1. Record Nr. UNINA9910731465203321

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Titolo	Technology Transfer : Drug Product Manufacturing Process / / by Ajay Babu Pazhayattil, Sanjay Sharma, Joe Paul Philip, Michelle Gischewski-Silva, Marzena Ingram
Pubbl/distr/stampa	Cham : , : Springer International Publishing : , : Imprint : Springer, , 2023
ISBN	3-031-32192-8
Edizione	[1st ed. 2023.]
Descrizione fisica	1 online resource (158 pages)
Collana	AAPS Introductions in the Pharmaceutical Sciences, , 2522-8358 ; ; 10
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Disciplina	615.1 615.19
Soggetti	Pharmacy Pharmaceutical chemistry Pharmacology Drug delivery systems Pharmacovigilance Pharmaceutics Drug Delivery Drug Safety and Pharmacovigilance
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di contenuto	Chapter 1: Current Status of Technology Transfer -- Chapter 2: Quality by Design (QbD) Process Design -- Chapter 3: Quality Risk Management (QRM) -- Chapter 4: Technology Transfer Process -- Chapter 5: Scaling-Up of Solid Orals: Granulation, Drying, Size Reduction, Blending, Compression, and Coating Technologies -- Chapter 6: Qualification, Continued Process Verification, and Lifecycle Management -- Chapter 7: Continuous Improvement Case Study: Transforming Legacy Products.
Sommario/riassunto	Currently, there are no textbooks on drug product manufacturing

technology transfer that incorporate the latest regulatory expectations. Recent guidance from regulatory bodies such as the US FDA, EMEA, WHO, and PIC/S has adopted the ICH Lifecycle approach harmonizing concepts across regulatory guidance. This allows organizations to align their technology transfer activities for all regulated markets. However, there is a need for consensus and direction in approaching technology transfer, particularly in understanding how to manage the scale-up effects to ensure regulatory compliance. This textbook offers technology transfer solutions and guidance to the pharmaceutical industry. The chapters provide a systematic understanding of applying the technology transfer concepts in pharmaceutical manufacturing, promoting standardization within the industry. Since Stage 1b is not specified in detail within the regulations, pharmaceutical organizations are left to determine the requirements of the stage. The need to justify the methodologies and utilization of sound science makes it more demanding. The textbook’s authors provide innovative solutions for technology transfer challenges, making it a comprehensive reference document. The approaches can be applied to both small-molecule and large-molecule drug product manufacturing segments, addressing the unmet needs of the industry.