Technical Report No. 52
Guidance for Good Distribution Practices (GDPs)
For the Pharmaceutical Supply Chain
The authors would like to acknowledge Abbott Laboratories for sharing some of their internal standards which were used as the baseline documents in the development of this guidance.
Table of Contents

1.0 INTRODUCTION ...................................................2
  1.1 Purpose and Scope...........................................2
  1.2 Responsibility ...................................................2

2.0 GLOSSARY OF TERMS .........................................3

3.0 REQUIREMENTS ....................................................4
  3.1 Stability ............................................................4
  3.1.1 Storage Temperatures ........................................4
  3.1.2 Shipping Temperatures .......................................4
  3.1.3 Stability Testing to Support Distribution ....5
  3.2 Distribution Control Management .....................5
  3.2.1 Qualification and Training of Personnel ......5
  3.2.2 Premises and Equipment ...........................5
  3.2.3 Material Handling ............................................6
  3.2.3.1 Receiving and Storage..............................6
  3.2.3.2 Product Status..........................................6
  3.2.3.3 Controlled Drugs .......................................7
  3.2.3.4 Counterfeit Products...............................7
  3.2.3.5 Records ................................................7
  3.2.4 Storage and Inventory Control ...................7
  3.2.4.1 Inventory ..............................................7
  3.2.4.2 Product Status Control ..............................7
  3.2.4.3 In-Transit Storage .................................8
  3.2.5 Transportation ............................................8
  3.2.6 Product Disposition and Distribution............8
  3.2.7 Product Protection......................................9
  3.2.8 Returns Management ......................................9
  3.2.9 Exception Management .................................10
    3.2.9.1 Corrective Action and Preventative Action (CAPA) System .......10
    3.2.9.2 Complaints ..........................................10
    3.2.9.3 Quality Holds ...................................10
    3.2.9.4 Product Action ..................................10
  3.3 Performance Management ..................................10
    3.3.1 Performance Measurement and Reporting ..........11
    3.3.2 Self-Inspection (Internal Audit) .................11
    3.3.3 Management Review Meetings ...................11
  3.4 Supply Chain Partner Management ................11
    3.4.1 Partner Selection ...................................11
    3.4.2 Quality Audit..........................................12
    3.4.3 Quality Agreements ................................12
  3.5 Business Review Meetings ............................12

4.0 APPENDIX ...........................................................13
  4.1 Good Storage and Shipping Practices Checklist ....13

5.0 ADDITIONAL READING .......................................31
  5.1 Selected Global Laws and Regulations ..........31
  5.2 Selected Publications .....................................31
  5.3 Selected Regulatory Authority Websites ....31

FIGURES AND TABLES INDEX

Table 1.1 Seven Pillars of Good Distribution Practices .................2