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Maintaining Compliance with Regulatory Requirements for Outsourced Activities

Wholesale Distribution Information Day, 28th September 2012

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Inspector

Overview

- Revision to European Commission Guidelines on GDP – Management of Outsourced Activities
- Impact Assessment & Implications
- Technical Agreement/Contract Contents
- Feedback from the Inspection Programme
- Next Steps



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Definition

Outsourcing is the process of contracting out a business activity to an external organisation instead of performing the activity internally.

Companies may choose to outsource business activities if the external organisation has the required expertise and can better perform the activities and/or can perform the activities at a lower cost than if the company were to perform the activities itself.

Outsourcing typically involves a contract between the company and the external organisation that stipulates the quality standards, costs and other conditions regarding the performance of the business activity.



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Questions

- Does your company outsource any GDP activities?
 1. Yes
 2. No

- Which activities are outsourced by your company:-
 1. Storage & Distribution
 2. Transportation
 3. RP Services
 4. All of the above

- Does your company's Quality Management System currently cover the control and review of outsourced activities?
 1. Yes
 2. No



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Questions

- How would you score your own knowledge/experience of management of outsourced activities?
 1. Poor
 2. Fair
 3. Good
 4. Excellent

- Did your company receive a deficiency relating to outsourced activities at the last inspection?
 1. Yes
 2. No



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Revision (DRAFT) to European Commission Guidelines on GDP (1)

Chapter 1 Quality Management	
Principle	All distribution activities should be clearly defined and systematically reviewed .
Quality System - Management of Outsourced Activities	The quality system should extend to the control and review of any outsourced activities related to the procurement, holding, supply or export of medicinal products. These processes should incorporate quality risk management and include: <ul style="list-style-type: none">i) Assessing the suitability and competence of the contract acceptor to carry out the activity and checking authorisation status, if required;ii) Defining the responsibilities and communication processes for quality related activities of the involved parties;iii) Monitoring and review of the performance of the contract acceptor, and the identification and implementation of any required improvements on a regular basis.

Revision (DRAFT) to European Commission Guidelines on GDP (2)

Chapter 1 Quality Management

Quality Risk Management

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products. It can be applied both proactively and retrospectively.

Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation of the process should be commensurate with the level of risk. Examples of the processes and applications of quality risk management can be found in the guideline Q9 of the International Conference on Harmonisation ('ICH').

Revision (DRAFT) to European Commission Guidelines on GDP (3)

Chapter 2 Personnel

Responsible Person

His responsibilities include:
'approving any subcontracted activities'

Chapter 3 Premises and Equipment

Premises

Where premises are not directly operated by the wholesale distributor, a **contract** should be in place and the premises should be covered by a wholesale distribution authorisation.

Chapter 4 Documentation

General

Documentation comprises all written procedures, instructions, **contracts**, records....

Revision (DRAFT) to European Commission Guidelines on GDP (4)

Chapter 7 Outsourced activities	
Principle	Any activity covered by the GDP Guide that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party.
Contract Giver	The Contract Giver is responsible for the activities contracted out.
	The Contract Giver is responsible for assessing the competence of the Contract Acceptor to carry out successfully the work required and for ensuring by means of the contract and through audits that the principles and guidelines of GDP are followed.

Revision (DRAFT) to European Commission Guidelines on GDP (5)

Chapter 7 Outsourced activities	
Contract Giver	An audit of the Contract Acceptor should be performed before commencement of, and whenever there has been a change to, the outsourced activities. The frequency of audit should be defined based on risk depending on the nature of the outsourced activities. Audits should be permitted at any time.
	The Contract Giver should provide the Contract Acceptor with all the information necessary to carry out the contracted operations in accordance with the specific product requirements and any other relevant requirements.
Contract Acceptor	The Contract Acceptor should have adequate premises and equipment, procedures, knowledge and experience, and competent personnel to carry out the work ordered by the Contract Giver.

Revision (DRAFT) to European Commission Guidelines on GDP (6)

Chapter 7 Outsourced activities

Contract Acceptor

The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements and an audit of the third party by the Contract Giver or the Contract Acceptor. Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original Contract Giver and Contract Acceptor.

