Budget constraints limit FDA inspections

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Budgetary constraints are one of the principal factors that limit the US Food & Drug Administration's ability to conduct frequent and rigorous site inspections of pharmaceutical manufacturers, according to research published in the *International Journal of Business Continuity and Risk Management*.

Warren Adis, Associate Professor of Information Sciences at the Hagan School of Business, Iona College, in New Rochelle, New York, has analyzed the FDA's risk methodology used for inspecting pharmaceutical manufacturing sites and reviewed its procedures, regulations, and violations as specified in the warning letters sent out by the Administration. The period on which Adis focused is 2004 to 2009, the time during which FDA was transitioning and formalizing its new approach to site inspections. The current research re-evaluates Adis' earlier study which compares the year 2005 when the new risk methodology was incorporated into the inspection process with the year 2008, to judge the impact of this new approach.

"A review of this composite period shows a more slowly declining using of warning letters and citations, with some leveling off in the last two to three years," explains Adis. "This current review therefore presents a more balanced evaluation of FDA performance." In his assessment, Adis suggests that budgetary constraints have led the FDA to use the inspection process as a policy tool to alert manufacturers on the necessity for installing quality risk-based systems, rather than a detailed analysis of manufacturer's violations.

"By failing to specify quality assurance violations, the FDA is not providing the necessary oversight and guidance to the pharmaceutical manufacturing industry," says Adis. Furthermore, by sustaining this less than rigorous approach, the FDA may be inadvertently allowing manufacturers to take advantage of the current system and to meet quality and standards obligations by building up complaints files and the like rather than addressing the actual safety and risk issues.

Adis has previously recommended that the FDA should use its risk methodology and its 820 regulations as tools to diagnose systemic weaknesses within a given manufacturer's production processes, and then provide detailed information that must be acted on. A more invigorated 820 inspection process will preclude manufacturers from the possibility of gaming the site inspections and improve safety across the industry and its products, says Adis.

More information: "Assessing FDA's risk methodology at pharmaceutical manufacturing sites" in the International Journal of Business Continuity and Risk Management, 2010, 1, 259-270

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