1.	Record Nr.	UNINA9910840587503321
	Autore	Bliesner David M
	Titolo	Validating chromatographic methods [[electronic resource]] : a practical guide / / David M. Bliesner
	Pubbl/distr/stampa	Hoboken, N.J., : Wiley, c2006
	ISBN	1-280-64898-8 9786610648986 0-470-04220-6 0-470-04219-2
	Descrizione fisica	1 online resource (301 p.)
	Disciplina	543.8 543/.8
	Soggetti	Chromatographic analysis - Validity Science - Methodology
	Lingua di pubblicazione	Inglese
	Formato	Materiale a stampa
	Livello bibliografico	Monografia
	Note generali	Description based upon print version of record.
	Nota di bibliografia	Includes bibliographical references (p. 283) and index.
	Nota di contenuto	VALIDATING CHROMATOGRAPHIC METHODS; CONTENTS; PREFACE; 1. OVERVIEW OF METHODS VALIDATION; 2. COMPONENTS OF METHODS VALIDATION; 3. STEP 1: METHOD EVALUATION AND FURTHER DEVELOPMENT; 4. STEP 2: FINAL METHOD DEVELOPMENT AND TRIAL METHODS VALIDATION; 5. STEP 3: FORMAL METHODS VALIDATION AND REPORT GENERATION; 6. STEP 4: FORMAL DATA REVIEW AND REPORT ISSUANCE; 7. SUMMARY; APPENDICES; I. GLOSSARY OF METHODS VALIDATION TERMS; II. TEMPLATE FOR AN EXAMPLE METHODS VALIDATION STANDARD OPERATING PROCEDURE (SOP); III. TEMPLATE FOR AN EXAMPLE END-USER REQUIREMENTS QUESTIONNAIRE IV. TEMPLATE FOR AN EXAMPLE METHOD REVIEW CHECKLISTV. TEMPLATE FOR AN EXAMPLE STANDARD TEST METHOD; VI. TEMPLATE FOR AN EXAMPLE METHODS VALIDATION PROTOCOL; VII. TEMPLATE FOR AN EXAMPLE METHODS VALIDATION REPORT; REFERENCES; INDEX
	Sommario/riassunto	All the information and tools needed to set up a successful method validation system Validating Chromatographic Methods brings order and Current Good Manufacturing Practices to the often chaotic process of chromatographic method validation. It provides readers with both

the practical information and the tools necessary to successfully set up a new validation system or upgrade a current system to fully comply with government safety and quality regulations. The net results are validated and transferable analytical methods that will serve for extended periods of time with minimal