

Ligand-binding assays : development, validation, and implementation in the drug development arena

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Abstrak

With increasing use of ligand-binding assays (LBAs) in the pharmaceutical industry, the need to critically evaluate technical and regulatory issues related to the use of these technologies has increased greatly. This book fills that void and provides a reference text covering critical aspects of the development, validation, and implementation of LBAs in the drug development field. It includes: immunochemistry and protein chemistry, method development, validation, statistics, software, regulatory issues, and applications to immunogenicity and biomarkers.