The Contract Acceptor should refrain from any activity, which may adversely affect the quality of the product(s) handled for the Contract Giver.

The Contract Acceptor must forward any information that can influence the quality of the product(s) to the Contract Giver in accordance with the requirement of the contract.

Revision (DRAFT) to European Commission Guidelines on GDP (7)

Chapter 9 Transportation

Transportation

If transportation is sub-contracted to a third party then the **contract** should encompass the requirements contained within Chapter 7.



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Revision (DRAFT) to European Commission Guidelines on GDP (8)

Purpose of inclusion

- Prescriptive requirements for outsourced operations
- Outline obligations of the Contract Giver and Contract Acceptor
- Reflect the range and extent of modern contracting operations
- Reflect the increased complexity in modern contracted arrangements



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Impact Assessment of Revision to Guide

- Technical arrangements for outsourced GDP operations more transparent
- Clearer and more consistent assessment of outsourced operations
- Set clearer standards and expectations for industry
- Harmonised regulatory policy



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Implications of Revision to the GDP Guide (1)

Inclusion of requirement for control over outsourced operations

Examples of activities to consider:-

Contracted Storage & Distribution

Contracted Transportation

Contract RP & Other Professional Services

Contracted Security

Qualification & Validation Activities

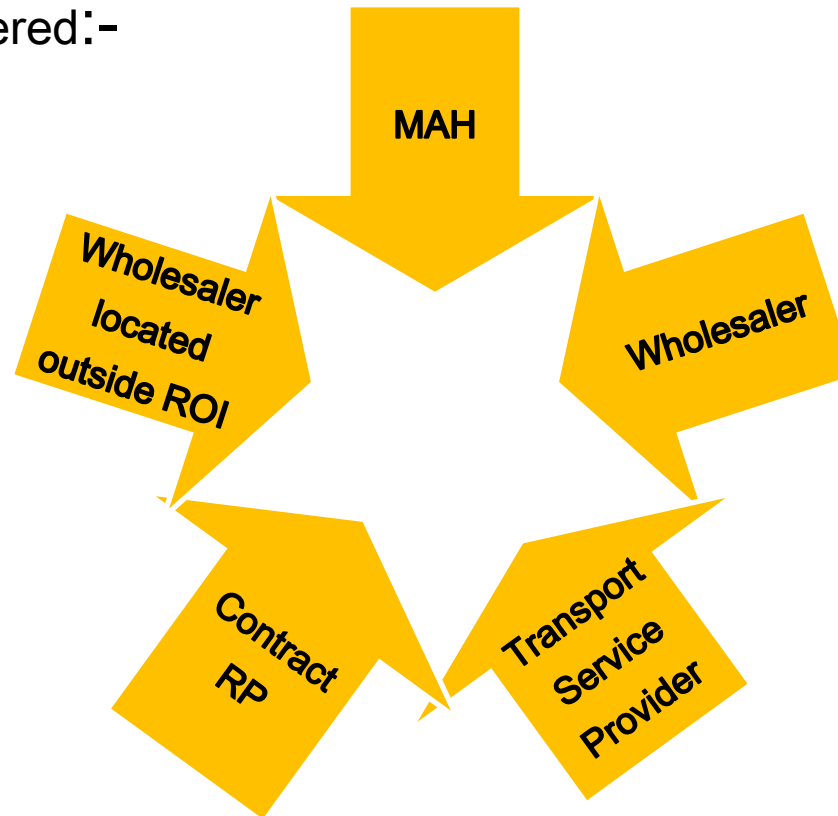
Maintenance & Calibration of Premises & Equipment



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Implications of Revision to the GDP Guide (2)

Relationships to be considered:-



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Typical Contents of a Technical Agreement/Contract

