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Process Chromatography: A Guide to Validation

Gail K. Sofer, L. E.E. Nystrom

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Research and development into biological products for therapeutic use has increased dramatically over the last 10 years. With this, strict regulatory requirements have been imposed by authorities such as the U.S. Food & Drug Administration, so that today validation has become a key issue in the biopharmaceutical industry.
This concise book addresses validation issues in the chromatography of biotherapeutics. It covers process design, qualification and validation, including an overview of analytical techniques commonly used in the validation of processes. A concluding section comments on product changeover and presents four case studies.

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