A GLOBAL REVIEW OF GOOD DISTRIBUTION PRACTICES

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CONTENTS

INTRODUCTION

Good Distribution Practice (GDP) is that part of quality assurance which ensures products are consistently stored, transported and handled under suitable conditions as required by the marketing authorisation (MA) or product specification.

With increasing regulatory scrutiny pharmaceutical supply chain stakeholders must focus their efforts on meeting the requirements of storage, transport and handling of time and temperature-sensitive products. However there are many factors to consider the temperature controlled distribution and storage of pharmaceutical products.

Regulatory GDP guidance has a large impact on the manufacture and distribution of pharmaceutical products and with over 30 regulations worldwide, it is a very complex environment. In this e-book we look at some of the GDP related regulations and guidance shaping the regulatory landscape for temperature-sensitive life science products.

"Changing product portfolios, requirements for good storage and distribution practices, regulatory expectations, quality management, and risk assessment factors bring many challenges to the handling of drug products,"

- DR. ÜMIT KARTOGLU WHO

GDP GOES INTERNATIONAL

By Dr. Nicola Spiggelkötter

Good Distribution Practice is a global matter. In March 2013 the EU GDP Guideline was published and this led to controversial discussions. Applying a more global approach it becomes apparent that this guideline is one small contribution among others (WHO, USP, Canada): For example, the revised USP 36 especially chapter 1079.

What are the joint efforts of all these guidelines that focus on the quality of the supply chain? We see two overall principles: temperature and qualification.

Aspect 1 Temperature:
The transport of medicinal products should be executed respecting the labeled conditions of the product. This implies in the majority of cases storage conditions are the same as transport conditions. For cold chain products common and accepted procedure, no debate about that. For ambient products, products that ask for +15°C to +25°C, general practice when we talk about storage, but a most recent development when the same temperature requirement are transferred to transportation.

When we proceed along the pharma supply chain, shipments from the pharmaceutical manufacturer to the wholesaler consists of palletized consignment, mostly full truckloads. In this segment, conditioning of trailers to ambient conditions is easy to realize, including the implementation of monitoring devices that assist in providing evidence that temperature requirements have been respected in transit. Proceeding further on the road of medicinal product to its final destination, the patient, shipments from wholesalers in the local pharmacy, are the next step. The local distribution, the last mile, when we take this term literally, is done with small vehicles, very often not equipped with any equipment to condition the load.

The key question, subject of great controversy in Europe: do the delivery parties have to provide conditioning devices for all their delivery routes regardless the transit time? The EU GDP Guideline provides an ambiguous answer: a risk management approach of the delivery routes decides on which routes temperature monitoring is obligatory. This leads to misunderstandings: the evaluation of risk cannot serve as an excuse to accept anticipated deviations, it is not a "card blanche". In a more US-oriented scenario, the argumentation slightly differs from the European: MKT is here the key word, but we will not further enlarge on this topic, due to the limited space for our paper.

Aspect 2 Qualification:
Equipment and premises have to be qualified, documented evidence has to be provided that they perform as they pretend to do. The qualification process is clear and more or less standardized; the technical reports of the PDA are treated as state of the scientific and technical knowledge. When we focus on the questions, is the equipment able to maintain the required temperature in all circumstances? The application of temperature profiles will answer these questions.

In regard to passive cooling systems, such as insulation boxes, ISTA profiles are similar are followed. Should these or equivalent profiles be transferred when qualifying trailers and vehicles. A common basis and mutual understanding about these profiles would of immense benefit as it helps to compare the individual performance of the vehicles. Everybody involved in test business knows that test results heavily depend on the intensity of the temperature impact: 20°C or 30°C is a decisive question as performance data will be completely different. Evaluating passive boxes it is understood that test runs are executed in qualified test chambers. When we talk about larger units, trailers, test runs in climatic chambers are the exception and not the rule, as it should be.

SOURCE

EUROPEAN COMMISSION

On March 7, 2013, the European Commission finalised and published the long awaited new Good Distribution Practice (GDP) guideline . This replaces the current GDP Guideline published in 1994 (94/C 63/03) and will apply to not only to the wholesalers and manufacturers of pharmaceuticals, but it also incorporates the specific requirements for brokers dealing with pharmaceutical products. Its requirements (Ref: 2013/C 68/01) will enter into force on 8 September 2013.

