GDP CONCEPT

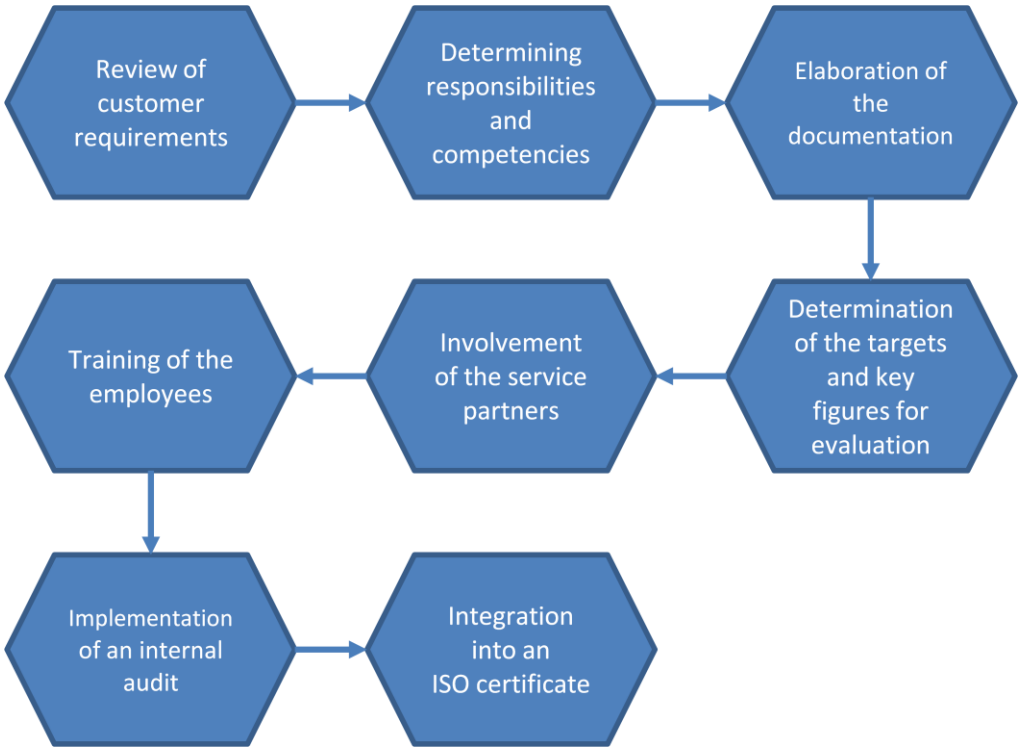
Guideline for implementation of the
Good Distribution Practices of the Pharmaceutical Industry

INTRODUCTION

Pharmaceutical customers require compliance with GDP guidelines. GDP stands for GOOD DISTRIBUTION PRACTICE and defines the correct handling of pharmaceutical products in the task areas of logistics, storage and transport.

Since these areas are often handed over to logistics partners as part of outsourcing, these partners must meet the requirements of the GDP guidelines and usually also prove this through auditing.

This concept explains the steps required to implement GDP.



Organizational procedure of the GDP introduction

(1) Review of customer requirements

When customer requirements are addressed to logistics partners, this is often done in the context of an inquiry, the submission of a contract, so-called quality guidelines or requirement profiles.

These documents contain clearly defined requirements, the acceptance of which is binding for us, possibly with liability consequences.

Therefore, it is important never to accept binding agreements without professional review. In the case of quality requirements, the central QM office should always be contacted to have them professionally reviewed.

In order to adapt to the requirements of the pharmaceutical industry, it is first necessary to clarify which risks can occur. The potential risks depend on the type of service demanded (logistics services, storage, transport) and on the sensitivity of the product (temperature range, special hygiene requirements, increased risk of theft, pest infestation, etc.).).

The customer may require compliance with GDP, but this does not fundamentally state, for example, that products must be kept within a certain temperature range (e.g. 15-25°C). This requirement depends on the product and must be specified by the pharmaceutical customer so that logistics partners can adjust to the necessary measures.

Possible GDP-related restrictions

- Storage / transport exclusively in the cold chain
- Mixed loading with certain substances, products not possible
- Use of only GDP-compliant service partners permitted
- GDP certified equipment required
- Pest control required
- Special security requirements due to high risk of theft
- etc.

(2) Determining responsibilities and competencies

GDP requires qualification and responsibility. It must always be determined who will assume the relevant tasks to ensure GDP compliance.

