Specialized US Food and Drug Administration investigators for enhanced protection of public health

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In September 2013, the United States Food and Drug Administration’s (US FDA) Commissioner began an initiative to organize US FDA inspectors along regulated commodity areas, such as pharmaceutical or device manufacturing, food processing, or bioresearch monitoring (human subject protection, clinical trial data reliability, compliance with US FDA postmarketing safety regulations). Increased specialization and dedication of inspectors in the bioresearch monitoring program will result in inspectors gaining more in-depth knowledge of regulations and industry practices and trends. This will enable inspectors to refine the unique skills needed to conduct inspections and provide reliable data to support the US FDA’s decision to approve US FDA regulated products. In turn, the change will result in higher quality inspections of US FDA regulated products. The poster presentation will discuss the objectives of the bioresearch monitoring program, purpose of the Commissioner's initiative and the plan to implement a vertically integrated commodity based program. The outcome of the Commissioner's initiative is greater protection of public health regarding US FDA regulated products.

Biography

Chrissy J Cochran completed her PhD from University of Maryland, Baltimore and Postdoctoral studies from Johns Hopkins University School of Public Health. She is the Director of the Division of Enforcement and Postmarketing Safety, in the Office of Compliance, Center for Drug Evaluation and Research, US Food and Drug Administration. She has published more than 10 papers in reputed journals and presented more than 30 abstracts.

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