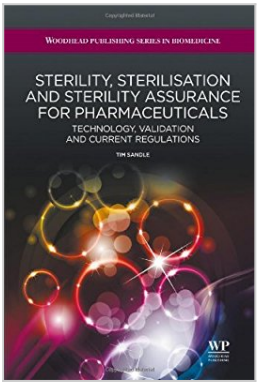

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals: Technology, Validation and Current Regulations (Woodhead Publishing Series in Biomedicine)

By Tim Sandle

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals: Technology, Validation and Current Regulations (Woodhead Publishing Series in Biomedicine) By Tim Sandle

Failure to adequately control any microbial challenge associated within process or product by robust sterilisation will result in a contaminated marketed product, with potential harm to the patient. Sterilisation is therefore of great importance to healthcare and the manufacturers of medical devices and pharmaceuticals. Sterility, sterilisation and sterility assurance for pharmaceuticals examines different means of rendering a product sterile by providing an overview of sterilisation methods including heat, radiation and filtration. The book outlines and discusses sterilisation technology and the biopharmaceutical manufacturing process, including aseptic filling, as well as aspects of the design of containers and packaging, as well as addressing the cleanroom environments in which products are prepared. Consisting of 18 chapters, the book comprehensively covers sterility, sterilisation and microorganisms; pyrogenicity and bacterial endotoxins; regulatory requirements and good manufacturing practices; and gamma radiation. Later chapters discuss e-beam; dry heat sterilisation; steam sterilisation; sterilisation by gas; vapour sterilisation; and sterile filtration, before final chapters analyse depyrogenation; cleanrooms; aseptic processing; media simulation; biological indicators; sterility testing; auditing; and new sterilisation techniques.

- Covers the main sterilisation methods of physical removal, physical alteration and inactivation
- Includes discussion of medical devices, aseptically filled products and terminally sterilised products
- Describes bacterial, pyrogenic, and endotoxin risks to devices and products

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Editorial Review

Review
"Very useful guide to sterility, sterilization and sterility assurance practices in pharmaceuticals. This book reviews all technologies: established and emerging, in a readable and straightforward way."
(Extract from 'Cleanroom Technology', January 2014)

"A good introductory text...belongs on every science bookshelf."
(European Journal of Pharmaceutical Science and Technology, Issue 4, 2013)

From the Author
The chapter list is:

- Sterility, sterilization and microorganisms
- Pyrogenicity and bacterial endotoxin
- Regulatory requirements and Good Manufacturing Practices (GMP)
- Gamma radiation
- Electron beam processing
- Dry heat sterilization
- Steam sterilization
- Gaseous sterilization
- Hydrogen peroxide vapor sterilization
- Sterilization by filtration
- Other methods of sterilization
- Depyrogenation and endotoxin
- Cleanrooms, isolators and cleanroom technology
- Aseptic processing and filling
- Media simulation trials
- Cleaning and disinfection of sterile processing facilities
- Biological indicators
- The Sterility Test
- Investigating sterility test failures
- Auditing sterilization processes and facilities.

From the Inside Flap

Dr. Tim Sandle is a chartered biologist and holds a first class honours degree in Applied Biology; a Masters degree in education; and has a doctorate from Keele University.
Dr. Sandle has over twenty-five years experience of microbiological research and biopharmaceutical processing. This includes experience of designing, validating and operating a range of microbiological tests including sterility testing, bacterial endotoxin testing, bioburden and microbial enumeration, environmental monitoring, particle counting and water testing. In addition, Dr. Sandle is experienced in pharmaceutical microbiological risk assessment and investigation.

Users Review

From reader reviews:

Julius Montanez:

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Stuart Rosado:

The book untitled Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals: Technology, Validation and Current Regulations (Woodhead Publishing Series in Biomedicine) contain a lot of information on the idea. The writer explains her idea with easy method. The language is very easy to understand all the people, so do not necessarily worry, you can easy to read that. The book was written by famous author. The author brings you in the new period of literary works. It is possible to read this book because you can read on your smart phone, or model, so you can read the book inside anywhere and anytime. In a situation you wish to purchase the e-book, you can wide open their official web-site in addition to order it. Have a nice learn.

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