FDA Vision

6-PART PLAN TO SUPPORT PUBLIC HEALTH

Commissioner of Food and Drugs Margaret A. Hamburg, M.D., has outlined her commitment "to prevent harm to the American people" through swift, aggressive, and effective enforcement of FDA laws and regulations.

She highlighted six initial steps designed to hone the effectiveness and timeliness of the FDA's regulatory and enforcement system:

1. Set post-inspection deadlines. The FDA will establish a clear timeline for regulated industry to respond to significant FDA inspection findings, generally giving no more than 15 days to respond to such findings before the agency issues a warning letter or takes other enforcement action.

2. Take responsible steps to speed the warning letter process. The FDA will streamline the warning letter process by limiting review of warning letters by the Office of Chief Counsel to those that present significant legal issues.

3. Work more closely with FDA's regulatory partners. In some cases, such as with food safety issues, state, local, and international officials can act more quickly than the FDA. When public health is at risk, the agency will coordinate with its regulatory partners to take rapid action.

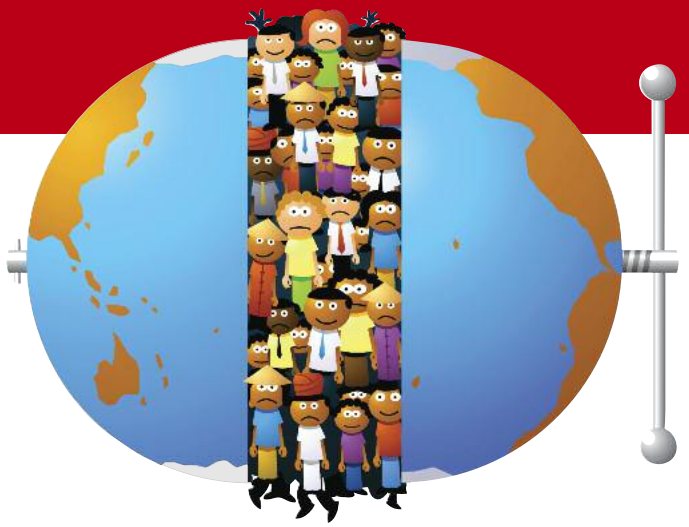
4. Prioritize follow-up on warning letters and other enforcement actions. The FDA will work quickly to assess and follow up on corrective action taken by industry after a warning letter is issued or major product recall occurs.

5. Be prepared to take immediate action in response to public health risks. To better protect the public health, the agency is prepared to act more quickly and aggressively to deal with significant public health concerns and violations. Such actions may occur before a formal warning letter is issued.

6. Develop and implement a formal warning letter "close-out" process. If the agency can determine that a firm has fully corrected violations raised in a warning letter the agency will issue an official "close-out" notice and post this information on the FDA Website. This will be an important motivator for corrective action by manufacturers.

By taking these steps, Commissioner Hamburg says the FDA will ensure that "violative inspection results are taken seriously, that warning letters and enforcement actions occur in a timely manner, and that steps are taken to protect consumers in cases where immediate enforcement action is not possible."

SOURCE: FOOD AND DRUG ADMINISTRATION.



CLINICAL OUTSOURCING UPDATE

Fewer Phase III Trials Outsourced

Surveyed companies now outsource an average of 46% of their Phase III clinical trial budgets. This shows a shift from the company's 2006 study, in which companies reported outsourcing an average of 59% of their Phase III budgets.

According to Cutting Edge Information, outsourcing represents a smaller portion of clinical trial budgets today than it did three years ago.

Although conducting the work in-house is more expensive, according to clinical development executives, many companies simply cannot accept the loss of control when outsourcing certain aspects of trials. Internal groups, such as data management teams, are not satisfied with the risk that their companies take when outsourcing. If poorly managed, trials could derail and cost much more to restart. For example, the average cost to amend a trial protocol even once approaches $500,000, according to Cutting Edge Information's data.

SOURCE: CUTTING EDGE INFORMATION.

