

### Pharmaceutical Analysis / Regulatory Affairs / Quality Assurance

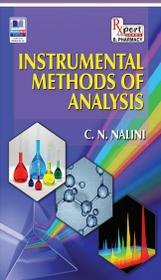
- ▶ **Pharmaceutical Quality Assurance**
  - ▶ GMP and GLP
  - ▶ Quality Assurance
  - ▶ Validation
  - ▶ Regulatory Affairs
    - ▶ IPR ▶ Regulatory ▶ Management
- ▶ **Pharmaceutical Analysis**
  - ▶ Pharmaceutical Analysis Practical
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### GMP & GLP



STUDENT FRIENDLY BOOKS WRITTEN AS PER PCI SYLLABUS BY DISTINGUISHED AUTHORS



### Instrumental Methods of Analysis

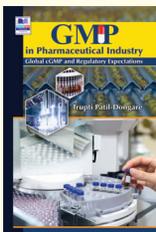


**C. N. Nalini**

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2023 | 9789391910877 | BSPMP | 268 pp | PB | Rs. 375.00

### GMP & GLP



### GMP in Pharmaceutical Industry Global cGMP & Regulatory Expectation

**Trupti Patil Dongare**

**Contents:** 1. GMP Regulations for Pharmaceutical Industry 2. Good Laboratory Practices in Pharmaceutical Industry 3. Good Microbiology Practice in Pharmaceutical Industry 4. Good Aseptic Practices in Pharmaceutical Industry 5. Good Clean Room Monitoring in Pharmaceutical Industry 6. Good Engineering Practices in Pharmaceutical Industry 7. Good Alarm Management Practices in Pharmaceutical Industry 8. Good Computer Validation System Practices in Pharmaceutical Industry 9. Good Distribution Practices—Supply Chain Integrity in Pharmaceutical Industry 10. Good Data Management System in Pharmaceutical Industry 11. Quality Agreements in Pharmaceutical Industry 12. Change control Management and its Applications 13. Technology Transfer of Pharmaceutical Product 14. Pharmaceutical Annual Product Quality Review 15. Statistical Tools for Pharmaceutical Industry 16. Application of Different Quality Tools in Investigation of Non-Conformance Observations 17. New Approach to the Internal Audit from Traditional to Risk based Approach 18. Quality by Design (QbD) Approach in the Product Life Cycle 19. Process Validation in Pharmaceutical Industry 20. Cleaning Validation and Cross Contamination Approach on Risk MaPP Concept 21. Pharmaceutical Water Generation and Distribution System and Regulatory Expectation 22. Pharmaceutical Heating, Ventilation and Air Conditionings (HVAC) and Regulatory Expectations 23. Manufacturing Execution System (MES) in Pharmaceutical Industry 24. Pharmaceutical Drug Master File 25. Common Technical Document in Regulatory Filing 26. European Union Marketing Authorization 27. Site Master File 28. Standard Operating Procedure (SOP) 29. Quality Manual 30. Human Error Reduction: Pharma Industry Challenge 31. Regulatory Inspections: Face Challenges through Proactive Measures 32. Pharmaceutical GMP: Past, Present, and Future – A Review

Rpt. 2020 | 9789387593800 | BSPMP | 310 pp | PB | Rs. 395.00

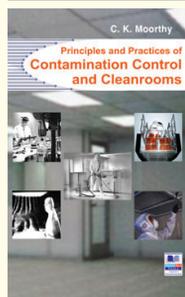


### Good Laboratory Practices and Compliance Monitoring

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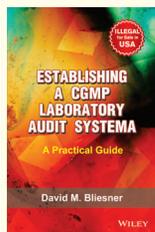
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## GMP &amp; GLP



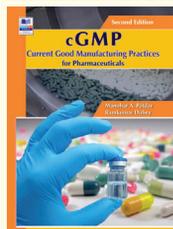
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David M. Bliesner

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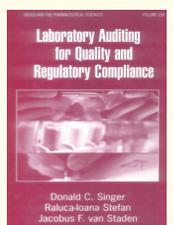


