

Development of Specifications for Biotechnology Pharmaceutical Products

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This volume contains the proceedings of a two-day symposium on 'Development of Specifications for Biotechnology Pharmaceutical Products', held in May 1996. Speakers and panelists from industry and regulatory agencies discussed specifications and the degree to which they are appropriately applied during the various stages of drug development. Presentations evaluating raw material, in-process and final product specification throughout the drug development timeline for biotechnology pharmaceutical products were given. Specifications for identity, purity and activity at various stages of drug development were also considered. Further contributions examined assay and process validations and their effects on specification setting, stressing that the quality of the validation directly affects the setting of a suitable specification. Finally, standards and reference materials, and their selection for in-house use and as the basis for setting future global standards were discussed. As a result, it was emphasized that the development of specifications evolves with the product through a continuum of improved processes and characterisations leading to superior product quality.

Bringing together the world's leading experts in the field, this book will be a valuable reference for pharmaceutical development professionals involved in research, development and commercialisation including members of quality control, quality assurance, regulatory affairs, process development, analytical development, validation and regulatory compliance groups.

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