Record Nr. UNINA9910271049203321 Continuous manufacturing of pharmaceuticals / / edited by Peter **Titolo** Kleinebudde, Dsseldorf, Johannes Khinast, Graz, Jukka Rantanen Pubbl/distr/stampa Hoboken, New Jersey;; Chichester, England:,: Wiley,, 2017 ©2017 **ISBN** 1-119-00133-1 1-119-00135-8 1-119-00134-X 9781119001324 Descrizione fisica 1 online resource (630 pages): illustrations Collana Advances in Pharmaceutical Technology Classificazione SCI013060 Disciplina 615.1/9 Soggetti Pharmaceutical technology Pharmaceutical industry ebook Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Nota di bibliografia Includes bibliographical references and index. Nota di contenuto 1.1 Introduction; 1.2 Advantages of Continuous Manufacturing; 1.3 Engineering Principles of Continuous Manufacturing -- 2.1 Introduction ; 2.2 Pharmaceutical solid dosage manufacturing processes ; 2.3 Mathematical modeling approaches; 2.4 Unit operations models; 2.5 Process control of continuous solid-based drug manufacturing: 2.6 Summary; 2.7 References -- 3.1 Introduction; 3.2 Regulatory considerations; 3.3 Quality/GMP considerations; 3.4 Quality considerations for bridging existing batch manufacturing to continuous manufacturing; 3.5 General regulatory references -- 4.1 Introduction; 4.2 Micro Flow Technology; 4.3 Multi-step synthesis of active pharmaceutical ingredients in micro flow; 4.4 Larger scale syntheses; 4.5 Current industrial applications; 4.6 Conclusion and Outlook; 4.7 References -- 5.1 Introduction; 5.2. Principles of Crystallization; 5.3 Crystallization Process Development: 5.4 Continuous Crystallizers and Applications; 5.5 Process Monitoring, Analysis and Control; 5.6 Particle Characterization; 5.7 Concluding Remarks -- 6.1 Abstract; 6.2 Introduction; 6.3 Operation of fermentation systems; 6.4 Continuous

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## Sommario/riassunto

"A comprehensive look at existing technologies and processes for continuous manufacturing of pharmaceuticals As rising costs outpace new drug development, the pharmaceutical industry has come under intense pressure to improve the efficiency of its manufacturing processes. Continuous process manufacturing provides a proven solution. Among its many benefits are: minimized waste, energy consumption, and raw material use; the accelerated introduction of new drugs; the use of smaller production facilities with lower building and capital costs: the ability to monitor drug quality on a continuous basis: and enhanced process reliability and flexibility. Continuous Manufacturing of Pharmaceuticals prepares professionals to take advantage of that exciting new approach to improving drug manufacturing efficiency. This book covers key aspects of the continuous manufacturing of pharmaceuticals. The first part provides an overview of key chemical engineering principles and the current regulatory environment. The second covers existing technologies for manufacturing both small-molecule-based products and protein/peptide products. The following section is devoted to process analytical tools for continuously operating manufacturing environments. The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state-of-art approaches for innovative new manufacturing principles. Brings together the essential know-how for anyone working in drug manufacturing, as well as chemical, food, and pharmaceutical scientists working on continuous processing Covers chemical engineering principles, regulatory aspects, primary and secondary manufacturing, process analytical technology and qualityby-design Contains contributions from researchers in leading pharmaceutical companies, the FDA, and academic institutions Offers an extremely well-informed look at the most promising future approaches to continuous manufacturing of innovative pharmaceutical products Timely, comprehensive, and authoritative, Continuous Manufacturing of Pharmaceuticals is an important professional resource for researchers in industry and academe working in the fields of pharmaceuticals development and manufacturing"--"This book covers key aspects of the continuous manufacturing of pharmaceuticals. The first part provides an overview of key chemical engineering principles and the current regulatory environment. The second covers existing technologies for manufacturing both smallmolecule-based products and protein/peptide products. The following section is devoted to process analytical tools for continuously operating manufacturing environments. The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state-of-art approaches for innovative new manufacturing principles"--