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For purposes of this document, the term OOS results includes all test results that fall outside the specifications or acceptance criteria established in drug applications, drug master files (DMFs ...

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Microbiology laboratories should
be separated from production
areas and have an air handling

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system separated from the production areas. Microbiology laboratories should be designed and have sufficient space to suit the operations carried out in them and to avoid mix ups, contamination and cross contamination. If necessary,

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and Drug Administration (FDA) has announced the launch of a new guidance to help drug makers evaluate lab test results that fall outside the specification

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(USP) for pharmaceutical microbiology testing, including antimicrobial effectiveness testing, microbial examination of non-sterile products, sterility testing, bacterial endotoxin testing, particulate matter, device bioburden and environmental

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monitoring testing. The goal of this manual is to provide an ORA/CDER harmonized framework on the knowledge, methods and tools needed, and to apply the appropriate scientific standards required to assess the safety and efficacy of medical

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products within FDA testing laboratories. The PMM has expanded to include some rapid screening techniques along with a new section that covers inspectional guidance for microbiologists that conduct team inspections. This manual was

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developed by members of the Pharmaceutical Microbiology Workgroup and includes individuals with specialized experience and training. The instructions in this document are guidelines for FDA analysts. When available, analysts should use

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procedures and worksheets that are standardized and harmonized across all ORA field labs, along with the PMM, when performing analyses related to product testing of pharmaceuticals and medical devices. When changes or deviations are necessary,

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documentation should be completed per the laboratory's Quality Management System. Generally, these changes should originate from situations such as new products, unusual products, or unique situations. This manual was written to reduce compendia

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method ambiguity and increase standardization between FDA field laboratories. By providing clearer instructions to FDA ORA labs, greater transparency can be provided to both industry and the public. However, it should be emphasized that this manual is a

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supplement, and does not replace any information in USP or applicable FDA official guidance references. The PMM does not relieve any person or laboratory from the responsibility of ensuring that the methods being employed from the manual are fit for use,

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Relying on practical examples

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from the authors' experience, this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non-sterile pharmaceuticals. Offers a comprehensive guidance for non-

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strategy and practical examples from the authors' experience in globalized pharmaceutical companies and expert networks Offers a comprehensive guidance for non-sterile pharmaceuticals microbiological QA/QC Presents the latest developments in both

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regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors' experience in globalized pharmaceutical

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companies and expert networks

In recent years there has been increased interest in the possibility of rapid microbiological methods offering enhanced potential error detection capabilities. However, these

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methods raise a number of questions, such as how to validate new methods, will they be accepted by the pharmacopoeias, and, most importantly, how will the regulators respond?

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This guidance book is meant as a resource to manufacturers of pharmaceuticals, providing up-to-date information concerning required and recommended quality system practices. It should be used as a companion to the regulations/standards themselves

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and texts on the specific processes and activities contained within the QMS. This book includes chapters on US current Good Manufacturing Practice (GMP); international GMP; global GMP guides and harmonization; detailed analysis

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of the requirements and guidances; missing subparts; what inspectors are looking for; and the price of noncompliance. It also includes an appendix with two tabulated comparisons: the first compares US, European-PIC/S, Canadian, and WHO cGMPs,

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while the second compares US cGMPs with effective quality system elements. The companion CD contains cGMP regulations for sterile products produced by aseptic processing; it also includes updated data of statistical enforcement by the

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FDA, both domestically and abroad; a detailed glossary; and dozens of FDA guidance documents as well as international regulations (EU and Canada) and harmonization documents (WHO, PIC/S, and ICH). A very comprehensive

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checklist for a cGMP audit that is based on risk management criteria is also included. Finally, a comprehensive GMP exam is also included.

This book provides insight into the world of pharmaceutical

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quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter

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flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory

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Written by twenty-eight experts, filled with recommendations that can immediately be put into action, this book provides the strategies and tactics required to link and harmonize manufacturing

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inspection relationships, discussions with management regarding privileged information, seizure and prosecution, HACCP, bioengineered food, dietary supplements, cosmetics, bioterrorism, and product disposition. The manual also

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includes a directory of Office of Regulatory Affairs offices and divisions.

In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances,

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accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutica

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I products to keep abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-

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follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA

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representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the

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topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a

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case study on microbial identification in support of a product contamination investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical

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microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

Pharmaceutical manufacturing

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can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of

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several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is 'current good manufacturing

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practice (CGMP)", which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle,

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patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new

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professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and

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management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial

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manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

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A comprehensive introduction for scientists engaged in new drug development, analysis, and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates—especially chemistry,

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analytical chemistry, pharmacy, and pharmaceutical majors—into its ranks. However, because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult. Designed

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to assist both recent graduates, as well as experienced chemists or scientists with limited regulatory, compendial or pharmaceutical analysis background, make that transition, Pharmaceutical Analysis for Small Molecules is a concise, yet

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comprehensive introduction to the drug development process and analysis of chemically synthesized, small molecule drugs. It features contributions by distinguished experts in the field, including editor and author, Dr. Behnam Davani, an analytical

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chemist with decades of technical management and teaching experience in compendial, regulatory, and industry. This book provides an introduction to pharmaceutical analysis for small molecules (non-biologics) using commonly used techniques for

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drug characterization and performance tests. The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their

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products. In addition, related required supporting studies including good laboratory/documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include: Drug Approval

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standards) Common methods in
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topics on both regulatory (ICH) and Compendial harmonization are also highlighted.

Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process, including

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analytical chemists,
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