Good Distribution Practice (GDP) is the part of quality assurance which ensures that products are consistently stored, transported and handled under suitable condition as required by the marketing authorisation (MA) or product specification. There is no single global GDP standard. Cold Chain IQ has created this easy-to-assimilate summary of GDP requirements around the world, enabling you to navigate the landscape. You can keep it as a handy reference, share it around your colleagues or even stick it on your wall!

This information is accurate to the best of the respondents knowledge at that time, and may subsequently have changed. Cold Chain IQ cannot take responsibility for the accuracy of this information. Reference: David Ulrich presentation “Good Distribution Practices (GDP’s) & Pharma Supply Chain Management” at the 2011 PDA Pharmaceutical Cold Chain Management Conference.

CANADA
• Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069)
  Health Canada

UNITED STATES
• USP General Chapter <1079> Good Storage and Shipping Practices
• USP General Chapter <1083> Good Distribution Practices—Supply Chain Integrity
  United States Pharmacopeia (USP)

ARGENTINA
• ANMAT Ley 26.492, Regulación de la cadena de frío de los medicamentos, 2009
  National Administration of Drugs, Foods and Medical Devices (ANMAT)

BRAZIL
• Opens public consultation on GMP and GDP Requirements on January 15.
  Deadline for comments March 12, 2013
  The National Health Surveillance Agency (Anvisa)

IRELAND
• IMB - Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007, (S.I. 207) of 2009
• IMB Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medical Products and Active Substance
  Irish Medicines Board (IMB)

DENMARK
• Executive Order No. 823 (DRAC 148444): Distribution of Medicinal Products, August 2012
  Danish Health and Medicines Agency

UK
• Guidance in the Transportation of Medicinal Products, ambient and refrigerated
  Medicines and Healthcare products Regulatory Agency (MHRA)

EUROPEAN COMMISSION
• Revised Commission guidelines on the distribution of medicinal products in the EU will enter into force September 8, 2013
• Guidelines on Good Distribution Practice of Medicinal Products for Human Use
• The principles of GDP are stated in Directive 92/25/EEC
  European Medicines Agency (EMA)

CHINA
• Coming Soon: The newly revised Good Supply Practice for Pharmaceutical Products (GSP) will go into effect as of June 1, 2013
  State Food and Drug Administration, P.R. China (SFDA)

INDIA
• Guidelines on Good Distribution Practices for Biological Products
• DRAFT: Guidelines on Good Distribution Practices for Pharmaceutical Products
  Central Drugs Standard Control Organization (CDSCO)

SINGAPORE
• DRAFT Guidance notes on Good Distribution Practice
  Health Sciences Authority (HSA)

Australia
• Australian code of good wholesaling practice for therapeutic goods for human use
  Therapeutic Goods Administration (TGA)

WHO
• Model requirements for the storage and transport of time and temperature sensitive pharmaceutical products TRS No. 961, Annex 9 (2011)
  World Health Organization (WHO)

PDA
• PDA Technical Report TR 58 Risk Management for Temperature-Controlled Distribution
  Parenteral Drug Association (PDA)

IPEC EUROPE
• The IPEC – Europe Good Distribution Practices Audit Guideline FOR PHARMACEUTICAL EXCIPIENTS 2011
  International Pharmaceutical Excipients Council (IPEC)