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Return on Investment in Patient Recruitment
Thought Leader: Rick Malcolm, Acurian

Featured Webinar

Owning the Prescription Pad: Driving Brand Decisions in a Multi-Influence World
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Register: www.pharmavoice.com/emerging

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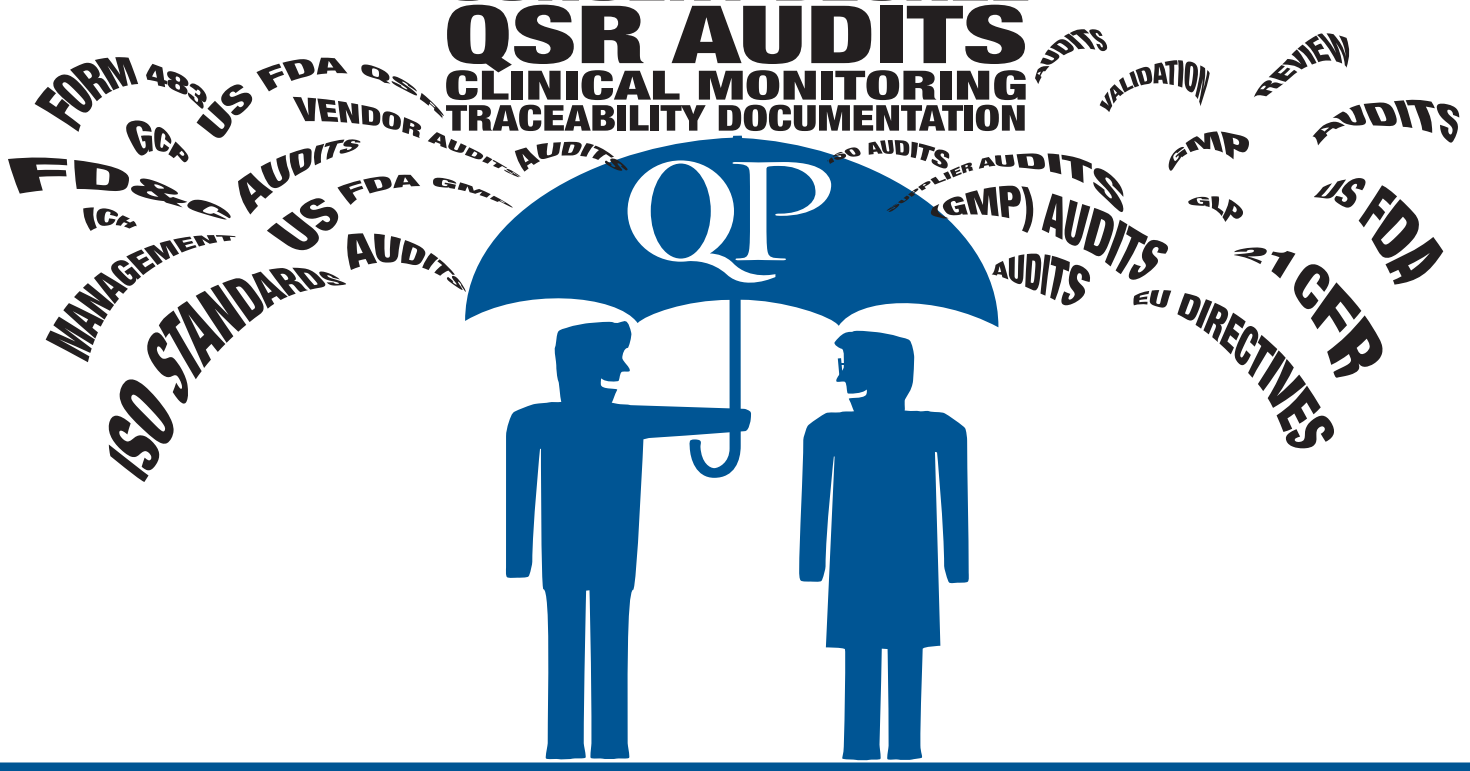

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