Design Talk: Roadblocks to Managing Supplier Quality

Matthew Kopecky, Product Manager, Sparta Systems

In the medical device industry, designers continue to face unique challenges that stem from the broader manufacturing process. These can include anything from shorter product lifecycles and increased regulatory scrutiny to the need to source materials from a myriad of suppliers across the value chain. More than ever, medical device designers need to proactively voice their supplier quality issues before incidents arise that can do significant damage to their careers, their businesses, or more importantly, the well-being of the patients their products ultimately serve.

Sparta Systems has identified three specific challenges related to supplier quality that currently face the medical device industry. These unique roadblocks are culled from extensive dialogue with both medical device companies and FDA regulators.

- Reticence to Implement Performance-Based Scorecards for Supplier Quality Management—Companies need to implement a systematic approach to grading and assessing suppliers that evaluates performance, material quality, and operational stability. The result is reduced costs of time and money for the organization, guaranteeing reliable suppliers and a quality finished product.
- Inefficient, Decentralized Reporting—Due to the daunting audit process in the medical device market, companies dealing with multiple suppliers are forced to provide detailed reports of their quality-related operations. Only by implementing a centralized system for tracking of data can organizations streamline their reporting efforts and realize the benefits of a more efficient compliance process across the enterprise.
- Lack of C-Level Involvement in Supply Quality Management—Supplier quality is often left to siloed departments that lack visibility into the correlation between supply quality management and supply chain

management. Medical device designers need to voice their concerns in ensuring that supplier relationships are effectively maintained and that the correct procedures are in place for gauging supply quality and evaluating processes, ultimately balancing quality with efficiency of the broader manufacturing process.

Device designers and engineers that take a more active voice in the supply quality management process can ensure that the design of the products manufactured is in line with both industry regulation as well as the processes implemented within the organization. This will ensure that they are working within the parameters to develop products that will advance and improve the quality of care for patients for years to come.

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