

Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements,Second Edition

By Lucia Clontz

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In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, 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/biopharmaceutical 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-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 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 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 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 microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

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Diosynth Biotechnology, a part of Schering-Plough, Morrisville, North Carolina, USA

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