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Microbiological Control in a Pharmaceutical Manufacturing Environment An Overview of Quality Assurance in Pharmaceutical Industry

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Microbial Quality Assurance in Pharmaceuticals, Cosmetics ...

David Roesti, PhD, works at Novartis Pharma AG in Stein, Switzerland, and is responsible for defining the microbial control strategy at the site and is a global subject matter expert in microbiology for the Novartis group. He is also is an elected member of the General Chapters Microbiology Expert Committee of the Unites States Pharmacopoeia 2015–2020 revision cycle.

Pharmaceutical Microbiological Quality Assurance and ...

Pharmaceutical Microbiological Quality Assurance and Control

offers a thorough and practical guide for professionals working in the field of non-sterile drug manufacturing. Drawing on the authors' experience working in the field, the book contains a thorough and up-to-date approach to controlling and monitoring microbial contaminations during the manufacturing of non-sterile pharmaceuticals.

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Quality Assurance - Pharmaceutical Guidelines

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.

Pharmaceutical Microbiological Quality Assurance and Control

Quality assurance of pharmaceuticals : a compendium of guidelines and related materials. Vol. 2, Good manufacturing practices and inspection. – 2nd ed. 1. Drug and narcotic control – standards 2. Drug industry – standards 3. Pharmaceutical preparations – standards 4. Biological products – standards

Quality assurance of pharmaceuticals - WHO

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The Guide to the Inspection of Pharmaceutical Quality Control Laboratories provided very limited guidance on the matter of inspection of microbiological laboratories.

Microbiological Pharmaceutical Quality Control Labs (7/93

...

The microbiological acceptance criteria of non-sterile drug products are generally based on the tripartite harmonized informational chapters of the Ph. Eur./USP and JP and are composed of a quantitative total aerobic microbial count and total yeasts/molds count and the absence of specified microorganisms.

Microbiological Examination of Non-sterile Final Dosage ...

Quality assurance of results and quality control of performance 10.1 Internal quality control ... Good practices for pharmaceutical quality control laboratories (1); General ... 2.1.5 Access to the microbiological laboratory should be restricted to authorized

personnel. Personnel should be made aware of:

Annex 2 WHO good practices for pharmaceutical microbiology ...

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