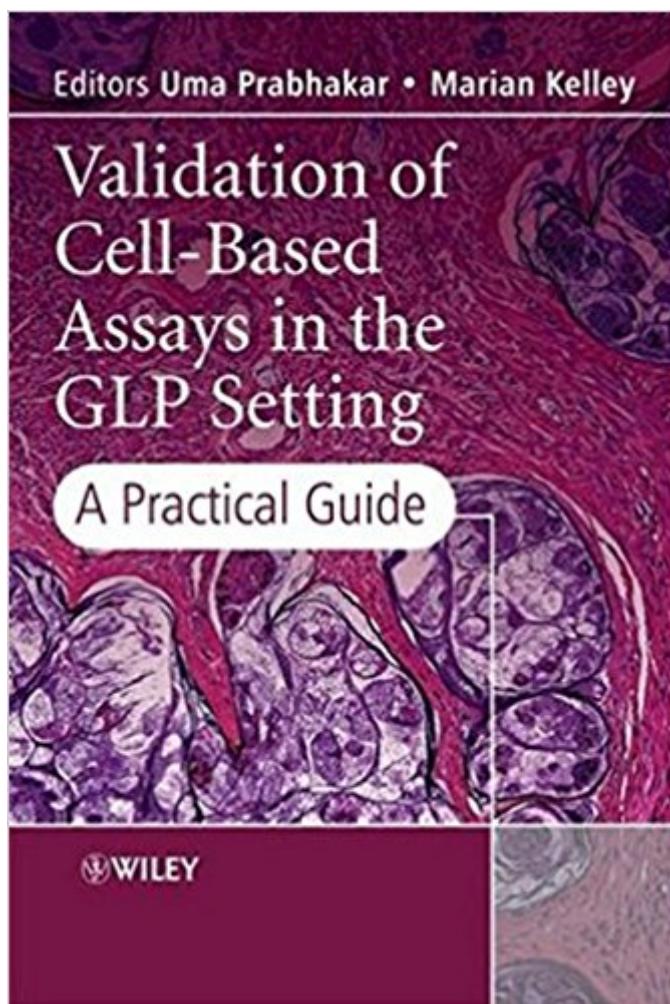


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Validation Of Cell-Based Assays In The GLP Setting: A Practical Guide



Synopsis

The use of cell-based assays within pharmaceutical and biotechnology companies is driven in large part by the need to evaluate the plethora of drug targets derived from genomics and proteomics. In addition, the potential of biomarkers to facilitate the development of effective and safe drugs is being recognized as an integral part of all phases of drug development, and cell-based technologies are a critical part of biomarker discovery and development. Despite this critical role, cell-based assays have not been standardized and made compliant with Good Laboratory Practice guidelines. In this book, the editors have collected assays for which validation procedures have been developed, making this a vital purchase for anyone using such assays in drug development. This book:

- Describes the development, optimization and validation of cell-based assays, including procedural documentation required for Good Laboratory Practice
- Presents validations of cell-based assays for select targets, with step-by-step instructions, allowing the reader to reproduce the assay conditions and results
- Provides details of techniques used in the evaluation of immunodeficiency, autoimmune and oncological disorders, including assessment of cancer vaccines
- Offers a compendium of validation parameters that need to be considered when using these methods to develop a new drug
- Includes detailed protocols for the evaluation of cytokines and of neutralizing antibodies directed against protein therapeutics

Validation of Cell-based Assays in the GLP Setting provides the professional with an invaluable reference source, featuring key guidelines. The book will prove extremely useful to all scientists working in the areas of drug development.

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Uma Prabhakar, Ph. D. Director, Department of Clinical Pharmacology & Experimental Medicine, Centocor Inc, PA, USA Marian Kelley, M.A., Director of Compliance, Department of Clinical Pharmacology & Experimental Medicine, Centocor Inc, PA, USA

Doesn't discuss regulatory requirements for validation of GLP assays. Doesn't discuss why certain validation parameters should be validated in cell-based assays. Doesn't discuss lack of standards issues for cell-based assays. Doesn't discuss why GLP assays should be validated. Doesn't discuss GMP regulatory requirements which would be very important if you were doing GLP studies. Is just technical articles on cell-based assays. Title is very misleading.

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