Understanding FDA's Consent Form Requirements

The Food and Drug Administration issued a new consent form requirement for FDA-regulated clinical trials effective this March 7, 2012. Consent forms of drugs, biological products or devices that are subject to FDA regulation are required to contain certain specific statements provided by the FDA. The statement is applicable to clinical trials initiated on or after March 7, 2012, the statements are intended to advise the participants that the clinical trial information is available on the ClinicalTrials.gov database.

The question now is how should the industry comply in a cost effective manner that does not compromise the integrity of the science.

The Knowledge Group has assembled a panel of key thought leaders and regulators to help health executives understand all the important issues with respect to this important topic. This live webcast is a must attend for all health executives who need to be in the know with respect to FDA's new consent form requirement. The panel will address the key issues and will answer the following main concerns:

- The Applicable Clinical Trial – What are those trials and how to identify an applicable clinical trial?
- What clinical trials are specifically excluded from the definition of "applicable clinical trials?"
- Do sponsors and/or investigators need to obtain approval for informed consent documents with the new statement – Why and How?
- Can the new requirements be waived? In what specific situations?
- Do informed consent documents for studies conducted outside of the United States have to comply with the new regulations?
- What new responsibilities of an IRB will be faced under the new rule?

Register for this "Free" webinar here: Webinar Registration – Jan, 17th, 2013 (9am PST- 11am PST)