- Title/Document Reference/Version No./Review Period
- Scope of Services covered
- Name & Address of Contract Giver
- Name & Address of Contract Acceptor
- Table of Contents
- Introduction
- Responsibilities for all GDP related activities
- Continuity of supply of Medicinal Products to Irish Market
- Notification/Pre-approval of changes
- Notification/Approval of deviations
- Arrangements for Sub-contracted activities
- Permit to audit
- Approval Section
- History of change section
- Appendices
 - Responsibility Matrix
 - Contact details (including out of hours) for Key Personnel
 - List of Product(s)/Licence No.(s)/Storage Condition(s)/Shelf-life(s)
 - Details of Approved Sub-contractors



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Technical Agreement – Responsibility Matrix (1)

	Contract Giver	Contract Acceptor
Quality Management		
Quality System (including change control & deviation reporting)	X	X
Management of Outsourced Activities (including permit to audit)	X	X
Management Review and Monitoring	X	X
Quality Risk Management	X	X
Personnel		
Responsible Person	X	X
Other personnel	X	X
Training	X	X
Hygiene		X
Premises and Equipment		
Premises		X
Temperature and Environmental Control		X
Equipment		X
Computerised Systems		X
Qualification and Validation		X

Technical Agreement – Responsibility Matrix (2)

	Contract Giver	Contract Acceptor
Documentation	X	X
Operations		
Qualification of Suppliers	X	
Qualification of Customers	X	
Receipt of Medicinal Products		X
Storage		X
Destruction of obsolete goods		X
Picking		X
Supply		X
Continuity of Supply to Irish Market	X	X
Export to third countries	N/A	N/A
Complaints	X	X
Returned Medicinal Products		X
Suspected falsified Medicinal Products	X	X

Technical Agreement – Responsibility Matrix (3)

	Contract Giver	Contract Acceptor
Medicinal Product Recalls	X	X
Outsourced Activities (e.g. sub-contractors)		
Written contract		X
Audit		X
Self-Inspections	X	X
Transportation		
Transportation		X
Containers, packaging and labelling		X
Products requiring special conditions		X
Specific Provisions for Brokers	N/A	N/A



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Feedback from Inspection Programme (1)

Findings

There were no service level agreements in place with companies who were contracted for transportation of medicinal products to customers

The service level agreement with contracted hauliers did not include the following:-

- Responsibilities for ensuring drivers were trained in the requirements of GDP
- Requirement to ensure that medicinal products were not contaminated by other products or materials during storage and transportation
- Requirements for handling returns

The service level agreement with the contracted security company:-

- Had not been approved
- Details of the contracted arrangements and responsibilities of the security company had not been documented
- The company had no knowledge of the procedures used by the security company to vet employees

Feedback from Inspection Programme (2)

Findings

There were no technical agreements in place with the UK based wholesalers to whom the company had supplied medicinal products

Technical agreement with contracted storage and distribution company:-

- The approved/signed version of the agreement could not be located at the time of the inspection
- The contact details for key personnel were not documented
- The criteria for acceptance and arrangements for handling medicinal products which required to be returned were not documented
- The responsibilities of each party in relation to complaints, recalls and suspected counterfeit medicinal products were not adequately defined
- References were made to refrigerated storage, ocean freight and air freight which were not relevant to the contract

The agreement did not reflect the current RP at the company and the change to the RP had not been notified as required by the change control section of the agreement

Feedback from Inspection Programme (3)

Findings

The procedure for managing changes to technical agreements was not documented under the company's quality management system. In addition, the change request forms which had been used were not controlled documents.



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Main Principles of Management of Outsourced Activities

Assessment of Suitability & Competence of Contract Acceptor

Definition of Responsibilities & Communication Processes

Monitoring & Reviewing of Performance



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Next Steps

GDP Guide

- Review revised GDP Guide

Operations

- Identify outsourced operations & subcontracted arrangements
- Conduct Gap Analysis with respect to audits & technical agreements/contracts

QMS

- Update QMS to cover control of outsourced activities (*via change control*)
 - SOP's
 - Audit checklists/report templates
 - Technical agreement/contract templates
- Schedule & Conduct audits
- Review/Implement technical agreements
- Periodic Review



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Final Question

Compared to the start of the presentation, how do you now score your own knowledge of management of outsourced activities?

1. About the same
2. More now
3. Much more now



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