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## Clinical biomarkers in drug development: Quantitative PCR-based fit-for-purpose assay qualification

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Biomarkers play a significant role during all phases of drug discovery and development. Clinical biomarker-based studies provide early information on target engagement, help guide rational selection of drug combinations, optimization of dose and schedule, serve as tools for stratifying patients and has the potential to predict clinical outcome. A “fit-for purpose” assay development and validation to meet the clinical requirements plays an important role in biomarker estimation. While a rigorous validation is usually not required for discovery-phase work, as a drug progresses into preclinical and early-phase clinical evaluation, more thorough method validation increasingly becomes valuable. The real-time quantitative polymerase chain reaction (qPCR) technology is accurate, sensitive and fast and has become the method of choice for clinical biomarker detection and quantification. Numerous quality issues may arise throughout the entire workflow influencing the accuracy of the qPCR results and the reliability of the data interpretation and conclusions. Development and use of qPCR technology for robust, accurate and reliable method is required for the emerging “fit-for-purpose” biomarker assay qualification. Key factors influencing assay performance such as sample matrix, sample preparation, experimental precision, reproducibility, sensitivity, specificity, dilution linearity and dynamic range and their impact on the assay outcome will be discussed. Based on these, we will put forth recommendations for consideration and optimization while qualifying a qPCR-assay for analysis of clinical samples. As biomarkers become integrated into drug development and clinical trials, assay qualification becomes important with an increasing emphasis on establishing standardized guidelines for analytical methods.

### Biography

Shashwati Basak obtained her PhD from Indian Institute of Science, Bangalore, India. She carried out Post-doctoral research from The Salk Institute for Biological Sciences, San Diego and Stanford School of Medicine, Palo Alto. Research in these two places was focused on understanding the role of tumor suppressor p53 in Cancer Signaling Pathways. She worked as a Research Scientist in the Veterans Affairs Medical Center, San Francisco, before moving into the current role as a Lead Investigator in Early Clinical and Translational Research, Biocon Bristol-Myers Squibb Research and Development Center, Bangalore. Current research interests involve assay development and qualification for Clinical Biomarkers and its use in clinical sample analysis during drug development.

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