Pharmaceutical Consultancy Services

Responsible Person

Example job description for Responsible Persons in the European Union.

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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

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.

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

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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

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EXAMPLE Job Description

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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:

+31 (0)182 503 280

info@pcs-nl.com

SCHEDULE A MEETING

Talk to one of our experts directly.

Click here!

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