Good Distribution Practice - Current Regulations

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Good Distribution Practice (GDP) is currently discussed in a lot of companies. Reasons for continuing discussions are:
- Upcoming complexity of the global supply chain and distribution
- Increased numbers of incidents
- Increased requirements in the EU GDP draft regulation

There are a significant number of regulations in place that have to be followed when transporting drug products. In the following we would like to give you an up-to-date overview of the current GDP regulations for the handling and transportation of pharmaceutical products.

As a consequence of the discussions GDP is divided into the following topics:
- Temperature Control Management (TCM)
- Distribution Control Systems (DCS)
- Good Importation Practices (GIPs)

The goal of these regulations is to define measures for a global product protection (GPP).

In this feature we concentrate on general GDP regulations as well as on temperature control management regulations.

GDP Regulations

The following published regulations and guidelines are relevant for the distribution of pharmaceutical products. The most important regulations in the European framework are the regulations of the WHO and those of Europe. If you intend to deliver to one of the countries below you have to consider the appropriate local requirement. (Documents available in the internet are linked in the text.)

   → Weblink

2. WHO: Model requirements for the storage and transport of time and temperature sensitive pharmaceutical products TRS No. 961, Annex 9 (2011)
   → Weblink

3. Europe: Commission Guidelines on Good Distribution Practice for Medicinal Products for Human Use (Draft 2011)
   → Weblink

4. Europe: International Pharmaceutical Excipients Council (IPEC) IPEC Good Distribution Practices Audit Guideline
   → Weblink

   → Weblink

6. IATA: Logistics for Temperature Sensitive healthcare products (chapter 17)

7. FDA: (Congress) to Revise Component of GMP’s (and develop new GDP’s) to related to Supply Chain Security (3 “Bills” to amend the FD&C act)

8. USP: Chapter 1118 - Monitoring device-Time, Temperature and Humidity (and others)
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9. USP: Chapter 1083 Good Distribution Practices
   → Weblink
10. Saudi Food & Drug Authority: Temperature Monitors
   → Weblink

11. Taiwan: Precaution of on-site sampling for vaccine testing and sealing operation (Draft)

12. Romanian Directive: Legislation Change - Control of temperature/humidity during transportation

13. Singapore: Health Sciences Authority
   Guidance notes on GDP’ (Draft)
   → Weblink

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   → Weblink

16. India: Pharma Manufacturers Guidelines (not issued by the Gov’t but endorsed by the Gov’t)
   → Weblink

17. Egypt: Minister Decree for Wholesalers - Circular No. 4/2009

18. Australia: Code of Good Wholesaling Practice
   → Weblink

19. Indonesia: GMP Requirements on warehousing or distribution

20. Pakistan: Drug Act of 1976
   → Weblink

21. Brazil: Resolution RDC No. 234 (accelerated vs. real time data)
   → Weblink

22. Canada: Health Canada: Guidelines for Temperature Control of Drug Products during Storage and Transport GUI-0069
   → Weblink

23. Ireland: Irish Medicines Board (IMB) - Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (SI 201 of 2007)
   → Weblink

24. Ireland: IMB Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medical Products and Active Substances
   → Weblink

25. Japan: Biological Pharma revision H15.5.15 (rPAL)

26. UK: MHRA - GDP Risk Assessment Strategy
   → Weblink

27. UK: MHRA – Good Distribution Practice: Guidance and Legislation
   → Weblink

28. Israel: The Status of Current GDP Regulations in Israel (adopt EU &/or WHO)

29. Turkey: GDP’s temperature management and interoperable serialization/pedigree/TnT

30. Saudi Arabia: Control and monitor 100% of pharma imports (cold chain by March 1st and CRT by June 1st)

31. ASEAN: GMP Guidelines
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Technical Reports

In addition the PDA (Parenteral Drug Association) has published a number of Technical Reports (TR) supporting the interpretation of guidelines.

1. TR 39: Guidance for Temperature Controlled Medicinal Products
2. TR 46: The Last Mile, Guidance for GDPs for Pharma Products to the End User

3. TR 52: Guidance for GDPs for the Pharmaceutical Supply Chain (MoH GDPs)

4. TR 53: Stability Testing to Support Distribution of New Drug Products (ICH)

5. TR 54: Implementation of Quality Risk Mgt (QRM) for Pharma and Biotech Mfg’ing Operations

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References:

Presentation of Dave Ulrich, PDA Annual Meeting, Phoenix, AZ, USA, April 18, 2012

Presentation of David Ulrich, PDA März 2011

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Coolpack Website

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