

CASE STUDY

Expedited Set-Up

To support effective MAA management in different jurisdictions

Visual Snapshot

Product & Therapeutic Areas

3 Biosimilar products used in Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing spondylitis, Arthritis

Background/Project Overview

- Local QPPV service in 26 countries worldwide: 16 EEA, 2 non-EEA (UK and Switzerland), 6 MENA (Israel, Kuwait, Oman, Qatar KSA, and UAE), 3 APAC (Australia, New Zealand, and Taiwan) and 2 EEU (Russia and Ukraine) countries.
- Support with MAA for 2 MENA and 1 APAC countries
- Safety reporting where required to be performed by local QPPV

26
countries
worldwide

Challenge

- Expedited appointment of Local QPPVs required
- Set up of new countries where PVL did not have presence before
- Vague legislation in MENA region

Approach

- Appointment of qualified and experienced local QPPVs
- Development of regulatory requirements checklist covering RMP, Aggregate report, PV System Master File, Case Intake & FU, Case Processing & Reporting, Local PV SOP, Signalling & Significant Safety Issue (SSI) Reporting etc. to clarify PV documents required for MAA (PSSF, RMP, local QPPV, PSUR) and establishment of PV system
- Adequate local QPPV training and introduction to client PV system and their SOPs (as relevant per country)
- Local QPPV and RA&PV Network support in developing Summary of the PV System and National PV System file

Result

- Clients's timelines for local QPPV appointment met
- MAA successfully managed
- Client relied on local QPPV support in keeping abreast with national requirements and adapting their processes
- Local QPPVs supported client in establishing relevant operating procedures (e.g., Special Reporting Requirements for Safety Issues), RMPs, update of safety information, safety reporting requirements