The revised guidelines introduce the following changes:

- the maintenance of a quality system setting out responsibilities, processes and risk management principles in relation to wholesale activities;
- suitable documentation which prevents errors from spoken communication;
- sufficient competent personnel to carry out all the tasks for which the wholesale distributor is responsible;
- adequate premises, installations and equipment so as to ensure proper storage and distribution of medicinal products;
- appropriate management of complaints, returns, suspected falsified medicinal products and recalls;
- outsourced activities correctly defined to avoid misunderstandings;
- rules for transport in particular to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport;
- Specific rules for brokers (person involved in activities in relation to the sale or purchase of medicinal products).

[Website: http://ec.europa.eu/index_en.htm]

DOWNLOAD THE REVISED GUIDELINES

WANT TO KNOW MORE? INDUSTRY EXPERT CLAUDE AMMANN DISCUSSES THE MAIN CHANGES

New EU GDP Guideline – What Are The Main Changes?

The new EU GDP Guideline of 8 March 2013 on Good Distribution Practice of Medicinal Products for Human Use (2013/C 68/01) is not a slight revision of the previous guideline as it contains completely new content. It is addressed to wholesale distributors, but applies also to other stakeholders involved in the distribution of medicinal products such as brokers.

The Table of content is structured in a similar way as the EU GMP Volume 4 and sounds familiar to the pharmaceutical reader. It is divided in the following chapters:

1. Quality management
2. Personnel
3. Premises and equipment
4. Documentation
5. Operations
6. Complaints, returns, falsified medicines and recalls
7. Contract operations
8. Self-inspections
9. Transportation
10. Brokers

CONTINUED OVERLEAF

The following items are new:

Chapter 1

Quality Management describes the Quality System including management review, continuous improvement, Corrective actions / preventive actions (CAPA) and Risk management. Deviations must be investigated and CAPA process implemented. Some interesting precisions are given concerning Risk Management.

- Control and review of any outsourced activities should include risk management principles.
- Temperature mapping of e.g. storage areas should be repeated according to the results of a risk assessment
- A risk based approach should be utilized when planning transportation routes.

Management should have a formal reviewing process including performance indicators to monitor the effectiveness of the quality system.

Chapter 2

Personnel now requires the wholesale distributor to designate a Responsible Person with a "desirable" degree in pharmacy. Their main responsibilities are defined as Quality Management / Training / Recall-/ Complaints / Returns / Falsified Medicines /Approval Suppliers / Outsourcing / Records / Self- Inspections and so on. The Responsible Person should fulfill his/her Responsibilities personally and should be continuously contactable. "The RP may delegate duties but not responsibilities".

The organizational structure of the wholesale distributor should be clearly described and the roles and responsibilities of key persons described in job descriptions.

Initial and continuous training have to be planned and recorded.

Chapter 3

on Premises and Equipment introduces new requirements concerning storage areas. They should be temperature mapped and the mapping should include initial mapping prior to use, seasonal variations and be repeated based on risk assessment.

- Location of temperature monitors should be based on mapping.
- All equipment should be maintained to a suitable standard and preventive maintenance should be registered.
- Equipment (e.g. temperature monitoring devices) should be calibrated at defined intervals based on a risk and reliability assessment.
- Records should be sustained
- Alarm systems should be in place and tested periodically.
- Any system replacing physical segregation, such as electronic segregation based on a computerized system, should provide equivalent security and should be validated.
- Products pending a decision as to their disposition or products that have been removed from saleable stock should be segregated either physically or through an equivalent electronic system.

Chapter 3 also includes a Qualification / Validation subchapter which states that key equipment should be qualified and key processes (such as storage, pick and pack) should be validated, based on a documented risk assessment approach. Observed qualification and validation deviations should be investigated.

Chapter 5

Operations specifies that Suppliers must be qualified meaning that they are in possession of a wholesale distribution authorisation, or are in possession of a manufacturing authorisation which covers the product in question. The wholesale distributor should carry out due diligence of new suppliers and periodically recheck that qualification and approval are confirmed.

Chapter 7

on Contract operations is adapted from the GMP Chapter 7 and gives Contract Giver responsibility to assess Contract Acceptor competences through audits. Contract Acceptor should have adequate facilities and experience to carry out contracted work safely and efficiently.

