

The Design and Analysis of Potency Assays for Biotechnology Products

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The complexity of the structure and function of many biotechnology-derived products necessitates a wide range of analytical procedures to characterize adequately the product. Physicochemical techniques provide little, if any, information regarding the potency of biologicals. Therefore, the development and analysis of biological assays that measure the ability of a material to elicit a function are essential to successful product development. Bioassays such as *in vivo* or cell based assays often exhibit inherent variability due to the use of living materials. It is necessary to design and execute bioassays to reduce variability as much as possible whilst enabling statistically valid measures of the reproducibility of potency estimates.

The manuscripts in this volume aim to describe statistical approaches currently being used in the design and analysis of potency assays for biotechnology products, and to identify factors influencing the appropriate choice of these approaches. Issues that impact on assay design, implementation, validation and interpretation are discussed, from both the analyst's and statistician's perspective.

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