Corsi Acanto

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Overview sulle normative GMP e GDP che regolano la supply chain

Fabio Dotto

Ispettorato Regionale

Medicamenti Svizzera del Sud

SCHWEIZERISCHER INSPEKTIONSDIENST
SERVICE SUISSE D'INSPECTION
SERVIZIO SVIZZERO D'ISPEZIONE
SWISS INSPECTION SERVICE

APIs

Starting materials

-System for evaluating suppliers of critical starting materials (7.11 7.13)

-Suppliers evaluation (history, questionnaire, audit, samples) (Expect.)

-Formal approval of suppliers by QU (7.12)

-Approved suppliers list should include original manufacturer (not only the trader) (Expect.)

APIs

Starting materials

-Companies should formally define (risk analysis) criticality of starting materials and how to evaluate relative suppliers (Expect.)

APIs

Starting materials

-Manufacturers of critical starting materials should be known (7.13)

-Change control for changing of source of critical starting material (7.14)

-Critical parameters (ex. impurity profile) checked on appropriate number of batches after change (Expect.)

APIs

Starting materials

-Starting materials for APIs are not subject to GDPs

but

-Systems in place to ensure appropriate transport and storage conditions (7.20)

APIs

Labels (outside the control of manufact.) (9.43 10.22)

-Name, address of manufacturer

-.....

-Special storage conditions

-Expiry date

-Retest date (could be on CoA only)

APIs

Seals (9.46)

-Validated sealing system (Expect.)

APIs

Transport

-Responsibility should be assigned (agreement, audit) (10.23)

-Assessment of transport conditions (T profile, data logger etc.) (10.21)

APIs

Illegal practice

-Change of labels and copy of CoA (9.43 11.44)

-Sub-contracting certain manufacturing operations by traders:

- -micronization
- -sterilization (gamma, beta)

Finished products

Starting materials

-Approved suppliers, better the manufacturer (5.26)

-Agreed specifications (5.26)

Finished products

Starting materials (if APIs)

-Audit of APIs suppliers (Expect.)

-APIs suppliers licensed in their country (CH)

-APIs from EU provided with Batch Certificate (EU/Switzerland)??

Finished products

Starting materials

-Companies should formally define (risk analysis) criticality of starting materials and how to evaluate relative suppliers (Expect.)

Finished products

Starting materials

-Appropriate storage conditions (provided, checked, monitored (3.19)

-Temperature mapping (representative or worst position) (Expect.)

Finished products

Contract manufacturing

-Assessment of the competence of Contract Acceptor (7.3)

-Technical agreement (*visit* of the facilities!) (7.14)

-Regular audits (Expect.)

Finished products

Contract manufacturing

-In case of countries whose GMP system is not recognized by Switzerland, Swissmedic can perform abroad inspections

-Finished products and/or intermediates coming from EU should be provided with a Batch Certificate (normally no inspections carried out) (EU/Switzerland)

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

Thank you for your attention

Regional Inspectorate Southern Switzerland

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