1. Record Nr. UNINA9910555136903321

Titolo	Pharmaceutical microbiological quality assurance and control : practical guide for non-sterile manufacturing / / edited by David Roesti, Novartis Pharma Stein AG, Switzerland, Marcel Goverde, MGP Consulting GmbH, Switzerland
Pubbl/distr/stampa	Hoboken, NJ : , : Wiley, , 2020 ©2020
ISBN	1-119-35612-1 1-119-35619-9 1-119-35611-3
Descrizione fisica	1 online resource (xxxv, 546 pages) : illustrations
Disciplina	615.19
Soggetti	Pharmaceutical technology - Standards Microbiological Techniques - standards Microbiological Phenomena Drugs - Testing Pharmaceutical chemistry Electronic books.
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Microbiological control strategy -- Microbial contamination risk assessment in non-sterile drug product manufacturing and risk mitigation -- Qualification of Microbiological laboratory personnel and equipment -- Introduction to culture media in pharmaceutical microbiology for non-sterile products -- Microbiological examination of non-sterile final dosage forms and raw material including acceptance criteria and testing frequency -- Microbial requirements and testing of primary packaging -- Utilities design and testing -- Microbiological Environmental Monitoring -- Identification of microorganisms -- Calculating alert levels and trending of microbiological data -- Exclusion of objectionable microorganisms from non-sterile pharmaceutical drug products -- Data integrity and microbiological excursion handling -- Rapid microbiological methods

-- Validation of a rapid microbiological method for the microbiological examination of non-sterile and non-filterable drug products, APIs and excipients -- An Ex-Regulator's View of the Microbiology QA/QC Functions in the US Pharmaceutical Industries -- Practical guide for microbiological QA/QC of non-sterile pharmaceuticals manufacturing for EU -- Which microbiological tests can better be performed in-house and what can be easily outsourced.

Sommario/riassunto

"This book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non-sterile pharmaceuticals. It covers state-of-the-art microbiology quality assurance and control (QA / QC) tests as well as risk mitigation strategies so that the reader can implement these methodologies in a facility or laboratory to meet microbiology current good manufacturing practices (cGMPs). Also, the authors discuss developments in microbiological testing technology. They share their long experience in practicing microbiological QA/QC in large multinational pharmaceutical companies and present real-life complex cases involving tough decision making"--.