## cGMP Current Good Manufacturing Practices for Pharmaceuticals, 2<sup>nd</sup> Ed.

Manohar A. Potdar and Ramkumar Dubey

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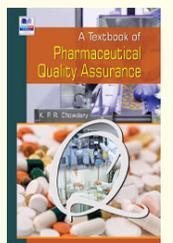
## Laboratory Auditing for Quality and Regulatory Compliance

Donald Singer, Raluca-Ioana Stefan and Jacobus van Staden

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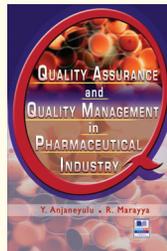
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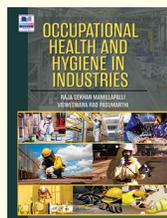
## Pharmaceutical Quality Assurance and Management

K. P. Bhusari, U. D. Shivhare and D. C. Goupale

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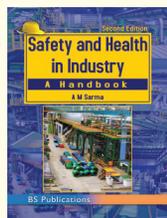
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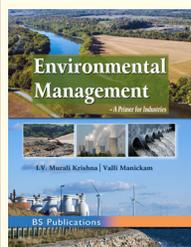
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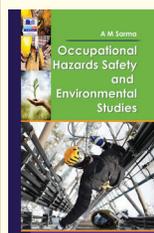
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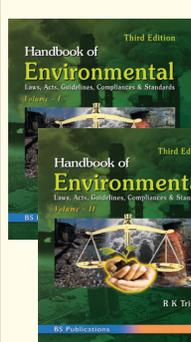


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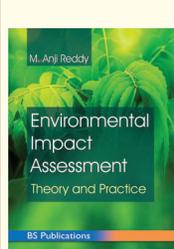


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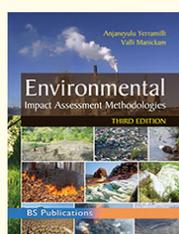
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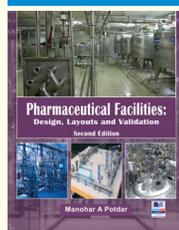
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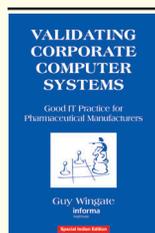


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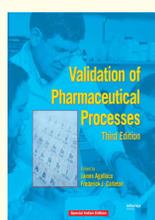
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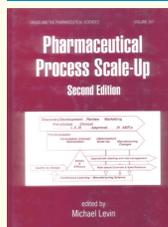
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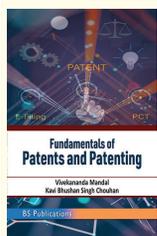
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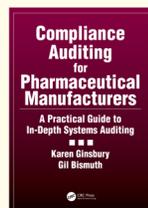


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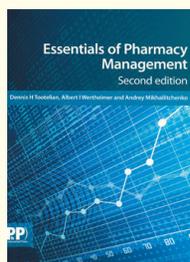
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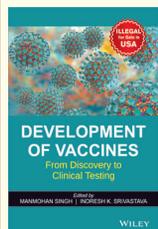
Dennis H Tootelian, Albert I Wertheimar, Andrey Mikhailitchenko

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**REGULATORY**



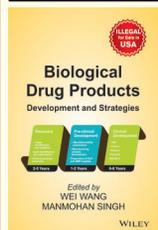
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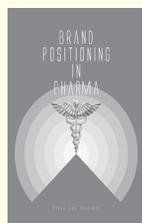
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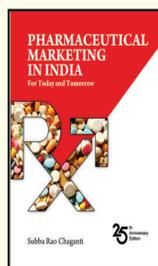
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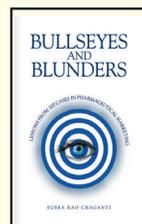


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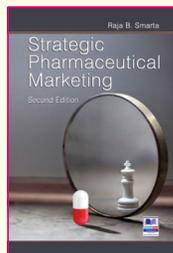
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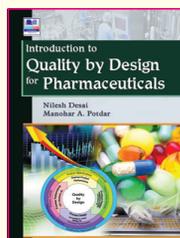


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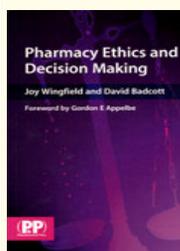


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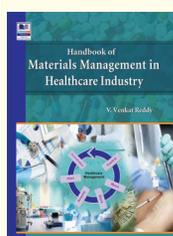


