



A biomarker is "a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention"^[1]. Biomarkers are commonly used in the pharmaceutical industry to evaluate the safety and/or effectiveness of drugs. For example, they can be used to assess the binding of drugs to their target, which can be critical. Biomarkers can also lead to significant cost reductions during drug development by enabling early proof-of-concept studies for novel therapeutic targets, thus reducing costly drug attrition rates. The study of diagnostic and predictive biomarkers is also an area of great interest, with increasing focus on point-of-care biosensor systems. We carried out a survey to gain insight into the techniques you use, the form of biomarker you work with and your approach to regulatory issues.

Reference

1. Biomarkers definitions working group. Biomarkers and surrogate endpoints preferred definitions and conceptual framework. Pharm. Ther. 69, 89-95 (2001).



Biomarkers in your laboratory



Do you work with...

Are the biomarkers you analyze...



Small molecules – 66%



Peptides – 52%

mm MicroRNAs – 15%



Large molecules – 60%

When analyzing biomarkers, which



Thankfully we are finally moving forward with regard to specific biomarker assay validation guidance and away from using the PK guidance almost *verbatim* – long overdue!

Regulatory issues

Do you set acceptance criteria before or after the method 'quantification/validation'

Do you use a tiered approach to biomarker validation?



Technical and Communication issues

What are the main technical challenges of biomarker analysis?

69%

Different endogenous concentrations/case-to-case variability

58%

Lot-to-lot variability of critical reagents and commercial immunoassays

Low-abundance analytes

49%

Obtaining samples of suitable quality from clinical trials/patients

Should there be more communication between the investigator requesting the biomarker and the analyst?

Too many samples are [not

controlled] with respect to

[aspects such] as diet and time

of day of sampling.

'es

91%

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9%