000 to 70,000 audits per year, with each costing $5000 and taking an entire man-day. That is not realistic. A risk-based approach to supplier quality adds value because you focus on efforts where risk is greatest.

You also have to incorporate business risk as well as compliance. Today that could mean ensuring continuity of materials, environmental issues and child safety concerns versus a straight GMP compliance lens. Each organization needs to define its risk drivers and levels in order to develop a corresponding program to mitigate those risks.

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Risk Managed Supplier Process

- Evaluation of candidate suppliers
- Selection of the supplier
- Understanding the process
- Setting control metrics
- Establishing a monitoring system
  - Auditing
  - Quality system reviews
  - Product reviews
- Quality Agreement
- Periodic business review with Suppliers
- Classification of the supplier based on risk

RCA Moderator Miller:

How do you prioritize risks? How does this theory play out in practice?

Iwicki: RCA sponsored a paper (http://bit.ly/SJ8u8p) on the topic of risk management within the global supply chain featured in Pharmaceutical Technology. This paper outlined a prioritization schema for typical GMP elements such as patient risk, volume of product manufactured, quality data like complaints and supplier history. Combined with supplier FMEA (Failure Mode Effects Analysis), risk can be assessed and supplier control plans can be established.

In doing a business-based risk management, I also look at factors such as high risk of failure or uniqueness of the supplier. For example, earlier in my career I had a sole supplier for whom we could not identify a back-up alternative. With this high risk, we escalated the control plan for this supplier.

RCA Moderator Miller:

What can we learn from other industries?

Anderson: It is no secret that the automotive and aerospace industries are further along the supplier quality learning curve than the life science industry. This is due, in part, to necessity as these industries have been challenged by eroding margins and the unsustainable cost of poor quality.

In particular the automotive industry has raised the bar in which manufacturers partner with their suppliers to drive both greater efficiencies and higher quality. They have largely accomplished this by focusing on technical variation and true process capability within the supply chain.

RCA Moderator Miller:

How does this work in life science?

Anderson: Manufacturers need to understand their key supplier's process, what is critical to quality and ensure a good process capability. It means thinking of your key supplier as an extension of your own manufacturing process.

Iwicki: It starts with supplier qualification. In the past, we looked at this as a process where engineering and purchasing screened suppliers, handing a short list off to quality engineering and supplier quality for approval. This can lead to suboptimal quality. The better approach is to include quality engineering and supplier quality upfront in vendor selection.

Anderson: As you are evaluating the supplier manufacturing process, you need to bring in technical knowledge as well as a review of the quality system. Truly partnering with your supplier means you understand their process just like you would understand your own.

Estrada: Essentially you are overseeing the supplier's quality management system not just managing a supplier.

Anderson: We had an example with batteries which were passing our incoming voltage acceptance tests but we were experiencing some product failures post market. When our engineer was working with the supplier, he noticed that storage temperatures were exceeding 120 degrees which is known to shorten battery life. This may not have been detected in a typical GMP audit.

Enhancing Key Supplier Relationships

- **Put in the time upfront:** Understand the business needs and the supplier process thoroughly before tacking the Supplier Agreement.
- **Get personal:** Establish relationships between key players on both the supplier and manufacturer sides. Include face-to-face meetings whenever possible so team members develop personal relationships which leads to trust.
- **Demonstrate trust** by giving the supplier the primary part of your business.
  - This does not eliminate the need to have alternative suppliers
  - Do not price shop around without telling them first. Word gets out and this destroys trust
- **Supplier Audit Package** – let your suppliers know upfront what to expect
- **Commit** to an in-person business review at least once per year
  - Review defects and other quality measure data
  - Review supplier QMS
  - Ask about the supplier – changes in personnel, business challenges

Estrada: Our industry tends to do a good job on the mechanics of quality such as risk management, FMEA, fault tree analysis and so on; but we tend to see problems in the handoffs.

Iwicki: One common problem in handoffs is clear communication of final specification requirements to the supplier. The manufacturer and supplier typically have early conversations and the supplier may not see the final requirements specification in print until just before they are asked to produce actual production volumes. This can uncover tolerances which are too tight for large scale production. Since the supplier has already invested time and effort and does not want to lose the manufacturer's business, they may agree to the requirements and figure out later how to actually meet them.

Estrada: All too often the yield rate is low because the manufacturing transfer is not critically examined until deviations are experienced in the first supplier run.

Iwicki: I see growing importance of process control with variable measurement data so you can see when something is starting to deteriorate. It is much more efficient than acceptance sampling which only tells you if there's a catastrophic failure on hand.

