GDP Audit Checklist for the Storage and Transport of Pharmaceuticals

More than 700 questions with references to regulations for preparing and carrying out GDP audits
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More than 700 questions
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for preparing and carrying out GMP audits
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Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>5</td>
</tr>
<tr>
<td>Index</td>
<td>9</td>
</tr>
<tr>
<td>1. Good Distribution Practice Checklist</td>
<td>11</td>
</tr>
<tr>
<td>2. Underlying regulations</td>
<td>11</td>
</tr>
<tr>
<td>3. How to use the checklist</td>
<td>12</td>
</tr>
<tr>
<td>4. Audit questions</td>
<td>14</td>
</tr>
<tr>
<td>4.1 General questions regarding the QMS</td>
<td>14</td>
</tr>
<tr>
<td>4.2 Personnel</td>
<td>28</td>
</tr>
<tr>
<td>4.3 Premises and equipment</td>
<td>42</td>
</tr>
<tr>
<td>4.4 Documentation</td>
<td>74</td>
</tr>
<tr>
<td>4.5 Outsourced activities</td>
<td>90</td>
</tr>
<tr>
<td>4.6 Incoming goods (IG)</td>
<td>92</td>
</tr>
<tr>
<td>4.7 Warehousing</td>
<td>110</td>
</tr>
<tr>
<td>4.8 Picking</td>
<td>128</td>
</tr>
<tr>
<td>4.9 Dispatch</td>
<td>134</td>
</tr>
<tr>
<td>4.10 Transportation</td>
<td>144</td>
</tr>
<tr>
<td>4.11 Complaints/Returned products/Recalls</td>
<td>154</td>
</tr>
</tbody>
</table>
Index

<table>
<thead>
<tr>
<th>A</th>
<th>alarm system 62</th>
</tr>
</thead>
</table>
| C | CAPA 22  
change 22  
cleaning  
-program 54  
-schedule 54  
complaint 154, 156  
computerized system 68 |
| D | data  
-back-up 72  
-transmission 70  
delivering 152  
development 22  
-incoming goods 98  
document  
-archiving 78  
-change 80  
-external origin 82  
document management system 74  
documentation 74 |
| E | equipment 42  
-qualification 60  
expiry date 126 |
| F | facility  
-qualification 60  
falsified MP 20  
FEFO principle 124 |
| I | incoming goods 92  
insulated container 140  
inventory 116 |
| J | job description 32 |
| L | label 132  
light 58  
loading 144 |
| M | maintenance plan 64  
manufacturing authorization 24 |
| O | organizational chart 30  
outsourced activity 22, 90 |
| P | personnel 28  
-initial training 38  
-job description 32  
-responsibility 36  
-training 36, 40  
pest control 56  
picking 128  
-record 130  
-premises 42  
-visitor 46  
procedure  
-qualification 60  
product  
-expired 50  
-falsified 50, 162  
-hazardous 52  
-recalled 50 |
| Q | QM manual 74  
qualification  
-equipment 60  
-facility 60  
-procedure 60  
-vehicle 150  
qualified person 30  
quality assurance system 14  
-monitoring 18  
-senior management 18  
quality management system 14  
quarantine 118 |
| R | radioactive material 52  
recall 154, 164  
refrigerated warehouse 100, 112  
responsible person 20, 28  
returned product 154, 158  
risk analysis 22 |
| S | self-inspection 11, 24  
senior management 18  
service 64  
SOP 76  
-CAPA 22  
-change 22  
cleaning 38  
-complaint 154  
-deviation 22 |
dispatch 134
falsified MP 154
outsourced activity 22
personnel hygiene 38
picking 128
recall 154
returned product 154
review 84
self-inspection 24
vehicle maintenance 152
vehicle operation 152
storage
area 44, 118
condition 110
humidity 58, 110
light 58, 110
plan 118
temperature 58, 110
supplier 96
supply chain 20, 94

T
temperature 58
documentation 114
theft 122
training 40
documentation 40
transportation 144
equipment 148
vehicle 148

V
vehicle
qualification 150

W
warehouse management
system 104
warehousing 110
wholesale authorization 24
wholesale distributor 96
1. **Good Distribution Practice Checklist**

Simone Dietz

Here you will find answers to the following questions:

- What questions can be asked during a self-inspection in order to check compliance with the GDP requirements?
- What specific references in the relevant regulations are to be used as a basis?

The following checklist is designed to support the preparation and conduct of self-inspections that focus on Good Distribution Practice (GDP).

The checklist covers the product life cycle stages of a finished medicinal product after manufacturing up to delivery to a pharmacy. This life cycle phase of a finished medicinal product is characterized by storage and transportation activities that are usually collectively referred to as Good Distribution Practices. The primary objective of this checklist is to carry out a detailed check for compliance with all GDP requirements.

The checklist can be used for all companies involved in this phase of the product life cycle, i.e. pharmaceutical manufacturers, supply chain service providers, wholesale distributors and agents. This checklist is not only intended for self-inspection but can also be used for auditing service providers in the areas mentioned above.

2. **Underlying regulations**

The EU-GDP guidelines of March 08, 2013 require that the specific product quality of finished medicinal products is ensured in the supply chain so that the required patient safety can be guaranteed. These guidelines and the Good Manufacturing Practice (GMP) guidelines overlap in many areas because the EU GMP guidelines describe the requirements for the entire product life cycle of a medicinal product from pharmaceutical development to product discontinuation. Since this life cycle also comprises the distribution of the medicinal product, GDP cannot be considered separately. Therefore, the GMP guidelines Part I with its annexes (EudraLex Volume 4) is listed as reference in the checklist in addition to the EU GDP guidelines.

In 2010, the WHO published a technical report on GDP which is also listed as a reference. Large parts of this document are now reflected in the EU GDP guidelines.

The demands on the handling of medicinal products are also increasing. To reach a consensus at an early stage, EN ISO 13485 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes is listed as a reference. EN ISO 13485 includes most of the requirements specified in EN ISO 9001. Many
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Find out whether your company meets all the requirements in the Good Distribution Practice (GDP) field. The checklist navigates you through planning, preparing and carrying out self-inspections and audits with a focus on GDP. It covers the entire life cycle of the finished pharmaceutical product, from the manufacturer’s premises to the pharmacy shelf.

The GDP Audit Checklist works great for all companies involved in the distribution of a pharmaceutical product, including pharmaceutical manufacturers, supply chain service providers, traders and brokers.

The results of the audit can be recorded directly in the checklist. There is also plenty of room for more detailed observations. For each question, the Audit Checklist includes a reference to relevant guidelines and standards, including the EU-GDP-Guideline and EN ISO 13485.

The checklist features audit questions regarding

- Personnel
- Premises and equipment
- Documentation
- Warehousing
- Dispatch
- Transportation

GMP Audit Checklist