GMP Training Course

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EU GMP Requirements

Good Distribution Practices

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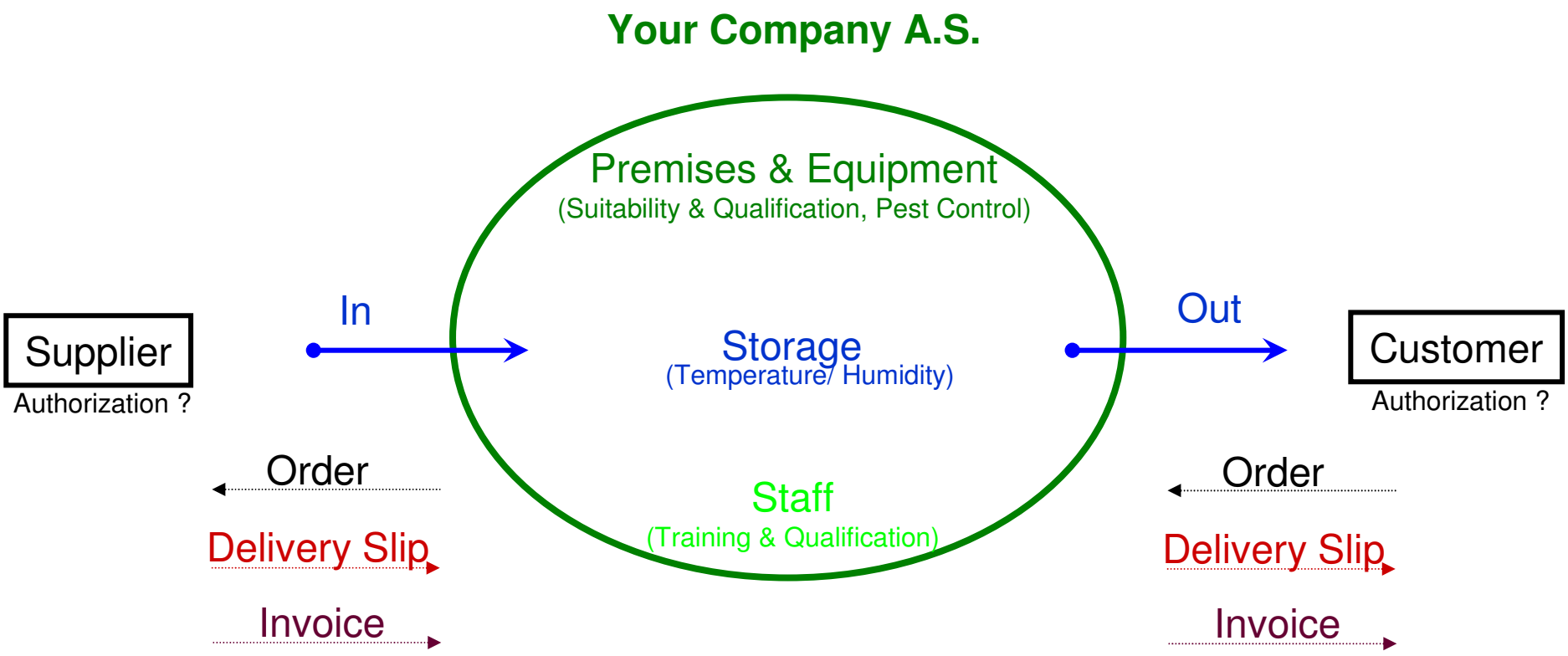
Member of:

EU:	**GDP Drafting Group**
PIC/ S:	**GDP Working Group**
Germany:	**Head of GDP Project Group of the competent authorities**

Basic Elements of Wholesaling



Relevant and legally binding documents

- **DIRECTIVE 2001/83/EC**
  - Definition of Wholesale
  - Art. 76 -85
- **Guidelines on *Good Distribution Practice* of Medicinal Products for Human Use (94/C 63/03)**

DIRECTIVE 2001/83/EC Definition

17. *Wholesale distribution of medicinal products:*

All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned.

What are the principles of wholesaling in the EU ?

