



Pharmaceutical Dosage Forms - Parenteral Medications, Third Edition: Volume 3: Regulations, Validation and the Future

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This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals.

First published in 1984 (as two volumes) and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high quality illustrations.

Volume three presents:

- An in-depth discussion of regulatory requirements, quality assurance, risk assessment and mitigation, and extractables/leachables.
- Specific chapters on parenteral administration devices, injection site pain assessment, and parenteral product specifications and stability testing.
- Forward-thinking discussions on the future of parenteral product manufacturing, and siRNA delivery systems.
- New chapters covering recent developments in the areas of visual inspection, quality by design (QbD), process analytical technology (PAT) and rapid microbiological methods (RMM), and validation of drug product manufacturing process.

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