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Altri autori (Persone)	ChanChung Chow
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Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Overview of pharmaceutical product development and its associated quality system / Chung Chow Chan and Eric Jensen -- Potency method validation / Chung Chow Chan -- Method validation for HPLC analysis of related substances in pharmaceutical drug products / YC Lee -- Dissolution method validation / Chung Chow Chan, Neil Pearson, Anna Rebelo-Cameirao, Y.C. Lee -- Development and validation of automated methods / Chantal Incledon and Herman Lam -- The analysis of pharmaceutical inactive ingredients / Xue-Ming Zhang -- Validation study of JP heavy metal limit test / Yoshiki Nishiyama -- Bioanalytical method validation / Fabio Garofolo -- The procurement, qualification and calibration of laboratory instruments: an overview / Herman Lam -- Performance verification of UV-VIS spectrophotometers / Herman Lam -- Performance verification of HPLC / Herman Lam.
Sommario/riassunto	Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements

of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation.