Rapid announcement of inspectional observations

< ORANGE* Letter >

Pharmaceuticals and Medical Devices Agency

*Observed Regulatory Attention / Notification of GMP Elements

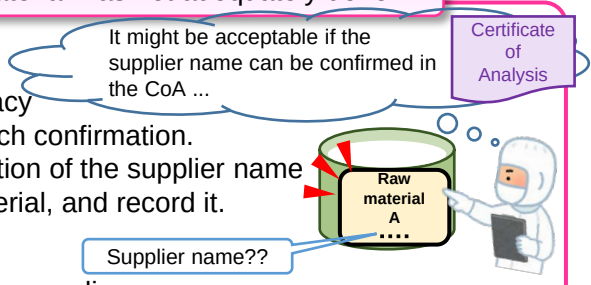
Failure to confirm adequacy of raw materials

<< Related GMP Ministerial Ordinance Clause: Article 10, Item 5 >>**

** GMP Ministerial Ordinance: Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs (MHLW Ministerial Ordinance No. 179 dated December 24, 2004)

Observation

Confirmation of the supplier of an incoming material was not adequately done.



< Background information>

- GMP Ministerial Ordinance requires confirmation of adequacy of each lot of incoming materials, and documentation of such confirmation.
- The procedure of that manufacturing site requires confirmation of the supplier name on the label attached to the container of the incoming material, and record it.

< Actually observed situation >

- The label on the container of raw material A did not have the supplier name. However, the raw material receipt record documented that the supplier name was confirmed based on the container label.
- The person in charge of receipt confirmed the supplier name based on the CoA for the raw material A without checking the container label.

<Possible problem and risk >

- If a manufacturing site fails to check the label on the container of incoming material, there is a risk that receipt of wrong materials instead of correct ones cannot be detected.
- Use of a wrong material poses a negative impact to the quality of the drug product.

(observed at an active substance manufacturing site in Japan)

Check Point

- ☐ Are label check and recording of the check done according to the procedure? (If those are not done, investigation of the cause, adequate improvement, and impact assessment are necessary.)
- ☐ Do the operators understand the meaning of their duties?
- ☐ Is the awareness of adherence to the site's procedure penetrated throughout the site?

Your "confirmation" establishes quality!!

- ✓ Recently, there was an incident that an operator loaded a wrong active substance of sleep inducer into the manufacture of an antifungal drug product. This incident resulted in death of a patient who took the product.
- ✓ Label check and other confirmation by multiple sections in the manufacturing site from receipt up to loading to batch processing are necessary to mitigate the risk of mix-up or use of wrong raw materials. On the other hand, this type of risk mitigation does not work if the labeling or the content is not correct.
- ✓ Thorough confirmation of label content of the incoming materials is absolutely important, and this is the foundation for prevention of using wrong raw materials.