Microbiology

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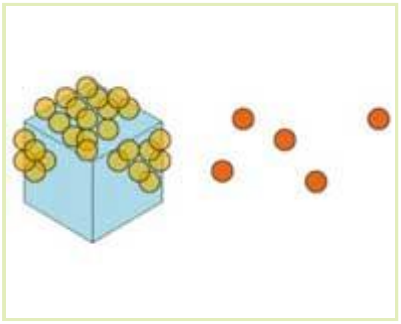

Microbiology Regulatory Handbook

I. Introduction

Microbiology has a clear impact upon the pharmaceutical industry, and regulatory authorities are keen to ensure that medicinal products of all kinds are controlled with regard to potential contamination of products by microorganisms. Pharmaceutical microbiology ensures medications not to contain harmful levels of microorganisms. Regulations exist to minimize the risk of possible contaminants and ensure drug safety various regulations are in place.

These regulations are set forth by regulatory bodies (FDA, CDC, ICH, EMA and other organizations like PIC/S, USP, JP, ISPE, PDA, etc). These regulations are dynamic and are constantly changing. In the context of microbiology, regulations are related to facility design, environmental and gowning requirements, environmental monitoring programmes, sterilization validation, process simulation testing, investigation of laboratory failures (e.g., sterility test failures), disinfection policies, and validation of water systems and utilities, etc. A single source of updated information on these regulations is found essential for the pharmaceutical industry in order to be compliant with the current regulations. This Microbiology Regulatory Handbook aims to provide a comprehensive list of the current regulations about microbiology in the field of pharmaceutical.