Preface

The science of drug development is an evolutionary one, something we can see clearly in the world of biomarkers. Not so long ago the concept of using biomarkers in drug development was relegated to a few "research-only" kits. Bioanalysis in support of drug development focused solely on the pharmacokinetics (PK) of new drug entities. Unfortunately, PK-only approaches can no longer support today's drug development targets. While drug pipelines were full, and research was thriving, very few new drugs were being approved. To address the high attrition of drug development projects and attempt to improve the success rates, the FDA implemented the Critical Path Initiative in 2004. The FDA's strategy was to drive innovation by using the newest tools to more successfully translate discovery into viable therapies. Integrating biomarkers into the drug development process, especially in the pre-phase 3 stage, was central to the initiative. The challenges of including biomarkers in drug development were daunting until insightful colleagues started breaking it down to usable building blocks. A groundbreaking paper authored by Dr. Jean Lee and associates (2006) cited the need to improve the efficiency and economy of drug development by the use of well-validated biomarkers and biomarker assays. Workshops were developed, many notably led by Dr. Ron Bowsher, to help researchers understand the difference between a well-developed biomarker and a well-developed biomarker assay. This concept was solidified by Dr. Woodcock (2009) in a pivotal white paper which re-emphasized the need for an iterative method development process following the progress of the New Drug Entity through the drug development continuum and by the publication in 2011 by the ICH of the E16 Guidance for the Industry describing the requirements for biomarkers used in regulated submissions. Biomarker research has become such an integral facet of drug development that some pharmaceutical companies have implemented a policy of requiring a biomarker (target engagement, pharmacodynamics, and patient selection) to be included in all programs as a gating item to move into clinical development. The world of biomarkers has exploded in both depth and breadth. A cursory look over the table of contents in this e-book provides a thumbnail sketch of the innovation taking place in the modern day

bioanalytical lab to help produce new drug entities quickly and efficiently. Finally, to illustrate the importance of using biomarkers to drive clinical development, the FDA issued a draft bioanalytical method validation guidance in 2013 that will now contain a biomarker section describing the "fit-for-purpose" need to validate biomarker methods when using the data to support a regulatory submission.

Edison, USA Russell Weiner
West Chester, USA Marian Kelley

http://www.springer.com/978-3-319-40792-0

Translating Molecular Biomarkers into Clinical Assays
Techniques and Applications
Weiner, R.; Kelley, M. (Eds.)
2016, XIII, 212 p. 24 illus., 16 illus. in color., Hardcover
ISBN: 978-3-319-40792-0