Pharmaceutical Consultancy Services

Wholesale Distribution License Support

Whitepaper

for Distributors of Medicinal Products wanting to obtain a WDL.


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Services
PEOPLE, PATIENT, PROCESS.

About PCS

OUR CEO

Mr. Jaap Koster, Eng.

Jaap Koster has 42 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 whitepaper 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 Wholesale Distribution License.

In this document you will find an introduction to the requirements of obtaining a Wholesale Distribution License and how PCS can help you obtain it.

What is a Wholesale Distribution License?

A Wholesale Distribution License (WDL) is a license applicable to **distributors** of medicinal products **within the European Union**.

Where compliance to e.g. ISO requirements are checked by a commercial organization, the implementation of the requirements to obtain a WDL **are inspected by the government**.

Every distributor in medicinal products that holds medicinal products for longer than 72 hours must register their legal entity with their local regulatory authority.

What is a Wholesale Distribution License?

After registering with your local regulatory authority you **will receive a date for an inspection**.

Inspectors from the government will assess your compliance against the **Good Distribution Practice (GDP)** regulatory requirements.

After passing the inspection, you will receive a Wholesale Distribution License. Additionally, **a GDP certificate will be issued** by the regulatory authority.

If you fail the inspection you must submit an improvement plan.

What are the requirements for a WDL?

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.

WDL Obtainment Process

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Starting with the basics

In order to successfully apply for a Wholesale Distribution License (WDL) you have to get a large number of quality elements organized and implemented properly.

Obtaining a WDL is not **difficult**, but requires **commitment** and **discipline**.

Our seven-step process helps you obtain a WDL

Step 1 : Strategy discussion

REQUIRED TIME
2 days

DELIVERABLES
WDL action plan

We hold a strategy discussion to get an understanding of your **plans**, expected **timelines** and **budget**.

We make an inventory of what you already have (e.g. ISO quality system, GDP-compliant equipment, warehouse).

During the two days we will assess your company's plans and draw up a draft action plan.

The action plan will be sent to you for review.

Step 2 : Gap assessment

REQUIRED TIME
14 days

DELIVERABLES
Gap assessment report

If you already have a facility or a quality system, we will perform a gap assessment of your **systems & facility against the GDP requirements**.

We offset our findings against the plan we submitted. Is it still achievable? Can we ✓ off certain aspects? Or do we need to expand our plan?

The gap assessment itself will take eight hours or less. The report will be submitted within 14 days after completing the gap assessment.

The report will contain deviations from the GDP requirements & suggestions on how to fix the deviations.

Step 3 : Project plan & GANTT-chart

REQUIRED TIME
5 days

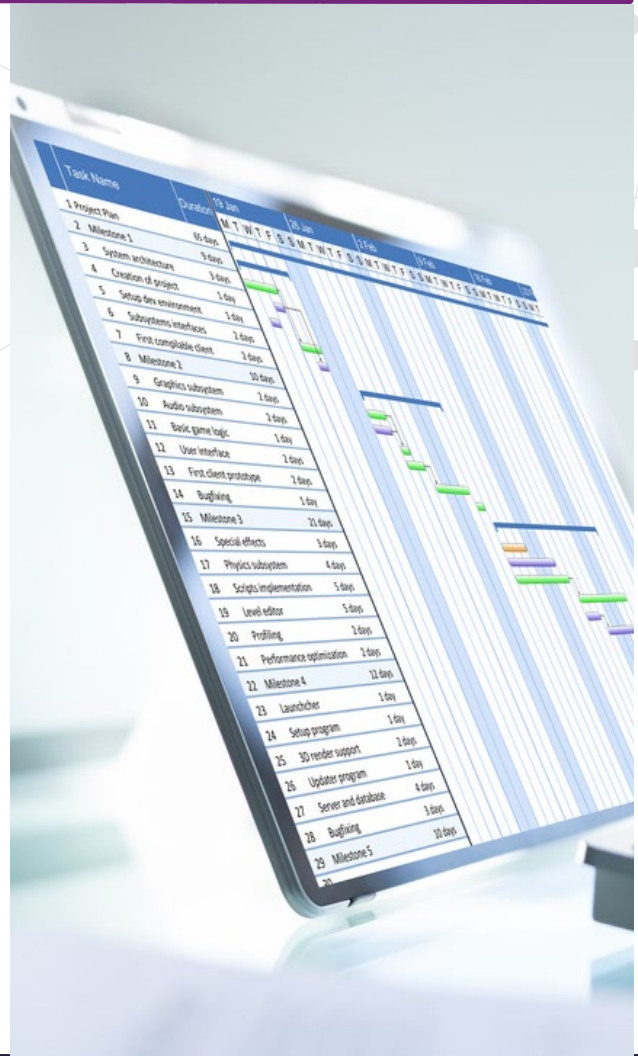
DELIVERABLES
Project plan, GANTT chart

Using your plan and the observations from the gap assessment we will develop a **detailed project plan**.

