TABLE OF CONTENTS

I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for passing of inspection of the Marketing Authorization Holder's (MAH) Pharmacovigilance (PV) system organized by Regulatory Authorities (RA) of the countries where PharmExpert LLC (Pharmex) has responsibility.

II. SCOPE

This procedure shall apply to the preparation and conduction of an inspection of the PV system.

This SOP is intended for all stakeholders involved in the preparation and conduction of the inspection of the PV system.

III. RESPONSIBILITIES

Role	Responsibility
Managements of Pharmex and/or MAH	• Organizing of inspection • Appointments of responsible person (RP) • Supporting the process with required resources
Pharmex's RP, MAH's QPPV (Qualified Person responsible for PV)	• Fully adhere to this SOP
Quality Assurance Manager (QAM)	• Compliance monitoring • Storage of the inspection documents

IV. DEFINITIONS

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

Inspection – examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.

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

V. PROCEDURE

A. General Specification

1. Objectives of Inspections

The objectives of PV inspections are:

1. Appointment of Inspection

Management of Pharmex, MAH's QPPV within 24 hours:

a) Upon receipt of information/notification letter about inspection inform all stakeholders about pending event and timing of conduct.

b) Discuss the reasons and aim of inspection.

2. Preparation of Inspection

Management of Pharmex/ MAH's QPPV

a) Conduct preliminary meeting with all stakeholders within 3 business days after getting the IP.

b) Study and discuss the IP.

c) Appoint internal audit procedure in accordance with internal SOP of the party responsible for PV system.

Note. If discrepancies are identified, major changes are not made to the procedures. If necessary, based on the results of the inspection, within the agreed time frame, the NC Report is prepared and provided to the Inspectors.

d) Appoint RP (s) for expediting the inspection within 1 business day after the preliminary meeting,

Note. RP may be any employee of Pharmex or outsourced LCPPV (Local Contact Person responsible for Pharmacovigilance) in the country' of responsibility.

3. Conduction of Inspection

Pharmex's RP, MAH's QPPV:

a) Present at the opening and closing meeting of an inspection.

b) On the 1st day of inspection provide Inspectors the presentation of PV system.

c) Cooperate with Inspectors, participate in interviews.

d) Answer to Inspector's questions truthfully and honestly, in the most direct manner to ensure prompt provision of information and adherence to the inspection schedule timeliness.