Chapter 9

Transportation states that "the required storage conditions for medicinal products should be maintained during transportation within the defined limits as described by the manufacturers or on the outer packaging". This new requirement is in contradiction with the new General Chapter ←1079→ of the USP 35. Storage conditions are defined during stability studies following ICH stability instructions. There are no official guidelines for transport conditions. This point will require additional efforts from the manufacturers and distributors even for products having demonstrated sufficiently that their quality remained satisfactory after a short period out of storage conditions as for example during transportation. The transport of products by patients from the pharmacy to their house is another source of deviations from this requirement.

Chapter 10

defines the responsibilities of brokers. They are subject to registration requirements and should set a quality system in place with special emphasis on emergency plan in case of recalls.

As conclusion, the revised version of the EU GDP requires that wholesaler distributors implement a quality system corresponding to current standards applied in other industries. The timelines for the enforcement is September 8, 2013.

SOURCE

CANADA

In 2013 Health Canada begins its 3 year cycle of updating Guidlines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069).

Canada is playing an increasingly large role in the biopharma industry, with some of the major players making significant investments in recent years.

Health Canada's latest guidelines, GUI-0069, came into force on April 28th 2011, superseding that released in October 2005. The guide discusses Health Canada's guidelines for temperature control of drug products during storage and transportation.

Much of the focus of these new guidelines is in improving monitoring, recording and supervision of existing good practice in the field of temperature controlled distribution, rather than imposing new obligations.

The additions introduced in GUI-0069 build on the good practice that has formed around the distribution of temperature controlled pharmaceuticals in recent years, in part as a result of the greater emphasis being placed on the growing biopharmaceutical and life sciences industries.

FIND OUT MORE ABOUT IMPLEMENTING HEALTH CANADA'S REVISED GUIDELINE:

CLICK TO VIEW GUIDELINES FOR TEMPERATURE CONTROL OF DRUG PRODUCTS DURING STORAGE AND TRANSPORTATION (GUI-0069)

INDIA

In January 2013, The Central Drugs Standard Control Organization (CDSCO) of India, the country's Authority for Medicinal Product, published a draft Guidelines on Good Distribution Practices for Pharmaceutical Products for public opinion.

The objective of these guidelines is to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process. These aspects include, but are not limited to procurement, purchasing, storage, distribution, transportation, documentation and record-keeping practices.

The draft guidance does not yet have a date by which it will become effective.

The Indian pharmaceutical market remains attractive and is expected to grow to US$ 55 billion by 2020 according to the McKinsey & Company report titled " India Pharma 2020: Propelling access and acceptance realising true potential".

Although India is one of the most significant emerging markets, there are challenges around product quality and regulatory complexity. The new guidelines will have a positive impact on the SME industry in India.
The pharmaceutical distribution system in India is undergoing a paradigm shift and we will continue to see improvements, through compliance with the latest standards and the implementation of the latest technologies for supply chain management.

In an interview with Cold Chain IQ, Bhusan Mohapatra, Head-Commercial Indian Immunologicals, noted that the predicted growth in the Indian vaccine market indicates a lot of opportunities for those involved in the cold chain, from the manufacturer to logistics service provider, the technology provider to trace & track and related software provider.

TO VIEW THE GUIDELINES CLICK HERE

Published on the website of www.cdsco.nic.in on 10/01/2013
www.cdsco.nic.in

CHINA

China's importance within the global pharmaceutical industry is growing. However, this growth requires a supporting infrastructure which allows pharmaceutical companies to transport drugs and related equipment in a safe, timely and cost-effective manner.

Henning Voss, director for World Courier, North Asia, described the challenges and situation in China as complex.
"In addition, domestic transport companies do not yet fully understand the many international standards at play in handling these types of shipments," Voss said.

To remain competitive in the global pharmaceutical industry the country is taking steps to improve the quality of its pharmaceutical supply chain. In January this year the Chinese State Food and Drug Administration (SFDA) published a newly revised Good Supply Practice for Pharmaceutical Products (GSP), which will go into effect as of June 1, 2013. The revised guidance sets higher qualification requirements, increases standards for drug distribution and also has higher requirements for quality management.

The revised GSP is made of four chapters, including the General Provisions, Quality Management for Wholesale of Pharmaceutical Products, Quality Management for Retail of Pharmaceutical Products and Supplementary Provisions.
The revised GSP means that many local pharmaceutical companies will need to lift their game when storing and handling drug products or they risk getting left behind their competitors

Charlie Xu, Vice President for Clinical Operations at Frontage Lab China said that compared to multinational companies, many local players don't have stringent compliance records and the regulations are intended to raise the standards of GSP in the country.

