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Online packaging line controls

Excerpt from the GMP [Compliance Adviser](#), [Chapter 13.B.6.2](#)

by Vera Werner

Modern packaging lines have a large number of online controls that continually monitor the process and certain parameters. Depending on the type of design, they can take various actions in case of non-compliant results:

- Stop the line with a corresponding error message, or
- Automatically eject the affected pack or package component.

It must be determined in advance which errors should cause which actions. In general, it is advantageous for the stable running of the packaging line if faulty packages or package components are automatically ejected and the line can continue running normally.

There are situations, however, when stopping the line is a better response:

- Serial defects:
the repeated occurrence of a fault indicates a systematic cause that must be eliminated.
Example: repeat error in the product inspection due to a blocked feeder.
- Defects that cannot be ejected by the packaging line itself
Example: Error message of the ejection cross-check, i.e. a package that was intended for ejection was not ejected.
- Faults which could lead to damage to the system or secondary faults:
Example: The check shows that product is sticking out of the cavity. This could lead to damage to the subsequent product inspection or to sealing problems. Therefore, the line should stop here and the operator must remove the protruding element before the line can be restarted.

From a GMP perspective, the online control functions are critical because product quality is directly dependent on them. Basically, all online control functions must function flawlessly and reliably. The functions must therefore be qualified and calibrated at the outset and kept in this condition. In addition, they must be checked regularly for proper function (see Chapter 1.1.6.3).

Older packaging lines may not have all the control functions mentioned. In these cases, manual processes must provide protection. It must be considered whether reliable production with manual controls is possible or whether a technical upgrade is necessary.

The most important and common control functions during packaging will be explained in detail below.

Bulk filling inspection

Bulk filling inspection is responsible for controlling that the primary packages (e.g. blister cavities) are filled completely.

Usually these are optical systems (cameras). Depending on the technical level, they only check the presence of the filling material or can also monitor other parameters. These parameters can be, for example, the colour (differentiation from other tablets of the same shape) or the shape (differentiation from other tablets of the same colour, detection of defective tablets, and detection of fragments or foreign particles).

Very simple systems are also used to monitor double filling of cavities. For example, a gate switch which is triggered by protruding filling material and then stops the packaging line. These can be combined with camera systems.

In order to avoid unnecessary rejects and to make the product inspection as effective as possible, the error thresholds must be clearly defined. The parameters must be adapted to the respective tablet and the respective blister and cavity.

Code reader

Code readers check the identity of the packaging materials used and are therefore used at various points in the packaging process. This ensures that a 100% identity check is done and therefore only correct packaging material can be used. This applies to printed foils, package inserts, folding cartons and labels.

The code readers must only allow correct packaging material to pass through. This means they must stop or eject both when reading an incorrect code and when not reading at all.

The code readers must be set to the correct material before a packaging order is started. Depending on the design of the system, this is done directly at the packaging line or via a networked computer.

Print inspection for text and variable data

The correct printing of text does not have to be carried out on pre-printed packaging materials, as the manufacturer has already done this. In this case, monitoring the codes is sufficient to ensure identity.

When printing on foil in-house, it must be ensured that the print is present and legible and must therefore be monitored.

If the variable data is printed, it must always be 100% monitored. The data on the blisters as well as on the folding cartons and labels must be read and checked for correctness. This prevents the data from either being printed incorrectly or illegibly.

Other inspection systems

Included in the category of other inspection systems are various control units for sorting out defective products. These include, for example:

- Devices for detecting suspended solids in liquid medicinal products.

- Sensors for the monitoring of splices between foil rolls or detecting holes in foils. On the one hand, these ensure that defective blisters are not supplied to the patient. On the other hand, depending on the design of the packaging line these may also prevent the impacted blisters from being filled, which prevents the unnecessary waste of the bulk product.
- Scales for sorting out over or underfilled packs. These serve to ensure that only correctly and completely filled packs make it to the patient.
- Control for presence of labels and leaflet inserts which ensure that only correctly labelled packs containing the right insert leaflets make it to the patient
- Sensors for monitoring the correct closer of carton flaps
- Control check for the successful ejection of rejected products

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