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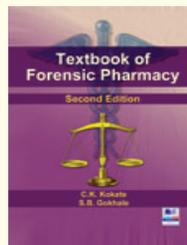


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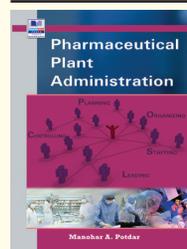


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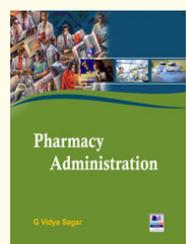


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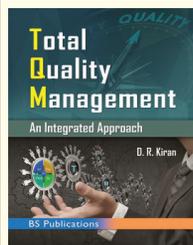
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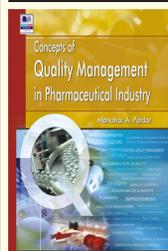
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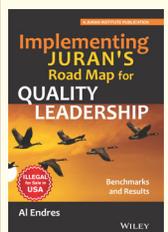


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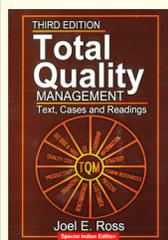
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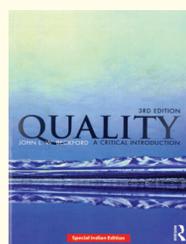


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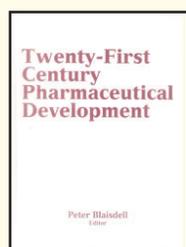


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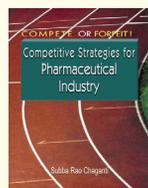


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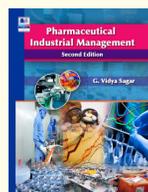
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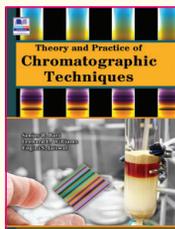
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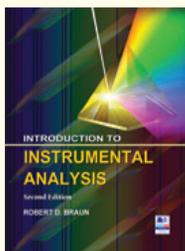


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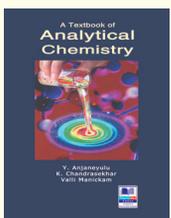
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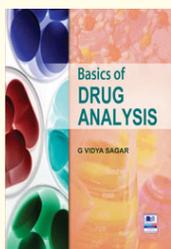
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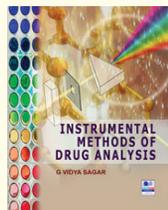


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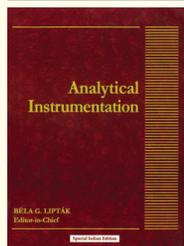


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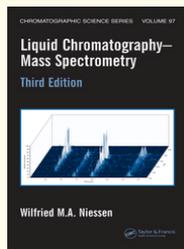


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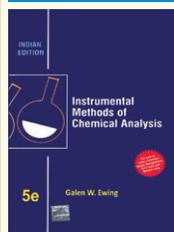
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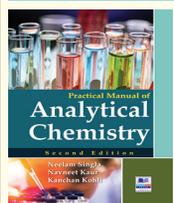
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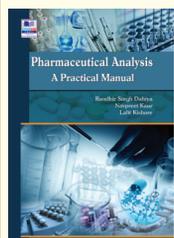
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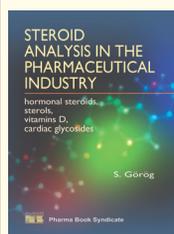
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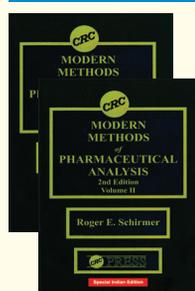
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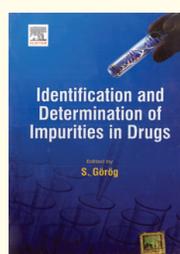


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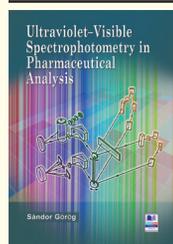


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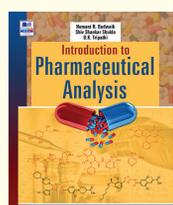


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