Pharmaceutical Consultancy Services

GDP Inspection Checklist

for Distributors of Medicinal Products
preparing for a regulatory inspection.


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PEOPLE, PATIENT, PROCESS.

About PCS

OUR CEO

Mr. Jaap Koster, Eng.

Jaap Koster has 40 years of experience in pharma and biotech, based in various positions (including auditing and training) within (pharmaceutical -and food-) operations in USA, Asia and Europe in bulk chemicals, (aseptic) biologics, medicinal cannabis and packaging.

Notable Clients

NOVARTIS	MERCK	UNIDO	SUN PHARMA	GE Healthcare
Switzerland	The Netherlands	Switzerland	India	GE Healthcare USA

For 31 years, PCS has assisted both small and large organizations in achieving EU GMP, U.S. FDA or WHO regulatory compliance.

Introduction

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Introduction

This inspection preparation checklist is intended for **distributors of medicinal products** who store products for more than 72 hours.

If you do not store medicinal products for more than 72 hours you will not be able to receive a GDP inspection.

In this document you will find a summary checklist to prepare for a regulatory GDP inspection.

What are the GDP requirements?

The **European Commission** issues the rules and regulations governing the pharmaceutical industry in the European Union.

The rules for medicinal products for human and veterinary use can be found by following the link below:

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

Go to: **Other documents related to GMP** and select the latest GDP guideline.

Checklist

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Checklist - disclaimer

This checklist is not an all-encompassing list of elements to prepare before a GDP inspection. The contents of the checklist are provided for informational and educational purposes only. All information is provided on an “as is” basis without any warranties of any kind. PCS makes no representations and disclaims all expressed and implied warranties and conditions of any kind, including without limitation, representations, warranties or conditions regarding accuracy, timeliness, completeness or fitness for any particular purpose. PCS assumes no responsibility to the user or any third party for the consequences of any errors or omissions. PCS shall not be liable to you and/or any third party for any damages of any kind arising out of or relating to the use of, or reliance upon, this checklist. Including, but not limited to, any lost profits, lost opportunities, special, incidental, indirect, consequential or punitive damages, regardless of your advice to PCS to the contrary.

Organizational matters (1)

- [ ] My organization is registered with the Chamber of Commerce
- [ ] The warehouse/site address listed with the Chamber of Commerce is correct.
- [ ] I have staff employed. Note: contractors are not considered staff. The owner is also considered a staff member.

If the office is a rented virtual office, ensure the following:

- [ ] The office is furnished, including a printer, working internet, filing cabinet, etc.
- [ ] The office is actively used, does not appear as “first time use” during inspection.

Organizational matters (2)

- [ ] A floor plan to the warehouse/office is available.
- [ ] A Chamber of Commerce excerpt is available.
- [ ] A signatory authority is present during the inspection.
- [ ] Documents are available detailing the activities performed and a justification for these activities.
- [ ] An organogram is available.

Quality management system

- [ ] I have a Site Master File conforming to the EU template for a Site Master File.
- [ ] All required SOP's are implemented and authorized.
- [ ] The SOP's are written in a compulsory, directive style.
- [ ] If you use a digital quality management system; the software is validated.
- [ ] If you use a paper-based system; printed copies are available.
- [ ] If you use a paper-based system; printed copies are available.
- [ ] Audit reports are available.

The Responsible Person

- [ ] For each Responsible Person, a curriculum vitae is available.
- [ ] For each Responsible Person, a certificate of competence (GDP) is available.
- [ ] For each Responsible Person, an employment / consultancy contract & mandate are available.
- [ ] For each Responsible Person, all training certificates are available.

Risk Management

- [ ] A risk management sheet on the supply chains is available. (or multiple sheets)
- [ ] All transport routes have been validated.
- [ ] If you use a digital quality management system; backup and restore safeguards have been implemented, according to regular schedule and have been proven to work.

Other matters / documents

- ☐ A list of (future) customers and suppliers is available.
- ☐ A graphic visualization of the supply chain is available.
- ☐ Job descriptions of all employees are available, that includes a job description for the Responsible Person(s).
- ☐ (draft) Quality Agreements with suppliers / customers are available.

Get support today!

Need help preparing for your **GDP inspection**?

Get input from our experienced consultants to make the process efficient, first-time-right and painless!

We're ready to help! Get in touch:

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SCHEDULE A MEETING

Talk to one of our experts directly.

Click here!

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