# New FDA Regulations Streamlining the Governance of Combination Products Detailed in New White Paper

Microtest Laboratories

New Federal Food & Drug Administration (FDA) regulations have streamlined the governance of combination products — medical devices embedded with pharmaceutical or biologic components. A new white paper titled Combination Products 3.0: Applying the New FDA Regulations in 2013 *[1]* discusses the implications for manufacturers. The whitepaper is available to download at http://microtestlabs.com/combination-products-30 [2].

Combination products are a large and growing segment of the medical device market. Some analysts estimate they represent over 30% of all new FDA product submissions.

"Over the last 10 years, FDA regulatory centers have struggled with the changes and challenges that these new technologies present. For manufacturers, the convergence of drugs, biologics, and devices has created both a host of regulatory issues — and many exciting opportunities," according to Steven Richter, Ph.D, President and Chief Scientific Officer of Microtest Laboratories, Inc., and author of the new white paper.

The new FDA publication, "*21 CFR Part 4 — Current Good Manufacturing Practice Requirements for Combination Products*," revises regulations by establishing different categories of products. These included single-entity products (such as a drug-eluting stent) and co-packaged products (such as a packaged syringe and pharmaceutical). The rules also distinguished between a drug with a device, a biologic with a device, and a device with an HCT/P.

The new white paper discusses, in detail and example, how the new FDA rules guide a manufacturer into one of two approaches, depending upon the characteristics of their product.

According to Dr. Richter, "the FDA's new streamlined approach for regulating combination products is a big step forward for the practitioner. It applies parts of both the QSR and GMP quality systems in a way that makes sense for the unique characteristics of each combination product. 21 CFR Part 4 closes the gaps in the 2004 guidelines and succinctly clarifies the process for establishing quality systems that ensure compliance and patient health and safety.”

Download the new white paper, Combination Products 3.0: Applying the New FDA Regulations in 2013 *[1]*, from http://microtestlabs.com/combination-products-30 [2]. The white paper is presented by Microtest Laboratories, a leader in testing services and contract manufacturing for the medical device, pharmaceutical, and

biotechnology industries.

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