Iwicki: The evaluation process of a new supplier needs to go beyond the initial approval of the supplier at a point in time, and if/when requirements change, a candid reappraisal must occur on both sides before approval is given for full production volumes. Adding to Matt Anderson's statement about the supplier's manufacturing process being an extension of the manufacturer's, the same is true about the manufacturer's design control process and its extension to key suppliers.

Estrada: To sum it up, the cross functional team on the manufacturer's side and the suppliers need to be talking early and throughout the project to avoid these handoff issues. Early investment in the supplier relationship can pay dividends in averting future potential problems.

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RCA Moderator Miller:

How does this shift to supplier partnering impact your culture?

Anderson: Establishing deep relationships with suppliers significantly alters the business climate. Now we work together on shared goals. In the past, our focus on audits and quality agreements were not real friendly to suppliers. They did not build the relationship. Rather we tend to use quality agreements as a legal document to punish when the supplier made a mistake.

Focal Points:
Tips from the Experts:

- **Cross-functional teams** – include purchasing, engineering, quality engineering, supplier quality, etc. very early in the process to select and qualify new suppliers.
- **Change Control** – Suppliers may not recognize the impact of changes, therefore, manufacturers need a robust change process. Specify that all changes as well as when and how must be communicated to you.
  - Example: The manufacturer selects an international service center who decides to swap out the US battery for a cheaper local alternative which appears to be equivalent until there are product failures.
- **Quality Agreements** – Resist the temptation to use boilerplate documents. Spend time upfront to define the critical areas. Engage cross functional experts in engineering, quality and purchasing from both the manufacturer and supplier side.
  - Example: A rushed supplier agreement resulted in an amendment 6 months later. For the supplier, it meant changing the manufacturing process and leading to increased costs. Purchasing had already locked-in the price. The relationships soured because of this upfront short-cut.
- **Process Control & Variable Measurement Data** – determine which manufacturing steps need to be controlled. This can highlight potential problems before they escalate, and minimize sampling on incoming goods.

Iwicki: I see organizations placing more importance on sustaining supplier relationships over time. It is so much easier to continually improve quality with a trusted supplier than continually seek and onboard new suppliers.

As personnel change out on both sides of the manufacturer and supplier, the replacement personnel need to understand the culture and respect the prior relationships. The culture should be about quality above cost, not cost above quality.

RCA Moderator Miller:

How do you instill a culture of cross-functional teamwork?

Estrada: This is a leadership issue and must come from the top. Quality is a team sport, and everyone at Zimmer understands that. As functional leaders we lead by example and our departments understand we all play on the same team.

Cross-functional exposure and training builds upon this foundation. Our trainers are subject matter experts (SMEs), so they have immediate respect with the trainees. When you do not have SMEs, you take early adopters and train them to be trainers.

Another best practice we have seen in the military is co-location where pilots and servicemen work in the same environment. I saw this work well at Abbott Diagnostics where Quality, R&D and Quality Engineering were co-located. They did a remarkable job with design transfer into manufacturing. Maybe it is because communication is in real-time and the team meets more informally. With work teams located all around the globe, we have seen SharePoint and other collaboration tools bring cross-functional areas together.

RCA Moderator Miller:

How does this impact your staffing considerations?

Iwicki: Experience matters. The supplier quality area is attracting more tenured personnel instead of being known as the jump-off point for new hires. The focus is on staff who understand the true supplier quality instead of trying to get a feather in their cap for nitpicking the suppliers. I see many organizations pair up the new hires with experienced staff.

Estrada: We seek cross-functional team players and continue to cross-train. For example, the purchasing personnel are trained by the quality organization in the areas of GMP, change control, obsolescence and areas for the elevation of issues. Our purchasing team has become more “big picture” in their thinking. It is not just about the pursuit of a low price; It is about cost, quality and delivery.

Building Cross-Functional Teams: *Tips from the Experts:*

Gone are the days when the quality team was isolated in its own building. Experts agree that working together ensures better company performance.

- Cross-functional leadership begins with the top. The functional leaders must work well together and set the example for their teams. You have to walk the talk.
- Consider co-location of cross-functional team members whenever possible
- Invest in collaboration tools like SharePoint and Rational Pro.
- Consider enrichment programs like cross-functional assignments for high-potential employees
- Invest in training led by subject matter experts
- Reward and promote cross-functional behaviors like:
- Employees who want to fix problems instead of running at the first sign of quality trouble
- Employees who volunteer for cross-functional projects
- Invest in 360 degree feedback programs

RCA Moderator Miller: The experts agree organizational risk-managed supplier quality focuses on the areas which most benefit from your attention. It also streamlines your quality management from the insurmountable task of scrutinizing every supplier with the same intensity. By engaging a cross-functional team approach to supplier quality, manufacturers develop better understanding of their suppliers which likely leads to improved quality and enhanced efficiencies.