AAPS/FDA WORKSHOP

AAPS/FDA Fifth Bioanalytical Workshop; Quantitative Bioanalytical Methods Validation and Implementation: The 2012 Revised FDA Guidance

Bringing Together Small and Large Molecules

Summer 2012 • Washington, D.C.

- To permit science-based industry perspectives to align and harmonize around the new proposals.
- To understand the implications and reasoning behind the revisions and new aspects of the guidance.
- To provide industry input to FDA.

Who should attend?

This workshop is intended for a diverse group of scientists who are responsible for the evaluation of safety and efficacy of the therapeutics in the drug development process. Primary audience is the bioanalytical scientists in the pharmaceutical, biotechnology, and CRO industry supporting small and large molecule support; scientists involved in quantitative biomarker analyses in those same industries; regulatory scientists who work on submission of investigational new drugs, biologic license applications, and new drug applications; pharmacokineticists (clinical, preclinical, and toxicokinetics) who use the bioanalytical data in interpreting the pharmacokinetic properties of the therapeutics; and finally statisticians who support the bioanalytical scientists.

Detailed Program information will be available at

www.aaps.org/BMV

Call +1. 877.998.AAPS or email *meetings@aaps.org* for more information.