

# **GMP in Practice, 4<sup>th</sup> Edition**

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**Foreword**

**Introduction and sources used in this book**

**Acknowledgements**

- 1. Management and Supervisory Responsibilities**
- 2. Quality Risk Management**
- 3. Knowledge Management and Organizational Learning (and tech transfer)**
- 4. Quality Management and Quality Systems**
  
- 5. Product and Process Monitoring**
- 6. Discrepancy Observation and Investigation**
- 7. Complaints**
- 8. Qualification and Validation**
- 9. Training and Performance**
- 10. Documents and Records**
- 11. Change Management**
- 12. CAPA – Corrective Action and Preventive Action**
  
- 13. Materials and Components**
- 14. Vendors, Third Parties, and Outsourcing**
- 15. Sampling**
- 16. Sample Preparation and Analysis**
- 17. Testing and Analysis/QC Laboratory Operations**
- 18. Equipment Cleaning**
- 19. Sanitation**
- 20. Facilities and Utility Systems**
- 21. Warehousing and Storage**
- 22. Distribution Practices**
- 23. Maintenance, Repair, and Calibration**
- 24. Materials Receiving**
  
- 25. Equipment**
- 26. Manufacturing and Packaging: GMP Concepts**
- 27. Manufacturing and Packaging: Operations**
- 28. Label Control**
- 29. Identity Control**
- 30. Batch Release**
- 31. In-process Controls**
- 32. Aseptic Processing**
- 33. Clothing and Personal Hygiene**

**About the author**