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Compliance and Regulatory Aspects of the Supply Chain

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SCHWEIZERISCHER INSPEKTIONSDIENST
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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)

Bibliography

- EU GMPs part I
- EU GMPs Part II
- PIC/S Aide-Memoire “Inspection of APIs” PI-030-1
- Ordinanza Autorizzazione Medicamenti (OAM)

Thank you for your attention

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