I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for the ensuring that the Qualified Person responsible for Pharmacovigilance (QPPV) is able to fulfill the Pharmacovigilance (PV) tasks and responsibilities in accordance with the Good Pharmacovigilance Practices (GVP).

II. SCOPE

This procedure shall apply to PV systems outsourced to PharmExpert LLC (Pharmex) by Marketing Authorization Holders (MAH) in line with the Safety Agreements.

This SOP is applicable to Pharmex's personnel appointed on role of QPPV.

III. RESPONSIBILITIES

Role	Responsibility
Pharmex/MAH	• Appointment of QPPV
Pharmex's personnel appointed as QPPV	• Fully adhere to this SOP
SPVS (Senior PV Specialist)/PVS (PV Specialist)	• Preparation and submission of Notification letter
Quality Assurance Manager (QAM)	• Compliance monitoring

IV. DEFINITIONS

Abbreviations used in the text are spelled out on its first mention.

Pharmex's personnel – staff of Pharmex and outsourced Local Contact Persons responsible for PV (LCPPV) in the countries of responsibility.

For other terms and definitions refer to the SOP-QA-003 «Pharmacovigilance Glossary».

V. PROCEDURE

A. General specification

1. MAH's Responsibility

As part of the PV system, the MAH shall have permanently and continuously at its disposal an appropriately QPPV. The duties of the QPPV shall be defined in a job description. The hierarchical relationship of the

QPPV maintains system oversight and overview of the safety profiles of all products. Such delegation should be documented.

B. Process

1. Appointment of QPPV

a) Pharmex's any personnel with appropriate education (medical, pharmaceutical) and professional level background in PV (at least 2 years) can be appointed to the role of QPPV for MAH's PV System.

b) SPVS/PVS shall prepare Notification letter about appointment of QPPV indicating contact details, address and experience.

c) Duly signed and sealed Notification letter (and Curriculum Vitae where required) is sent to the LCPPV for submission to the respective country's RA (SOP-PV-004 «Local PV Activity») in accordance with a local regulatory requirement, OR

d) Where applicable, make direct electronic submission of the appointment documents to the respective country's RA.

e) Save the proof of submission (PS) in the Quality Management System.

f) Provide to the MAH the PS (if required).

2. Change of QPPV/QPPV's contact details

a) When contact information of QPPV changes, SPVS/PVS shall prepare a new Notification letter.

b) SPVS/PVS shall submit this Notification letter to the RA within 30 business days (unless another time is specified by RA).

c) Information about QPPV shall be entered in the PSMF of the MAH.

d) Folder path for storage of Notification letter: <RA/ Country N/ Country Code_ QPPV_Authorization docs/Company N>.

3. Training

a) After appointment MAH/ Pharmex shall conduct required training for the QPPV regarding the PV System and further the QPPV shall start his taking responsibilities.

b) The training by Pharmex shall be performed in accordance with the SOP-HR-002 «Training» and training data shall be entered in the «Training Attendance Form» (R04F-SOP-HR-002).

c) QPPV acts in accordance with the internal SOPs of the Pharmex/MAH.

4. Hand Over Responsibility

Delegation of the responsibilities during absence of QPPV is ensured in accordance with the SOP-HR-004 «Substitution of QPPV_LCPPV».