Each site must ensure that GDP products are handled, treated or transported exclusively by GDP-trained personnel. In addition, the directive requires a GDP Responsible Person who is responsible for compliance. This GDP Responsible Person must also be staffed locally.

Nevertheless, some responsibilities can be centralized and assigned to the QM organization, provided that no risks are derived from the physical distance. Substitution arrangements must also be included in personnel planning.

Tasks / Responsibilities / Responsibilities	GDP trained person	GDP Responsible person	Central QM
Local contact person for GDP-relevant topics		X	
Informing all employees about the procedure for pharmaceutical transports (processing only by GDP-trained personnel)		X	
Ensure that only trained personnel perform GDP activities		X	
Responsibility for monitoring and compliance with GDP requirements		X	
Maintaining an up-to-date level of knowledge in the area of GDP		X	X
Coordination of GDP measures		X	X
Development of proposals for quality improvement in GDP transports	X	X	X
Reporting to branch / executive management on all GDP matters.		X	X
Monitoring the GDP-compliant use of qualified service partners	X	X	
Assessment / auditing of GDP service partners		X	X
Coordination and prompt implementation of the necessary measures within the scope of product recalls of the clients		X	
Ensure effective resolution of relevant customer complaints for pharmaceutical shipments.		X	
Initiate / perform qualification and approval of service partners, suppliers and customers as relevant to area of responsibility.		X	X
Approval of all contracts concluded between the Ordering Party and the Contractor to determine their respective responsibilities with regard to the transport of medicinal products		X	X
Ensure adequately regular performance of self-inspections / internal audits according to a planned program and implementation of necessary corrective actions.			X
Delegation of GDP tasks in case of absence and keeping minutes about it.		X	X

Participation in regular GDP trainings	X	X	X
Implementation of GDP requirements in day-to-day business	X		
Inclusion of deviations in connection with GDP products	X	X	
Participate in decisions to quarantine or dispose of returned, rejected, recalled, or counterfeit products as required by the contracting officer	X	X	

Responsibilities and accountabilities shall be documented through purchase orders or job descriptions or outlined in a responsibility matrix.

(3) Elaboration of the documentation

When implementing GDP at a site, documents are required that were not previously available or were not available with the GDP-relevant additions. It must therefore be ensured that ...

- relevant documents are identified / named
- relevant documents are added to the system
- existing relevant documents are supplemented as required

What documents are required for GDP compliance?

- Organizational chart with assignment of GDP responsibility (GDP responsible person)
- Matrix / Job description /Appointment GDP Responsible person
- Process description / SOP (Standard Operating Procedure) explaining the handling of pharmaceutical shipments.
- GDP training certificate for all employees who handle pharmaceutical shipments
- Training planning / system to maintain a consistent, up-to-date level of knowledge regarding GDP.
- Analysis of relevant risks and opportunities in the organization / execution of pharmaceutical transports
- Systematics for the selection and use of service partners (carriers / warehouse keepers)
- List of GDP service partners
- Evidence from the service partners regarding their GDP conformity
- Contract / requirements profile / transport order with GDP requirements
- System for recording, processing and evaluating deviations in pharmaceutical transports
- Key figures for evaluating the effectiveness of the GDP organization
- GDP contingency plan with clear guidelines in the event of deviations (reporting channels, measures, information obligations)

(4) Training of the employees

All employees at all levels who take on tasks within the scope of handling pharmaceutical transports must know, understand and implement the requirements of the applicable GDP guidelines relevant to their tasks.

GDP training courses can be implemented in-house if the instructor is suitably qualified. Alternatively, there are external institutions or training providers who convey requirements, risks and courses of action.

The following trainings are to be carried out

- GDP training on GDP implementation
- GDP training during induction of new employees
- Regular GDP refresher (specify rotation during risk assessment - usual: every two years).
- GDP training in case of changes in requirements

Training planning must be verifiable, e.g. by means of a training matrix.

The outcome of the training must be evaluated (effectiveness in terms of understanding and correct implementation).

Training records must be archived.

(5) Involvement of the service partners

Not every standard service partner can perform GDP transports. GDP conditions must be ensured along the entire distribution channel (supply chain).

Transport company road
Order processing requires the selection of suitable service partners for the upstream, main and downstream stages. These can be companies that can provide a GDP certificate or a GDP declaration of conformity.

Alternatively, service partners who confirm compliance with the GDP conditions in writing may also be used. A written confirmation of the transport conditions and/or drawing of a requirement profile with GDP conditions must be available before the order is placed.

