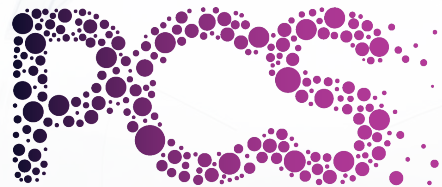




Pharmaceutical
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Responsible Person

Example job description for Responsible Persons in the
European Union.



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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, Africa, South America and Europe in bulk chemicals, (aseptic) biologics, vaccines, oral solid dosage, medicinal cannabis and packaging.

Notable Clients



Switzerland



The Netherlands



Switzerland



India



GE Healthcare

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.

What are the GDP requirements?

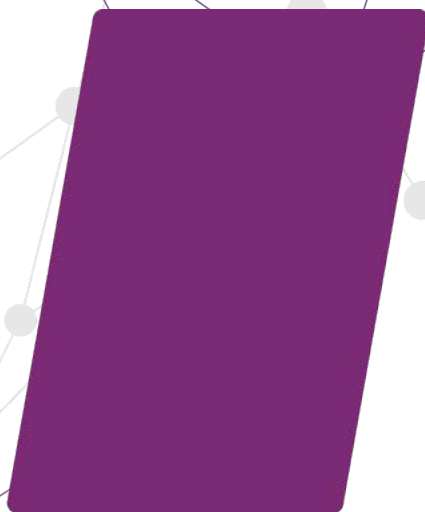


The **European Commission** issues the rules and regulations governing the pharmaceutical industry in the European Union.

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

The requirements for human and veterinary medicinal products are similar.



Introduction – RP

Introduction – Responsible Person

The **Responsible Person** is a functionary required under the EU GDP requirements.

An RP ensures the functioning of the quality system, coordinates recalls, releases medicinal product from the warehouse, amongst other duties.

The Responsible Person should carry out their duties in such a way as to ensure that the wholesale distributor can demonstrate GDP compliance and that public service obligations are met.

The **written job description** of the Responsible Person should define their authority to take decisions with regard to their responsibilities. The wholesale distributor should give the Responsible Person the defined authority, resources and responsibility needed to fulfil their duties.

Introduction – Responsible Person

This **example** Job Description provides insight into the RP's:

- ✓ Responsibilities,
- ✓ Tasks,
- ✓ Requirements.

You could use this Job Description to verify your current RP's job description or to get insight into what an RP does, and what the RP is responsible for.

Disclaimer

This document is not an all-encompassing list of the role, responsibilities, scope of work / activities of -or requirements for- a Responsible Person. The contents of this document 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 document. 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.



EXAMPLE Job Description

Educational Requirements

- ✓ A degree in pharmacy is desirable,
- ✓ The responsible person should have appropriate competence and experience as well as knowledge of and training in GDP,
(usually 1.5 years of experience with pharmaceutical logistics)
(ensure the GDP training has sufficient scope and depth, e.g. a 40 minute eLearning is not enough. Ensure to receive a training certificate after completing a training course on GDP.)

Primary Tasks

- ✓ Ensuring compliance with GDP requirements,
- ✓ Conduct GDP self-inspection,
- ✓ Coordinating training in the context of GDP,
- ✓ Conduct supplier/client audits,



Mandate

- ✓ Deciding on suitability of suppliers, customers and delivery addresses,
- ✓ Deciding on returns, recalls, rejects and counterfeit medicines,
- ✓ Approve outsourcing.

Responsibilities (1)

- ✓ Ensuring that a quality management system is implemented and maintained;
- ✓ Commit to the management of licensed activities, as well as to the accuracy and quality of documentation;
- ✓ Ensure that initial and in-service training programs are implemented and maintained;
- ✓ Coordinating and prompt implementation of drug recalls;
- ✓ Ensuring that relevant customer complaints are handled effectively;
- ✓ Ensuring that suppliers and customers are recognized;

Responsibilities (2)

- ✓ Approve any outsourced activities that may affect GDP;
- ✓ Ensuring that self-inspections are performed at appropriate and regular intervals according to a pre-established schedule and that necessary corrective actions are taken;
- ✓ Appropriately record delegated tasks;
- ✓ Decide on the final destination of returned, rejected, recalled or counterfeit products;

Responsibilities (3)

- ✓ Approve whether products are added back to salable inventory;
- ✓ Ensure that any additional requirements from national legislation that apply to certain products are complied with.



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INTERESTED IN GDP TRAINING?

Check our GDP training options at:

www.pcs-nl.com/training-courses

Training

eLearning

In-house

Get support today!

Need help finding a Responsible Person for your wholesale activities?

Get input from our experienced consultants to select the right person, with the right qualifications.

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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