



IRISH MEDICINES BOARD

Contracted Operations

Wholesale Distribution Information Day, 25/2/2010

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Topics

- Authorisation Requirements
- Identify the activities – who does what?
- Gap Analysis
- Technical Agreement
- Quality Management System
- Role of RP
- Common Deficiencies



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Authorisation Requirements

Legislation:-

Directive 2001/83 EC

Wholesale distribution:

“all activities consisting of procuring, holding, storing, supplying or exporting medicinal products, apart from supplying medicinal products to the public”.



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Authorisation Requirements

Definition repeated in

Medicinal Products (Control of Wholesale Distribution) Regulations 2007 and 2009

“Sale by wholesale means the sale or supply for the purposes of sale in the course of a business or for administration to patients.....shall also include all activities consisting of the procuring, holding or exporting of medicinal products...”



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Authorisation Requirements

Party conducting any wholesaling activities:

- Premises at which activities occur to be named on the Wholesaler's Authorisation
- RP on Authorisation must be management representative of Contract Giver (i.e. Authorisation holder)



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Additional Requirements

- Procedures relating to contracted operations to be included in Quality System of Authorisation holder
- Audit of Contract Acceptor required before operations commence
- Contract Giver must evaluate (e.g. by audit) and approve any arrangements between Contract Acceptor and any third party



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Identify the Activities

- List activities undertaken by Contract Giver
eg
 - Bona fide of suppliers
 - Bona fide of customers
 - Product set-up on systems
 - Raising purchase orders
 - Receive of customer orders
 - Transfer orders to warehouse
 - Returns
 - Recalls
 - Customer complaints



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Identify the Activities

- List activities undertaken by Contract Acceptor

eg

- Receive PO from Contract Giver
- Receive product into warehouse
- Confirm receipt back to Contract Giver
- Storage
- Receipt of customer order from Contract Giver
- Generate pick list
- Pick and assemble order (who directs batch no., expiry)?
- Dispatch
- Confirm order picked back to Contract Giver
- Returns
- Recalls
- Customer complaints



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Gap Analysis

- Identify where there is a gap
- Are all GDP activities covered?
- Are both companies involved in the same GDP activity (e.g. returns, recall, counterfeit)?
- Are there areas where information is shared?
- Quality Risk Management useful tool here



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Technical Agreement

Agreement should clearly indicate, in detail, which party is responsible for each GDP activity

Responsibility and roles clearly explained

Using the gap analysis and lists of activities, draft a Technical Agreement

GDP Responsibility Matrix useful tool



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GDP Responsibility Matrix

GDP Activity	Contract Giver	Contract Receiver
Supplier Approval		
Customer Approval		
Product set-up		
Documentation Control		
Training		
Receipt of Goods		
Approval / release of product		
Order Processing & Dispatch (including supplier name on customer documentation)		
Returned Products		
Customer Complaints		
Recall		



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GDP Responsibility Matrix

GDP Activity	Contract Giver	Contract Receiver
Process Deviations		
Storage/Temperature Monitoring		
Cleaning/Pest Control		
Self Inspection		
Counterfeit		
Waste disposal		



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Technical Agreement

Don't forget issues such as:

- Computer systems maintenance / validation
- Verification of third party delivery drivers
- Records for traceability in event of recall



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Quality Management System

- Must be under the control and review of Authorisation holder
- SOPs must be approved by RP named on Authorisation
- SOPs should document the linkages and interdependencies / interfaces between both parties



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Role of the RP

- Ultimately responsible to ensure processes are in place to ensure the control of outsourced activities
- Prior to outsourcing operations, assess the suitability and competence of other party
- Ensure the Quality Management System is implemented
- Communicate closely with contracted site
- Monitor and review performance
- Identify and implement improvements



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Common Deficiencies

- Inadequate Technical Agreements
- Lack of communication / understanding
- RP not involved in overseeing contracted operations
- SOPs not linking activities of both parties
- SOPs under a separate Quality Management System

- **Risks?**



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Thank You
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