Accompanying the project plan is a **GANTT chart**; the gantt chart visualizes the action plan and the timelines associated with it.

When all parties accept the project plan, PCS must receive a **mandate from senior management** to help implement the actions. Without a mandate, implementation will progress slower than desirable.

Work *really* starts after acceptance of the project plan.



Step 4 : Project plan implementation (1)

REQUIRED TIME
3-4 months

DELIVERABLES
GDP training, quality system procedures, validation & qualification support, etc.

During the implementation of the project plan your staff and PCS will cooperate to create, authorize and officially adopt each item in the project plan.

This includes (but not limited to):

- Helping your staff write procedures,
- Training everyone on the GDP requirements,
- Training staff on procedures,
- Qualification of equipment (providing written proof that equipment operates as intended),
- Validation of your transportation routes,
  and many other items...

Step 4 : Project plan implementation (2)

REQUIRED TIME
3-4 months

DELIVERABLES
GDP training, quality system procedures, validation & qualification support, etc.

During the implementation of the project plan your staff and PCS will cooperate to create, authorize and officially adopt each item in the project plan.

This includes (but not limited to):

- Helping your staff write procedures,
- Training everyone on the GDP requirements,
- Training staff on procedures,
- Qualification of equipment (providing written proof that equipment operates as intended),
- Validation of your transportation routes,
  and many other items...

Step 4 : Project plan implementation (3)

REQUIRED TIME
3-4 months

DELIVERABLES
GDP training, quality system procedures, validation & qualification support, etc.

The full list of support items is shown below:

- Action plan,
- Supply chain mapping,
- Finding/assessing 3PL,
- Quality Technical Agreement checks,
- Interim RP selection,
- Interim RP contract services,
- Equipment qualification,
- Temperature mapping support,
- Transport validation support,
- Establishing QMS,
- Customization of QMS,
- Risk assessments,
- Liaison with suppliers / clients,
- Manage computerized systems validation,
- Preparing license application,
- Submit license application,
- Liaise with authorities,
- Host inspection,
- Post-inspection support.

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INTERESTED IN GDP TRAINING?

Check our GDP training options at:

www.pcs-nl.com/academy

Training | eLearning | In-house

Step 5 : Inspection readiness

REQUIRED TIME
1 month

DELIVERABLES
Inspection readiness training, one-minute rule, mock-audit

We want you to be **ready** and **confident** when the inspector arrives.

During approximately one month we will prepare you and your staff to receive the inspection properly, **avoiding obvious mistakes**.

Inspection readiness training

1-minute rule implementation

Ensuring you can deliver information to the inspector within one minute of receiving the request

Mock-audit by ex-govt. GDP inspector

Step 6 : Inspection support

REQUIRED TIME
1-2 days

DELIVERABLES
On-site support during regulatory inspection

When the inspector is there, a senior PCS consultant will be there. Especially when it's your first inspection, you will want **senior support by a consultant** that has been through dozens (if not hundreds) of inspections.

A GMP or GDP inspection lasts between one and three days. **Our team will support you throughout the inspection**. The following support is often requested by clients during regulatory inspections:

- Back-office support (getting the documents ready in time),
- Expert support in the inspection room – help with Q&A,
- Guiding the inspector during the facility tour,
- Help discuss the observations during the wrap-up.

Step 7 : Inspection response

REQUIRED TIME
1-2 days

DELIVERABLES
Action plan & response letter, ready for submission

There will always be observations in the inspection report. Hopefully small observations, but there may be major observations. In both cases you will want to respond in a clear and concise manner. Your inspection response must be first-time-right.

In some cases you will need to write an action plan, detailing what you will do to remediate the GMP or GDP inspection observations.

PCS helps you draft the letter and to compile a solid action plan.

Ready to be sent to the government.

Get support today!

Are you ready to obtain a **Wholesale Distribution License (WDL)**?

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

We're ready to help! Get in touch:

+31 (0)182 503 280

info@pcs-nl.com

SCHEDULE A MEETING

Talk to one of our experts directly.

Click here!

PEOPLE, PATIENT, PROCESS.

Pharmaceutical
Consultancy
Services

Houttuinlaan 4
3447 GM Woerden
Nederland

t.+31(0)182 - 503 280
e. courses@pcs-nl.com

www.pcs-nl.com
KvK 30280650