

1.8.1 Pharmacovigilance System

*Kib 2015-004/02 Summary of Pharmacovigilance
System - dated 2015-02-26*



Summary of the Pharmacovigilance System

Kibion AB

PSMF id: MFL3505

1. Proof of disposal of QPPV

It is hereby confirmed that the applicant/MAH, Kibion AB, has at his disposal a qualified person responsible for pharmacovigilance (QPPV).

Signatures for confirmation are found in Section 6 of this document.

2. Member State where the QPPV resides and acts

The QPPV resides and carries out the tasks in SWEDEN.

3. Contact details of QPPV

The QPPV contact details are:

Name: Mrs. Margareta Svensson

Business address:

TFS Trial Form Support AB

Box 165

SE-221 00 Lund

SWEDEN

24-hours contact details: +46 46 280 18 48; Cell +46 708 54 14 30

E-mail 1: safety.tfs@tfscro.com

E-mail 2: margareta.svensson@tfscro.com

4. Statement of fulfillment of PV tasks and responsibilities

It is hereby confirmed that the applicant/MAH has the necessary means as well as a pharmacovigilance system in place to fulfill the tasks and responsibilities listed in Title IX of Directive 2001/83/EC as amended.

Signatures for confirmation are found in Section 6 of this document.

5. Location of the Pharmacovigilance System Master File (PSMF)

The Pharmacovigilance System Master File (PSMF) is located at the following address:

Kibion AB
Virdings allé 32A
(P.O. Box 303)
SE-754 50 Uppsala
SWEDEN

The rationale for this location is that it is the head office of the company. The QPPV resides and acts in another location but has access to the PSMF.

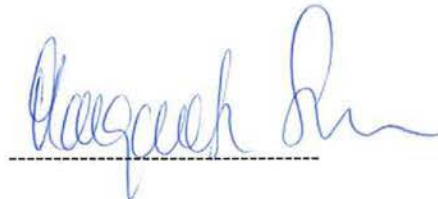
6. Signature

Uppsala, date: 2015-02-24

Lund, date: 2015-02-26



Petter Bäckgren
CEO



Margareta Svensson
EEA-QPPV