

## STERILE PRODUCT DEVELOPMENT%0A

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This comprehensive book encompasses various facets of sterile product development. Key concepts relevant to the successful development of sterile products.

[Sterile Product Development: Formulation, Process, Quality ...](#)

Sterile product formulation development is more than just deciding which excipients to use with the given drug substance.

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[Sterile Products - Pharmaceutical Development Center \(PDC\)](#)

PDC is experienced in the formulation, development, and manufacture of sterile solutions by aseptic processing.

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[Sterile Filtration Validation Best Practices](#)

For sterile products, the validation of sterilising processes should be of the Sterile Filtration Validation Best Practices [Quality by Design \(QbD\) of Sterile Dosage Form Packaging ...](#)

2. Riley, B.S. and Li, X., [Quality by Design and Process Analytical Technology for Sterile Products where are we now?](#) *AAPS PharmSciTech* 12: 114-118 (2010); 3.

[Manufacturing Sterile Products to Meet EU and FDA Guidelines](#)

[Manufacturing Sterile Products to Meet EU and FDA](#)

[Guidelines 3 Introduction](#) The sterility of a drug is defined as the complete absence of viable microorganisms. Testing for sterility of a preparation is evaluated statistically, creating a Sterility Assurance Level (SAL) (according to the European Pharmacopoeia 6, Main Volume 2008, Part 2.6.1).