

The Path From Biomarker Discovery To Regulatory Qualification

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The Path from Biomarker Discovery to Regulatory Qualification is a unique guide that focuses on biomarker qualification, its history and current regulatory settings in both the US and abroad. This multi-contributed book provides a detailed look at the next step to developing biomarkers for clinical use and covers overall concepts, challenges, strategies and solutions based on the experiences of regulatory authorities and scientists.

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Biomarker discovery. The initial phase in the biomarker development pipeline (Figure 1) (8) is to identify suitable candidates. Two general approaches can be employed (3): the first strategy uses a deductive reasoning to identify candidates based on existing knowledge of the pathophysiology of disease.

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