



Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements

By Lucia Clontz

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This invaluable book guides readers through the microbial limit testing methodologies of the major world markets, including the US Pharmacopeia, the European Pharmacopoeia, British Pharmacopoeia, and Japanese Pharmacopoeia. It compares and contrasts various methods and provides easy-to-follow approaches to validation of these test methodologies. Packed with practical guidance on all aspects of bioburden evaluation both for product and for support mechanisms, the book covers microbial ecology, preservation of pharmaceuticals, water, equipment/surfaces and environment, Rapid Test methods, and handling of aberrant data in the lab.

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About the Author

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