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ColdChainIQ
Temperature Control Logistics & Quality Network

COLD CHAIN GDP & TEMPERATURE MANAGEMENT LOGISTICS GLOBAL FORUM SPRING

A One Page Guide to Global GDP Guidelines

The Cold Chain GDP & Temperature Management Logistics Global Forum - Spring will examine the modern cold chain – including all temperature range products and their global GDP requirements. Don't miss out! Join us from May 22-25, 2017 in San Diego, California

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Cick for more information

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!

View the agenda to learn more

IATA

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

IATA Perishable Cargo Regulations (PCR)

Andrea Gruber of the IATA leads Workshop C on September 30, 2014

NEW FOR 2014

On 28 March 2014 the European Commission published a question and answers document related to the new guideline on Good Distribution Practice of medicinal products for human use applicable as of November 2013.
Download the EU Commission Q&A on GDP guidelines here

european commission

- Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)
- 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

- The revised Good Supply Practice for Pharmaceutical Products (GSP) went into effect as of June 1, 2013. Distributors will have 3 years to comply with the new requirements

State Food and Drug Administration, P.R. China (SFDA)

uk

- Updated MHRA Guidance: Medicines distribution in the maritime sector
- Guidance in the Transportation of Medicinal Products, ambient and refrigerated

Medicines and Healthcare products Regulatory Agency (MHRA)

denmark

- Executive Order No. 823 (IDRAC 148449): Distribution of Medicinal Products, August 2012

Danish Health and Medicines Agency

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)

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)

Mary Foster shares the latest USP updates on Main Conference Day One

Worldwide

WHO

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

World Health Organization (WHO)

On October 1, 2014 learn about the WHO's perspective on harmonized GDP Guidelines

singapore

- DRAFT Guidance notes on Good Distribution Practice

Health Sciences Authority (HSA)

Brazil *

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

The National Health Surveillance Agency (Anvisa)

Argentina

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

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

IPEC Europe

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

International Pharmaceutical Excipients Council (IPEC)

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 Suppo rt Distribution of New Drug Products
- PDA Technical Report TR 58 Risk Management for Temperature-Controlled Distribution

Parenteral Drug Association(PDA)

Australia

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

Therapeutic Goods Administration (TGA)

International Focus Day* October 3, 2014

- Targeted sessions on GDP in countries such as Brazil, India, Russia and Thailand. Learn more.

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.