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A ONE PAGE GUIDE TO GLOBAL GDP GUIDELINES

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!

ColdChainIQ
Temperature Control Logistics & Quality Network

KEY

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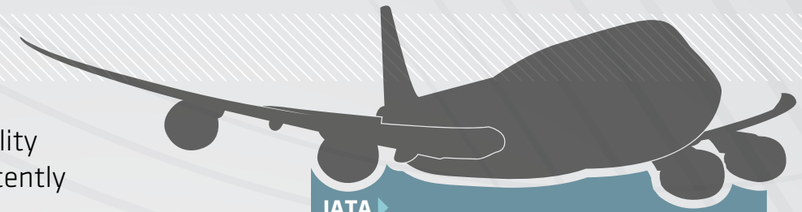

IATA

- **Chapter 17 "Air Transport Logistics for Time and Temperature Sensitive Healthcare Products"**

IATA Perishable Cargo Regulations (PCR)

EUROPEAN COMMISSION

- **Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use, 2011**
- **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)

UK

- **Guidance in the Transportation of Medicinal Products, ambient and refrigerated**

Medicines and Healthcare products Regulatory Agency (MHRA)

CANADA

- **Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069)**

Health Canada

IRELAND

- **IMB - Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (SI 201 of 2007)**
- **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 (IDRAC 148449): Distribution of Medicinal Products, August 2012**

Danish Health and Medicines Agency

INDIA

- **Guidelines on Good Distribution Practices for Biological Products**
- **DRAFT: Guidelines on Good Distribution Practices for Pharmaceutical Products**

Central Drugs Standard Control Organization (CDSCO)

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)

WORLDWIDE

WHO

- **Good Distribution Practices for pharmaceutical products TRS No. 957, Annex 5 (2010)**
- **Model requirements for the storage and transport of time and tem-perature sensitive pharmaceutical products TRS No. 961, Annex 9 (2011)**

World Health Organization (WHO)

SINGAPORE

- **DRAFT Guidance notes on Good Distribution Practice**

Health Sciences Authority (HSA)

BRAZIL

- **Opens public consultation on GMP and GDP Requirements on January 15. Deadline for comments March 12, 2013**

The National Health Surveillance Agency (Anvisa)

IPEC Europe

- **The IPEC –Europe Good Distribution Practices Audit Guideline FOR PHARMACEUTICAL EXCIPIENTS 2011**

International Pharmaceutical Excipients Council (IPEC)

AUSTRALIA

- **Australian code of good wholesaling practice for therapeutic goods for human use**

Therapeutic Goods Administration (TGA)

ARGENTINA

- **ANMAT Ley 26.492, Regulación de la cadena de frío de los medicamentos, 2009**

National Administration of Drugs, Foods and Medical Devices (ANMAT)

PDA

- **PDA Technical Report TR 52 (Aug 2011) Guidance for Good Distribution Practices (GDPs) for the Pharmaceutical Supply Chain**
- **PDA Technical Report TR 53 Guidance for Industry: Stability Testing to Support Distribution of New Drug Products**
- **PDA Technical Report TR 58 Risk Management for Temperature-Controlled Distribution**

Parenteral Drug Association(PDA)

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