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TOP LIFE SCIENCES CONSULTING EXECUTIVE OUTLINES EFFECTIVE CAPA SYSTEMS AT MEDICAL DEVICE CONFERENCE IN NEW YORK TOMORROW

(New York, NY) In the last few years, the fastest growing item cited in FDA warning letters to medical device and pharmaceutical companies is the identification of insufficient CAPA (Corrective and Preventive Action) programs as a source of significant quality system weakness. Debara R. Reese, Vice President, Quality and Compliance, at global life sciences compliance consulting firm, Maetrics, will speak on "Effective CAPA Systems" at MD&M East, at Javits Center in New York on June 10 at 1:20 p.m., one of the largest medical device conferences in the U.S.

Reese will cover best practices, how companies lull themselves into thinking they're covered, tips on solving CAPA issues, exploring challenges and pitfalls in the process, getting to the root cause of the CAPA stream, and more.

"People think they have a great electronic system, compliant procedures, sophisticated root cause analysis tools, and a staff that has been trained on the requirements, but that is only part of the battle. Even the largest companies get into hot water with the FDA due to their lack of a proper decision making process needed to alleviate the problem," explains Reese. "To be effective in handling CAPAs, one must think the problem all the way through, identify its root cause,

and then follow the process completely, looking at issues both upstream and downstream, as well as internally and externally," she said.

"Ultimately, developing a proactive CAPA program is ideal because correcting and preventing issues early on will cost significantly less than fixing them later on," Reese observed.

Ms. Reese and other Maetrics executives will be available by appointment, for confidential meetings during the conference. Attendees are also invited to visit the Maetrics booth #1133 in the main hall of the Javits Center.

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