"Good supply practices amongst local pharmaceutical companies are not great compared to international players. Unlike large companies, many smaller players don't have in-built QAQC [Quality Assurance and Quality Control] systems," said Mr Xu.

TO VIEW OR DOWNLOAD THE SFDA GOOD SUPPLY PRACTICE DECREE, CLICK HERE

TO VIEW OR DOWNLOAD THE SFDA GOOD SUPPLY PRACTICE GUIDANCE, CLICK HERE

SINGAPORE

Singapore - Health Sciences Authority Guidance notes on GDP

In August 2010 Singapore's Health Sciences Authority (HSA) published Guidance Notes on Good Distribution Practice.

This guide is intended for those involved in the storage, transportation and distribution of starting materials and medicinal products, collectively referred to herein as products. This guide applies to all steps in the distribution/supply chain.

The objective of the guide is to ensure that the quality and integrity of the products is maintained throughout the distribution chain. The manufacturers, agents, traders, brokers or distributors share important and distinctive roles and responsibilities to ensure that products are of the required quality for their intended use.

TO VIEW THE GUIDELINES CLICK HERE

BRAZIL

Brazil's National Health Surveillance Agency (Anvisa) opened a consultation on the 4th April to propose the formation of an electronic tracking system for drugs from point of production through to the point of dispensing to the patient.

The proposed tracking system is to be based on the two-dimensional barcode, the Datamatrix, that will be included on sales packaging as well as secondary packaging such as pill packs and hospital packs.

The CEO of Anvisa, Dirceu Barbano said: ***"Companies holding registration with Anvisa will be responsible for placing on each package a Unique Drug Identifier (IUM) formed by the drug registration number for the product containing thirteen (13) digits, plus the serial number, expiration date and lot number."***

THE COMMENT PERIOD CLOSES ON THE 9TH MAY 2013. FOR AN OUTLINE OF THE PROPOSAL CLICK HERE

USA

U.S. Pharmacopeia

←1079→ Good Storage and Distribution Practices for Drug Products – This general information chapter provides general guidance on good distribution and storage practices to ensure drug products (medicines) reaches the end user quality intact.

TO VIEW THE CHAPTER CLICK HERE

This general information chapter describes a set of recommended practices for helping to ensure supply chain integrity for drug components (drug substances and excipients) and drug products (medicines). Worldwide efforts to help protect the integrity of medicine supply systems are ongoing and quickly changing. The non-mandatory information in this chapter is intended to contribute to the growing body of resources and best-practices information to enhance and protect supply chain integrity.

GS1 Healthcare US

GS1 Healthcare US is an industry group working towards open, global standards to help healthcare companies improve the accuracy, speed, and efficiency of the supply chain and care delivery.

The first phase of the California state drug pedigree requirements become mandatory in 2015, marking the beginning of product serialisation and visibility in the US healthcare supply chain. Earlier this year the GS1 Healthcare US Secure Supply Chain Task Force published a new guideline to support the pending requirements titled "Applying GS1 Standards to U.S. Pharmaceutical Supply Chain Business Processes to Support Serialization, Pedigree and Track & Trace."

"This guideline will help organisations take an active role in the transformation of the healthcare system, meeting the goals of patient safety and regulatory compliance while making the supply chain more efficient," said Siobhan O'Bara, senior vice president of industry engagement, GS1 US. ***"This new guideline should be the 'first stop' for all organizations that are preparing their pharmaceutical supply chain systems and business processes to meet pending improved supply chain security regulatory requirements."***

The new guideline covers product serialisation, supply chain data exchange for pedigree and traceability and pilot learning and best practices.

TO READ THE GUIDELINE CLICK HERE

WORLDWIDE REGULATIONS

World Health Organization (WHO)

- Good Distribution Practices for pharmaceutical products TRS No. 957, Annex 5 (2010) **http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf**
- Model requirements for the storage and transport of time and temperature sensitive pharmaceutical products TRS No. 961, Annex 9 (2011) **http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf}**

Website: www.who.int/

International Pharmaceutical Excipients Council (IPEC) Europe

The IPEC –Europe Good Distribution Practices Audit Guideline FOR PHARMACEUTICAL EXCIPIENTS 2011 **http://www.ipec-europe.org/UPLOADS/IPEC_Europe_GDP_Audit_Guide__-_Revision_2011_final.pdf**

Website: www.ipec-europe.org

International Air Transport Association (IATA)

IATA is the governing Body that creates regulation for international air transport, including regulations controlling the transport of dangerous goods by air

- Chapter 17 "Air Transport Logistics for Time and Temperature Sensitive Healthcare Products" **http://www.iata.org/whatwedo/cargo/pharma/Documents/time-and-temperature-label-faq.pdf**
- IATA Perishable Cargo Regulations (PCR)

Website: www.iata.org

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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!