DIRECTIVE 2001/83/EC Art. 76 -85

DIRECTIVE 2001/83/EC Art. 76 -85

- Art. 76 Distribution of medicinal products only with MA
- Art. 77 Need of an Wholesale Authorization issued by CA
- Art. 78 Timeline for decision of CA to grant the authorization: 90 days

MA = Marketing Authorization

CA = Competent authority

DIRECTIVE 2001/83/EC Art. 76 -85

- Art. 79 Minimum Requirements for obtaining the authorization:
  - Suitable premises, installations and equipment
  - Staff
  - **Responsible Person**
  - Fullfilling other obligations as defined in Art. 80

DIRECTIVE 2001/83/EC Art. 76 -85

- Art. 80 Minimum requirements (running the business)
  - Suitable premises, installations and equipment acccessible to the persons responsible for inspecting them
  - Supply chain only from and to partners with wholesale authorization
  - Emergency plan for recall
  - Records of purchase and sales or any other transaction, achived for at least 5 years (blood, blood products: 30 years)
  - Compliance with the principles of GDP

DIRECTIVE 2001/83/EC Art. 76 -85

- Art. 81 Mutual acceptance of Wholesale authorizations within the member states of the EU. Any obligations imposed on wholesaler of another EU country exceeding the national requirements forbidden
- Art. 82 Minimum requirements of informations on the delivery slip to persons entitled to supply the public (i. e. pharmacies)

DIRECTIVE 2001/83/EC Art. 76 -85

- Art. 83 Special National requirements concerning
  - Narcotic/ psychotropic substances within their territory
  - Medicinal products derived from blood
  - Immunological medicinal products
  - Radiopharmaceuticals

More stringent national requirements are possible !

DIRECTIVE 2001/83/EC Art. 76 -85

- Art. 84 Commission shall publish the GDP
- Art. 85 Applicable to homeopathic medicinal products

Good Distribution Practices (GDP)

- Principle
- Personnel
- Documentation
- Premises and equipment
- Deliveries to customers
- Self inspections
- Provision of Information to Member Staes in relation to wholesale activities

Good Distribution Practices (GDP)

- Principles – the most important (GDP)
  - “The level of quality [of medicinal products] should be maintained throughout the distribution network.”
  - “A tracing system should enable any faulty product to be found.”
  - “There should be an effective recall procedure.”

Good Distribution Practices (GDP)

- Principles – the most important (GDP)
  - "The level of quality [of medicinal products] should be maintained throughout the distribution network."

<u>Consequences</u>

→ *Transport and storage are controlled and adequate*

→ *Contamination with other product to be avoided*

Good Distribution Practices (GDP)

- Principles – the most important (GDP)
  - "A tracing system should enable any faulty product to be found."

Consequences

→ *Where does the product is coming from ?*

→ *To where does the product goes ?*

→ *Batch traceability*

→ *Identification of any [authorized] player in the supply chain*

Good Distribution Practices (GDP)

- Principles – the most important (GDP)
  - "There should be an effective recall procedure."

<u>Consequences</u>

→ *Batch traceability*

→ *Stock inventory [ongoing, up to date]*

→ *Exercises of mock recall*

Inspection – Principles & Experience

- What is the main business ?
- From which business is the profit coming from?
- Do the invoicing (supplier, customer) fit to the purchase and delivery documents ?
- Do the documents tell the same story as the management does?
- Are there any hints that anything does not make feel you good?

Counterfeits

- In the legal supply chain
  - (responsible: CA)
- In the illegal supply chain
  - (responsible: police, enforcement dptm)

→ In any case:

The CA must be informed by the wholesaler

Counterfeits

- In the case of a detected counterfeit – what shall the CA do (at least)?

- → Start an *Rapid Alert Procedure [RAS]* according to the *Compilation of Community Procedures* and inform any CA within your country and any country affected

(Example: RAS Combivir)

New Developments in the EU

- New Legal Proposal

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10 December 2008
COM(2008) 668

Proposal for a

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amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source

New Developments in the EU

- Amendment of the Compilation of Community Procedures
  - Community Format for wholesale authorisation
  - GDP inspection report format
  - Guideline to GDP inspection process
  - Guideline on training and qualification of inspectors
  - Deficiencies in wholesaler inspections
  - Non Compliance Procedure
  - GDP Certificate
  - Issuance of wholesaler authorization

→ ongoing

New Developments in the EU

- GDP´s under revision → first draft for discussion: 2010

Thank you !