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# Change Control at the Wholesaker or Logistics Provider: Assessment of GxP Relevance

by Simone Ferrante

## Assessment of GxP relevance

Every upcoming change must be checked for GxP-relevance by the responsible person for GDP.

The change is GxP-relevant if it has a potential impact on product quality. This is checked on the basis of the following points:

- Effects on the qualification status of an equipment or premise
- Effects on the validation status of a system
- Effects on the course of a process

The result of this assessment is documented in an amendment.

- If the change is not GxP-relevant, it may be implemented without further change control. The assessment is confirmed with date and signature in the change request and the change request is filed as version 01. The process ends at this point.
- If the change is GxP-relevant, the further change control process must be gone through.

It is important to also document the decision "change is not GxP-relevant" and archive it in the system. This way, for example, it can be proven during audits or inspections that all changes are systematically recorded and evaluated and that an "informally" implemented change is not based on a lack of compliance but on a consciously made and documented decision.

## Examples of GxP-relevant changes

Examples of GxP-relevant changes are (list not exhaustive):

| GxP-relevant change | Example |
|---|---|
| Continuous improvement processes and process optimisations (if medicinal products/medical devices are processed) | Introduction of "Pick-by-Light" in the picking process |
| Business aspects (cost reduction, ensuring the ability to deliver) | Omitting a secondary control to save time and costs |
| Strategic considerations (change of supplier, product transfers) | Change of service provider for pest control or recalibration of temperature loggers |
| Changes to procedures/processes | Changes to an existing operational process such as goods receipt, picking |

| GxP-relevant change | Example |
|---|---|
| CAPA as a trigger for change | IT adaptation in the warehouse management system (e.g. automatic creation of packing lists for shipping) |
| Customer requests and agreements that have an influence on the operational day-to-day business | Changeover to another data logger |
| Modifications to qualified buildings/facilities/installations | • Relocation of the returns/quarantine warehouse to another hall section<br>• Integration of further temperature loggers into the monitoring system<br>• Extension of the cold storage<br>• Putting up more rows of shelves |
| Changes to the warehouse management system | • New client in warehouse management system<br>• New functions<br>• Introduction of interfaces |
| Changes to documents and records | Conversion from paper document to digital document |
| Changes to storage and transport | Moving goods to a new section of the hall |
| Changes to hardware and software | • Use of new scanner software<br>• Use of other scanners if GxP-relevant products are processed with them |
| Change to the QM system | Changeover of deviation recording from Excel lists to database-based solution |
| Modification to validated (computerised) systems | Version update |
| Temporary change | Temporary omission of the weight check when goods are booked out |

*The text is a translated excerpt from the knowledge portal in German language **GMP:KnowHow Pharmalogistik (GDP)**: SOP-120-001-01 "Änderungskontrolle (Change Control)", chapter 6.4.1.*

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