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Biomarkers in drug discovery: Potential use versus challenges

The role of biomarkers has been exponentially increasing in guiding decisions in every phase of drug development, from drug discovery into post-marketing studies. Also, biomarkers can predict patients' response to compound by identifying certain patient populations that are more likely to respond to the drug therapy or to avoid specific adverse events. This shift toward "personalized medicine is helping the drug industry achieve the goal of cost-effective and faster research, especially in poorly served areas such as neurodegenerative disorders and cancer.

Biomarkers assays range from esoteric type of assays performed on a fit-for-purpose basis to rigorously validated assays when a biomarker is used as a surrogate end point, for patient selection, or for randomization into different arms. Assay validation is essential, but of equal or even greater importance is the monitoring of assay performance and level of quality during production.

Despite all of the potential benefits of using biomarkers to advance pharmaceutical industry, discrepant results can pose a threat to development programs by triggering false decisions. Laboratory errors may be of pre-analytical, analytical, or post-analytical origin. Although clinical laboratory errors due to analytical problems have been, with momentous efforts, significantly reduced over time, the overall quality of clinical laboratory results can be compromised by the absence of true method-to-method or platform-to-platform standardization, or at least harmonization of test results.

This talk will highlight the following topics;

- Biomarkers and their potential utility in drug development.
- The major reasons behind discrepant results from biomarker laboratories and how to mitigate them.

Biography

Abdel Halim is a nationally recognized biomarker and clinical laboratory professional with more than 25 years of experience in all aspects of biomarker discovery, development, validation, and applications in patient management and pharmaceutical development. He is an expert in all biomarker techniques and platforms From safety lab POC till whole genome sequencing.

Abdel is leading the biomarker function within Daiichi-Sankyo pharmaceutical company and managing all safety and specialty biomarker aspects across different therapeutic areas in all phases of drug development.

Abdel holds Pharm D, and PhD in Clinical Biochemistry and Molecular Biology, and one of three lab professionals in the USA who are triple certified by the American Board in Clinical Chemistry, Molecular Diagnostics, and Toxicology.

Abdel is a member of 14 Clinical Laboratory Standard Institute (CLSI) subcommittees to establish guidelines promoting quality in clinical laboratories worldwide.