Service partners who do not provide a GDP certificate or a GDP declaration of conformity, but confirm compliance with GDP conditions, must agree to an audit. Verification of their suitability to carry out GDP transports must be planned and carried out on the basis of a risk assessment. On-site auditing of companies is expected in the pharmaceutical industry. Appropriate evidence of risk assessment, planning, implementation and tracking of corrections and potential improvements must be available.

GDP service partner requirement:

- GDP trained personnel
- Qualified equipment (qualified trucks, refrigerated containers, etc.)
- Temperature mapping (summer and winter) for equipment in use (if compliance with temperature specifications is relevant)
- Hygiene and cleaning requirements are met
- Temperature monitoring during the transport of GDP goods
- Alerting in case of deviations
- Calibration of the measuring systems according to specified intervals
- Emergency plan GDP

In addition to the GDP training certificate, drivers must carry vehicle-related calibration, GDP certification, and maintenance records and present them upon request.

Regular evaluation of deployed DLP based on meaningful criteria or regular audits is required

Carrier air / sea
The main air and sea transport is carried out by airlines and shipping companies. In accordance with the product requirements, the suitability of the respective carrier for compliant implementation must be checked in advance via the risk assessment.

The carriers usually have appropriately qualified equipment that is used for GDP transports.

It is the responsibility of GDP trained staff to select appropriate partners for the specific requirements and to demonstrably communicate the requirements when booking / ordering containers. Transport orders must clearly specify which specific requirements apply.

Cargo Consolidation

The consolidation of freight must be coordinated with the customer for GDP transports. Due to certain mixed loading prohibitions, it must be ensured that pharmaceutical products are not transported together with freight that could cause contamination / impairment of the pharmaceutical products.

Cargo loaded together with GDP goods must therefore be known and evaluated in terms of content or communicated to the customer for evaluation.

Storage

In the case of storage or transport-related intermediate storage of pharmaceutical products, defined requirements also apply to the storage or handling operation, depending on the sensitivity of the pharmaceutical product. Together with the customer, a risk assessment must be implemented in order to operate an appropriate effort.

General GDP requirements for storage

- Storage areas must always be clean and free of trash and dust. A cleaning program must specify which cleaning measures are required and how the performance of cleaning is to be documented.
- Suitable cleaning utensils and cleaning agents must be provided to prevent contamination.
- Structural design must ensure that insects, rodents and other pests cannot enter. A preventive pest control program must be implemented.
- Rest, wash and refreshment areas for personnel must be adequately separated from storage areas.
- Food, beverages, tobacco products or pharmaceuticals for the personal use of personnel are prohibited in the storage area.
- Storage areas must be suitable for maintaining the required storage conditions. Sufficient capacity for safe storage and handling of pharmaceutical products must be ensured.
- Pharmaceutical products must be clearly separated from other stored goods, either physically or by a computerized system.
- Products whose further use is to be decided on must be stored separately and also either physically separated or demarcated with a comparable system (e.g.: restricted area).
- Particularly required storage conditions for special products (temperature, radioactivity, psychotropic substances, etc.) must be ensured.
- In the case of temperature-controlled storage, factors influencing the temperature (e.g. solar radiation) must be taken into account.

- Humidity
- Temperature distribution study under representative conditions
- Temperature monitoring system
- Monitoring devices especially in the areas with the greatest temperature fluctuations
- Suitable alarm systems must report deviations from the predefined storage conditions
- Alarm levels should be set appropriately

(6) Determination of the targets and key figures for evaluation

As with the DIN EN ISO 9001 standards, targets must also be defined for the specific GDP processes within the framework of GDP. Targets must be measurable and evaluated.

Possible targets are

- No deviations from the specified temperature range
- no theft/loss of pharmaceutical shipments
- No contamination of pharmaceutical products
- no pest infestation
- etc.

Key figures through the evaluation of deviations serve to demonstrate the effectiveness of the GDP processes.

(7) Implementation of an internal audit

As with the DIN EN ISO 9001 standards, GDP also requires auditing of GDP processes and the associated records.

E.g. by means of a checklist, the GDP requirements are to be verifiably audited on a regular basis (at least annually). An internal GDP audit causes about the effort of one man-day including the audit documentation plus travel time and costs.

(8) Integration into an ISO certificate

If a certificate or declaration of conformity is officially required by the customer, this can be covered by a certifier.

Per site, an additional effort for GDP of 1.0 man-days can be expected for a joint audit of ISO 9001 and GDP compliance.

A separate audit increases the effort due to the additional travel and the associated time as well as the separate report and certificate preparation. Therefore, the joint auditing of all requirements is recommended.