

AFTI

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# Overview sulla nuova guideline GDP

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1



**S** SCHWEIZERISCHER INSPEKTIONSDIENST  
**I** SERVICE SUISSE D'INSPECTION  
**S** SERVIZIO SVIZZERO D'ISPEZIONE  
SWISS INSPECTION SERVICE

# GDP Guidelines

## New

- GDP of Medicinal Products for Human Use  
Public consultation until 31 December 2011  
Deadline: 6 months after publication

## Old

- GDP of Medicinal Products for Human Use  
(94/C 63/03)

# Quality management

## New

- Validation critical distribution processes and changes
- RP for each distribution site
- Quality risk management
- Quality manual
- Change control
- Agreement outsourced activities

## Old

- Cap I GMPs (Principle)

# Quality management (follows)

## New

- Monitoring performance of contract acceptor
- Management review (KPI, complaints, deviations, CAPA, self and external assessment)
- Quality risk management (ICH)

## Old

- Cap I GMPs (Principle)

# Personnel

## New

- Responsible person (qualification depending on member state)
- Degree in Pharmacy desirable
- Organizational chart
- Job descriptions (deputies)
- *Listed responsibilities*
- Written training program

## Old

- Responsible person (qualification depending on member state)
- Degree in Pharmacy desirable
- Training recorded

# Personnel (follows)

## New

- Continuous training for RP
- Training records and assessment
- Specific training (narcotics, falsified)

## Old

- Responsible person (qualification depending on member state)
- Degree in Pharmacy desirable
- Training recorded

# Premises & Equipment

## New

- If premises not directly operated: agreement (authorization)
- Adequate separation (receipt, dispatch, storage)
- Storage area temperature mapped (seasonal variat.)
- Preventive maintenance key equipment

## Old

- Less detailed

# Premises & Equipment (follows)

## New

- Preventive pest control
- Access control
- Alarm deviations from storage conditions
- Log-books repair, maintenance, calibration
- Computerized systems (*tested*, access levels, back up, restore)

## Old

- Less detailed



# Premises & Equipment (follows)

## New

- Qualification, validation by risk assessment
- CAPA

## Old

- Less detailed

# Documentation

## New

- Language understood by personnel
- Version control to the SOPs

## Old

- Available on request
- SOPs on different operations, signed by RP

# Operations / Qualification suppliers

## New

- Verification of authorizations (distributor, manufacturer)
- Supply chain known and documented
- SOP to qualify suppliers (periodic recheck)
- Risk based approach new suppliers

## Old

- Orders to authorized persons only
- Supply chain “one step behind”

# Operations / Qualification customers

## New

- Delivers only to authorized wholesalers or persons authorized to sell to the public (retail pharmacies); periodic recheck (website)
- Monitoring transactions to avoid diversion or misuse

## Old

- Delivers only to authorized wholesalers or persons authorized to sell to the public (retail pharmacies)

# Operations / Warehouse

## New

- Receipt of goods: from approved suppliers
- Storage: medicinal products should be stored separately
- Storage: stock inventory performed regularly
- Segregation: rejected, expired, recalled, returned (if electronic: validation)

## Old

- Storage: medicinal products should normally be stored separately
- Separation: .....

# Operations / Warehouse

## New

- Packing: containers should be sealed
- Destruction if medicinal products should be documented

## Old

- Packing: precautions against spillage, theft .....

# Complaints

## New

- Written procedures
- Investigation

## Old

- Not covered

# Returns

## New

- Written procedures
- Investigation
- Max 5 days if returns from customers without wholesaling authorization
- FEFO
- Handling of returned products approved by RP

## Old

- Less detailed but covered
- FIFO



# Recalls

## New

- Effectiveness periodically checked

## Old

- Less detailed but covered

# Contract operations

## New

- Written contract
- Competence contract acceptor assessed
- Audit before and periodically
- Contract accept. authorized if performing wholesaling activities
- Written contract other activities (pest control, cleaning)

## Old

- Not covered

# Self inspections

## New

- Audit of subcontractors
- Copy of audit report to senior mgmt
- CAPA activated

## Old

- Should be conducted and recorded

# Transportation

## New

- Medicinal products transported in accordance packaging information
- Vehicles suitable for their use (responsibility)
- Drivers (also contract drivers) trained on GDPs

## Old

- General articles about precautions

# Transportation (follows)

## New

- Procedures for vehicles maintenance
- Probes in vehicles and/or containers calibrated once a year
- Dedicated vehicles (possibly)
- Delivers directly to client
- Transportation hubs (max 24h, if longer wholesale authorization)

## Old

- General articles about precautions

# Transportation (follows)

## New

- Hubs for refrigerated products authorized (no time limit)
- Hubs or terminals audited and approved
- Selection of containers and packages (space, T extremes, transp. time)
- Safe and secure supply chain (narcotics, high active)

## Old

- General articles about precautions

# Transportation (follows)

## New

- Validated T control systems
- T data to customers (if requested)
- T probes refrigerated vehicles calibrated once a year
- T mapping refrigerated vehicles (seasonal variations)

## Old

- General articles about precautions

# Transportation (follows)

## New

- Product not in contact with cool-packs (personnel training, seasonal configuration)
- Physical distinction between frozen and chilled packs
- SOP for delivery of sensitive products (seasonal variations, vehicle breakdown)

## Old

- General articles about precautions



# Grazie per l'attenzione



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