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Book Review

Pharmaceutical Process Scale-Up; 2nd Edition, M. Levin, Editor, CRC Press, 2006, Hardback, 538, ISBN: 10 #1-57444-876-5, ISBN: 13 #978-1-57444-876-4

While only four years have passed since the first edition of this text was published, much change has occurred with respect to pharmaceutical manufacturing, scale-up, and their regulation. Therefore, it is entirely fitting that Michael Levin has updated this book for 2006.

This second edition puts emphasis on making the connection between scale-up and post-approval changes (SUPAC) and process analytical technology (PAT) guidances and keeping all regulatory references as current as possible. Two new chapters in this second edition that relate to these relatively recent regulatory changes include a chapter titled, "Engineering Approaches for Pharmaceutical Process Scale-Up, Validation, Optimization, and Control in the Process and Analytical Technology (PAT) Era" by Fernando Muzzio and a chapter titled, "Innovation and Continuous Improvement in Pharmaceutical Manufacturing" by Ajaz Hussain.

Other new chapters that have been added to this second edition include chapters to address scale-up of roller compaction processes, extrusion and spheronization, and powder-filled hard gelatin capsules.

Many of the former chapters underwent a thorough revision. For example, the chapter on compaction and tableting has been completely rewritten to reflect a more comprehensive perspective in both theoretical and practical aspects. Other chapters included in this text cover topics such as dimensional analysis and scale-up theory and industrial application, parenteral drug scale-up, nonparenteral liquids and semisolids, scale-up considerations for biotechnology-derived products, batch size increase in dry blending and mixing, powder handling, scale-up in the field of granulation and drying, batch size increase in fluid bed granulation, and scale-up of film coating.

Overall, the text provides an excellent reference for anyone involved in product development or pharmaceutical manufacturing, but is especially relevant to those involved at the interface between the two, dealing with process scale-up or technology transfer. This second edition text is the best attempt at combining the practical, theoretical, and current regulatory aspects of pharmaceutical process scale-up into one book. If you are involved in this area, you will find this book useful.

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