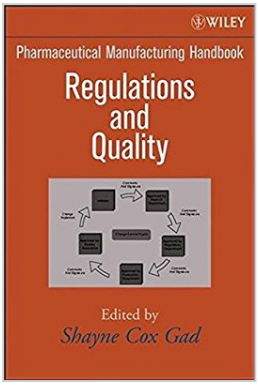

Pharmaceutical Manufacturing Handbook: Regulations and Quality

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With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

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Editorial Review

Review
This book is a valuable reference … .The book contains everything you need to ensure full compliance and superior quality control. (*Pharmaceutical Technology Magazine*, July 2, 2008)

From the Back Cover
Everything you need to ensure full compliance and superior quality control

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The team of expert authors, all familiar with the many issues involved in compliance and quality control, offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing. The editor, who has more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Among the key topics covered are:

- Enforcement of current good manufacturing practices
- Inspections by health regulatory agencies
- Creating and managing a quality management system
- Personnel training within pharmaceutical manufacturing
- Microbiology of non-sterile pharmaceutical manufacturing
- Pharmaceutical manufacturing validation principles

Following the handbook's carefully developed guidelines and advice helps you ensure your company's full compliance and avoid potential costly pitfalls. This publication should be readily accessible to all scientists, engineers, and managers involved in pharmaceutical manufacturing.

About the Author
SHAYNE COX GAD, PhD, DABT, ATS, is the Principal of Gad Consulting Services. Dr. Gad has more than thirty years of experience as a toxicologist, statistical consultant, manager, and general consultant on research and development in the chemical, consumer product, contract testing, biotechnology, medical device, and pharmaceutical industries. He is the author of twenty-nine books and numerous papers, presentations, and other publications.

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