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Revision of the EU GDPs and Implications for Wholesalers

Wholesale Distribution Information Day, 28th September 2012

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Why?

Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03)

- Last updated in 1994
- Out dated, lacking in detail
- Supply chain has changed (contract operations, persons not handling products, brokers)
- New technologies

Updated Guidelines

- Directive 2011/62/EU (Falsified Medicines Directive)
- Defines requirements for operators not within scope of 94/C 63/03
- Consistency across member states
- In line with WHO guidelines
- Falsified medicines controls

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Timeline

Currently still a draft!

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Chapters

INTRODUCTION

CHAPTER 1	**-**	**QUALITY MANAGEMENT**
CHAPTER 2	-	PERSONNEL
CHAPTER 3	-	PREMISES AND EQUIPMENT
CHAPTER 4	-	DOCUMENTATION
CHAPTER 5	**-**	**OPERATIONS**
CHAPTER 6	-	COMPLAINTS, RETURNS, SUSPECTED FALSIFIED MEDICINAL PRODUCTS AND MEDICINAL PRODUCT RECALLS
CHAPTER 7	**-**	**CONTRACT OPERATIONS**
CHAPTER 8	-	SELF-INSPECTIONS
CHAPTER 9	**-**	**TRANSPORTATION**
CHAPTER 10	**-**	**SPECIFIC PROVISIONS FOR BROKERS**

Glossary of Terms

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Chapter 1 - Quality Management

- RP must have defined authority and responsibility and is responsible for ensuring that QMS is implemented and maintained.
- Management
  - Must ensure that adequate resources are made available;
  - Must review QMS routinely and document findings;
    - Assess performance (complaints, deviations, CAPA, change control, risk assessments, inspections)
    - Emerging regulations, guidance and quality issues.

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Chapter 1 - Quality Management

- Change control system should be in place
  - Changes to key processes, equipment, documentation
  - Document, assess, approve, implement
  - Incorporate quality risk management principles
  - Include process, forms within QMS
- Deviation system should be in place
  - Documented and investigated
  - Corrective and Preventive Actions (CAPA)
- Management of outsourced activities
- Quality Risk Management (QRM)

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Chapter 2 - Personnel

- Responsible Person
  - Appropriate competence, experience along with knowledge and training in GDP
  - Fulfil their responsibilities personally
  - May delegate duties but not responsibilities
  - Must be ***continuously contactable***
  - Must be given defined authority, resources and responsibility
  - Should maintain competence through regular training

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Chapter 2 - Personnel

- Organisational chart should be in place
- Job descriptions for key personnel along with arrangements for deputisation
- Ongoing training relevant to persons role
- Training programme
- Specific training for specialised products
- Effectiveness of training should be periodically assessed and documented

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Chapter 3 - Premises and Equipment

- Any system replacing physical segregation should provide equivalent security and should be validated
- Falsified, recalled or rejected products should be stored in a dedicated area away from other medicinal products
- A preventive pest control programme should be in place
- Temperature mapping (repeated based on risk assessment or after significant modifications made)
- Monitoring locations based on mapping findings
- Equipment designed, located and maintained to a suitable standard
- Planned maintenance on key equipment

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Chapter 3 - Premises and Equipment

- Equipment used to control or monitor the environment should be calibrated at defined intervals based on risk and reliability
- Alarms / alarm levels / alarm testing
- Computerised systems
- Qualification and Validation
  - Ensures correct installation and operation
  - Scope based on risk assessment approach
  - Validation prior to use and following significant changes
  - Reports summarising results and deviations

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Chapter 4 - Documentation

- Documentation – SOPs, instructions, contracts, records, data, electronic or paper
- Readily available/retrievable
- In a language understood by personnel
- Any alteration should be signed and dated, original to be readable, reason for alteration may be required
- Documents to be reviewed regularly and kept up-to-date

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Chapter 5 - Operations

- Qualification & Approval of Suppliers
  - Must verify that suppliers comply with GDP & hold a WA
  - Conducted prior to any procurement
  - Results documented and periodically rechecked
  - Due diligence with respect to new suppliers

- Qualification & Approval of Customers
  - Qualify prior to any procurement
  - Periodic rechecks
  - Monitor transactions of controlled drugs
  - Comply with any public service obligations

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Chapter 5 - Operations

- For batches of products received from another MS
  - A control report as per Art 51(1) of 2001/83/EC

    or
  - Another proof of release based on an equivalent system

- Export to Third Countries
  - Exporters must hold a WA
  - GDP applies in full (apart from MA requirements)

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Chapter 6 - Complaints, Returns, Suspected Falsified Medicinal Products and Recalls

- Complaints
  - Quality of product vs. distribution
  - Person to be appointed for handling complaints
  - Complaints investigated and evaluated
  - Follow-up actions / CAPA

- Returns
  - Handled as per risk based process
  - Returns from non-WA customer within 10 days
  - Reasonable evidence that the product was supplied to that customer in the first place.
  - More stringent requirements for low temperature products

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Chapter 7 - Contract Operations

- Presentation in Session 2!

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Chapter 8 - Self-Inspections

- To monitor the implementation and compliance with GDP principles and to propose necessary corrective measures
- Compliance with regulations, guidelines and SOPs
- Document issues, CAPAs and follow-ups

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Chapter 9 - Transportation

- Risk based approach to be used when planning transportation
- Deviations during transportation
- Vehicles and equipment suitable for use
- Procedures for operation and maintenance of vehicles and equipment
- Risk assess to determine if temperature control required
- Cross-contamination (dedicated vehicles)
- Delivery to stated address
- Emergency deliveries
- Minimisation of temporary storage duration

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Chapter 9 - Transportation

- Qualification of transportation packaging (cold chain)
- Temperature mapping of refrigerated vehicles
- Customers to be provided with data to demonstrate that products remained within required temperatures (if requested)
- Use of ice/cool packs

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Chapter 10 - Specific Provisions For Brokers

Article 1 of Directive 2001/83/EC, (as amended)

All activities in relation to the sale or purchase of medicinal products, except for wholesale distribution as defined in point 17 of this article, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person

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Question

Level of Use of Brokering Services?

a) We use the services of a broker
b) We do not use the services of a broker
c) Not sure whether we use brokers
d) We act as a broker

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Chapter 10 - Specific Provisions For Brokers

- Do not procure, supply or hold
- Must have a permanent address in the EU
- Quality System required (incl. recall, complaints, counterfeit, record keeping, authority to supply)
- Training
- Documentation

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Batch Tracking

- For products bearing safety features
- Details to be in delegated act
- Timeline ~ 2017
- Consideration should be given now to methods for conducting batch tracking
- Consider these requirements if modifying an existing system

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Implementation

- 6 month implementation from publication (expected Dec 2012 / Jan 2013)
- Gap analysis
- QMS / Training / Update to systems
- Project timelines

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Thank you

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