

## Process Validation for Manufacturing Biologics and Biotechnology Products

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Regulatory documents and inspections have put increasing emphasis on process validation for all types of product, including biological and biotechnological ones. Until now, no description of a process validation for complex biological processes exists, let alone any concrete suggestion how to attain it; this book, however, attempts to fill the gap.

Taking the current state of scientific practice in process validation as a starting point, this volume portrays the expectations of the regulatory community and provides detailed examples of how various types of biological and biotechnological processes could be validated. Considering the sizeable difficulties in designing a single method of process validation suitable for all types of processes and products, the authors discuss the implications and present many possible routes to a successful validation process.

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Expectations for Process Validation: Industry Perspectives. R. Francis

**Session II: Strategies: Evolution of Validation Through the Product Life Cycle. Moderators: G. Roessling (Schering, Germany), J. Purves (European Medicines Evaluation Agency, U.K.)**

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