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BEST PRACTICES FOR CORRECTIVE AND PREVENTIVE ACTIONS (CAPA) PRESENTED BY DISTINGUISHED QUALITY AND COMPLIANCE EXECUTIVE AT MEDICAL DEVICE AND PHARMACEUTICAL LEADERSHIP ROUNDTABLE

(San Diego, California USA) During the last few years, there has been growing attention given by the Food and Drug Administration (FDA) to the implementation of corrective and preventive actions (CAPA) at medical device and pharmaceutical companies. Inspections and actions by the FDA are as concerned about the process for identifying and correcting an issue and making sure it doesn't happen again, as it is about the issue itself.

Recently, top medical device and pharmaceutical executives attended the second annual Sustaining Effective CAPA Systems Conference, to hear thought leader, Debara Reese, Vice President Quality and Compliance for Maetrics, a leading global compliance consulting firm, discuss best practices and common CAPA pitfalls at the exclusive conference in San Diego.

Reese set the tone for her talk by observing, "The most common pitfall I've seen regarding effective CAPA systems is underestimating the complexity of the project. It is more than just a root cause issue; it is a complete process which requires copious amounts of time and resources managed by a capable team with experience, decision making skills, and support at the highest levels

in order to manage the organizational change needed to result in an enhanced and sustained quality environment." She presented dozens of best practice tips together with several illustrative case studies during her talk.

Reese underscored the importance of giving CAPA a high corporate priority when she said, "developing a proactive CAPA culture is ideal because correcting and preventing issues early on diminish risk exposure for the company and cost significantly less than fixing them later on." According to Reese, "The ideal CAPA systems do not disrupt the overall process nor expose the company to unnecessary or avoidable risk."

Now in its thirtieth year, Maetrics is a leading global consulting firm specializing in compliance strategy and solutions:

- regulatory and compliance
- performance improvement
- risk management
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for top-tier medical device, pharmaceutical, and biotech companies. Maetrics' headquarters is in Indianapolis, Indiana, USA, and it supports its global client base through offices worldwide.

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