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

Tim Sandle
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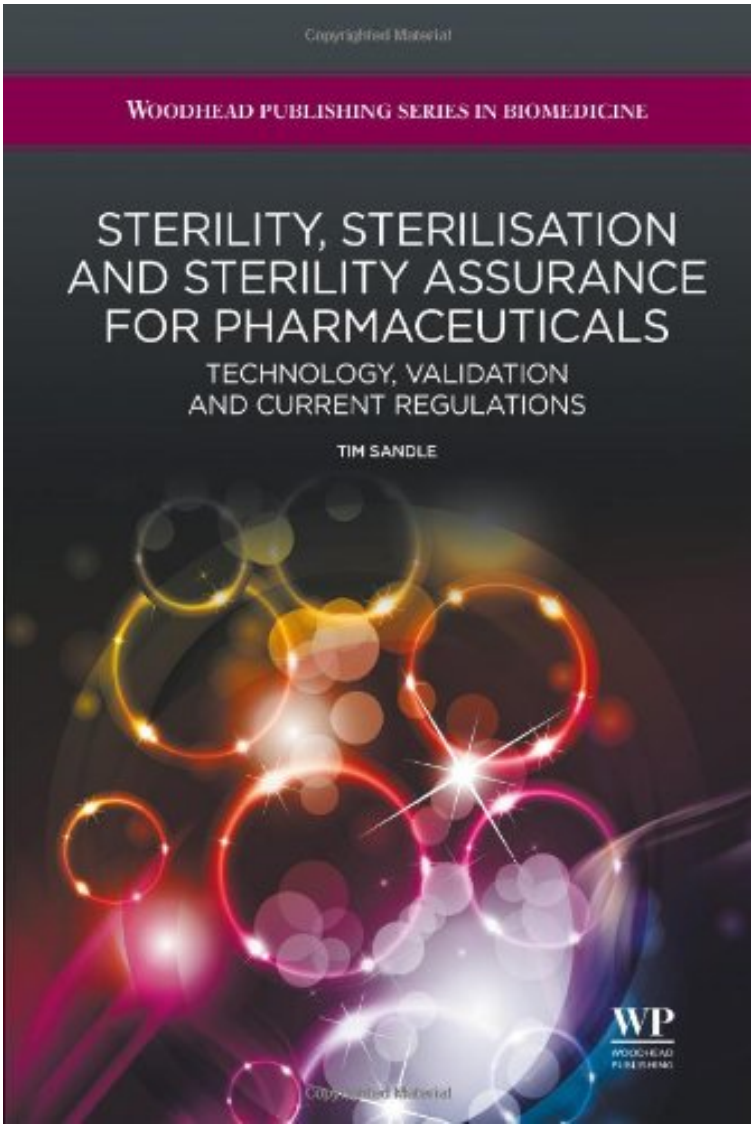

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Tim Sandle : Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals: Technology, Validation and Current Regulations (Woodhead Publishing Series in Biomedicine) before purchasing it in order to gage whether or not it would be worth my time, and all praised Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals:

Technology, Validation and Current Regulations (Woodhead Publishing Series in Biomedicine):

1 of 1 people found the following review helpful. Novel sterilization technologies explained.By Kindle CustomerThis book provides an informative overview of established and emerging sterilization technologies, as well as providing one of the clearest introductions to sterility assurance that I've come across. An important book for sterility, sterilization and microbiologist.

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 inactivationIncludes discussion of medical devices, aseptically filled products and terminally sterilised productsDescribes bacterial, pyrogenic, and endotoxin risks to devices and products

"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 AuthorThe chapter list is:Sterility, sterilization and microorganismsPyrogenicity and bacterial endotoxinRegulatory requirements and Good Manufacturing Practices (GMP)Gamma radiationElectron beam processingDry heat sterilizationSteam sterilizationGaseous sterilizationHydrogen peroxide vapor sterilizationSterilization by filtrationOther methods of sterilizationDepyrogenation and endotoxinCleanrooms, isolators and cleanroom technologyAseptic processing and fillingMedia simulation trialsCleaning and disinfection of sterile processing facilitiesBiological indicatorsThe Sterility TestInvestigating sterility test failuresAuditing sterilization processes and facilities.From the Inside FlapDr. 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.