KEY

Cick for more information

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)

BRAZIL

- Opens public consultation on GMP and GDP Requirements on January 15. Deadline for comments 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)

UK

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

Medicines and Healthcare products Regulatory Agency (MHRA)

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)

IATA

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

IATA Perishable Cargo Regulations (PCR)

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)

DENMARK

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

Danish Health and Medicines Agency

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)

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

Parenteral Drug Association(PDA)

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)

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MORE REGULATIONS

Australia

- Australian code of good wholesaling practice for therapeutic goods for human use **http://www.tga.gov.au/pdf/manuf-cgwp-tg.pdf**

Therapeutic Goods Administration (TGA)

Website: www.tga.gov.au

Argentina

- ANMAT Ley 26.492, Regulación de la cadena de frío de los medicamentos, 2009 **http://www.anmat.gov.ar/webanmat/Legislacion/Medicamentos/Ley_26492_cadena_frio.pdf**

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

Website: www.anmat.gov.ar/webanmat/institucional/que_es_la_ANMAT_en.asp

Denmark

- Executive Order No. 823 (IDRAC 148449): Distribution of Medicinal Products, August 2012 {hyperlink to **http://www.dkma.dk/en/topics/authorisation-and-supervision/company-authorisations-and-registrations/manufacture-and-import-of-medicines-and---ermediates/gdp-and-gmp**

Danish Health and Medicines Agency

Website: http://www.sst.dk/English.aspx

Czech Republic

- Czech Republic GDP Guidelines DIS-15 V.1 2009
- Guidelines for Correct Distribution Practice of Human Medicinal Products DIS-11 2009

State Institute for Drug Control

Website: www.sukl.eu/

Egypt

- MOH Minister Decree for Wholesalers 2009

Egyptian Drug Authority

Website: www.eda.mohp.gov.eg

Malaysia

- Guidelines on Good Storage Practice (GSP), 2004
- Guidelines on Good Distribution Practice (GDP); 1st Edition 2011 **http://portal.bpfk.gov.my/index.cfm?menuid=90&q=gdp**

National Pharmaceutical Control Bureau (NPCB) Ministry of Health (MOH) Malaysia

Website: http://portal.bpfk.gov.my/

South Africa

- MEDICINES CONTROL COUNCIL, GOOD WHOLESALING PRACTICE FOR WHOLESALERS, DISTRIBUTORS and BONDED WAREHOUSES, 2012. Wholesaler distribution forms part of the supply chain of pharmaceutical products manufactured. Wholesalers/ Distributors are responsible for the effective, efficient and safe handling, storage and distribution of such products ensuring the quality and identity of these during all aspects of the wholesaling and distribution process. This Guideline sets out appropriate steps for meeting this responsibility. **http://www.rx-360.org/LinkClick.aspx?fileticket=f149rGC_JZk%3D&tabid=314**

Medicines Control Council

Website: www.doh.gov.za/

Taiwan

- TFDA Precaution of on-site sampling for vaccine testing and sealing operation (cold chain temperature monitoring) 2010

Taiwan Food and Drug administration

www.fda.gov.tw/EN/index.aspx

United Kingdom

- Guidance in the Transportation of Medicinal Products, ambient and refrigerated **http://www.mhra.gov.uk/home/groups/is-insp/documents/websiteresources/con137881.pdf**
- MHRA GDP Risk Assessment Strategy 2008, GDP Risk Assessment Strategy 2009 Updated Policy on returns of non-defective refrigerated (2-8c) medicinal products 2010
- Medicines and Healthcare products Regulatory Agency (MHRA)

Website: www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodDistributionPractice/index.htm

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Temperature Control Logistics & Quality Network

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SOURCES

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- http://www.gmp-publishing.com/en/lead-article/gmp-aktuell/logfile-26-2012-gdp-current-regulations.html
- http://www.pts.eu/(S(vwukmi55w3lsqn55x5bvccnj))/anlagen/1209_10312012103830.pdf
- http://www.rx-360.org/Resources/LegislationRegulationGuidanceSummaries/tabid/289/Default.aspx