

MEA PV hub creation in Abbvie

On 08 May 2020, AbbVie completed its acquisition of Allergan plc; Allergan is now part of AbbVie. Initially, the two existing and separate PV systems were maintained, and a program of change was initiated with the intent of integrating the two PV systems into one comprehensive system. A qualified person responsible for PV in the EU (EU QPPV) has been appointed to cover all products in the combined portfolio.

Effective 24 June 2021, the legacy Allergan (L-AGN) Pharmacovigilance System Master File (PSMF) has been retired. A new bifurcated AbbVie PSMF has been created. This PSMF describes the PV system that is applicable to the combined AbbVie and L-AGN product portfolio. For some PV processes, the PSMF describes dual approaches for the legacy AbbVie (L-ABV) and L-AGN products to account for ongoing IT system integration and organizational structure alignment. Although the process requirements may be the same or similar for L-ABV and L-AGN products, the execution of work may still occur in separate systems, platforms, and role definitions.

Following the creation of the ABV bifurcated PSMF on 24 June 2021, all AbbVie Affiliates began updating their National PSMFs/PSSFs to adopt the description of the bifurcated PV system.

Since 04 Oct 2021, the PV systems at the Affiliate will complete their integration activities, and one PV system is managed under the responsibility of one National QPPV in each Affiliate.

At the same time, the MEA PV hub went live including 4 affiliates from both legacies, Levant E NWA, Saudi, Gulf and South Africa. The hub contains 17 FTEs and is organized into 4 PV activities that leverages the PV talents in the region, allow for role specialization and enhances better career opportunities for the key talents in the MEA region.

My role as a member of the core team for the ME PV hub project started on Jan 2021, and then I was appointed as the MEA PV hub Lead on May 2021, during that time, I was involved for setting the roadmap for this project, setting the strategies of the MEA V hub, proposed multiple draft structures and suggested ways of work in a matrix within the hub until we reached the current structure , all this while maintaining the business continuity and all safety deliverables in the ME countries .

Our proposal to assign one National QPPV for the bifurcated PV system to all the Health Authorities in the MEA region ensures better oversight of PV tasks and complies with the current AbbVie EU PSMF. This is also complemented with assigning the other legacy PV person as the Deputy NQPPV, therefore leveraging the safety knowledge of both legacy PV systems, and harnessing the collaboration and

interaction in the affiliates. This proposal was accepted by the Health Authorities in MEA and we have been operating through the Hub model successfully for more than 6 months now.

The MEA PV hub project gained acknowledgment from all global functions in Abbvie, from Pharmacovigilance and Patient Safety PPS, Global Medical affairs GMA and commercial leadership in the MEA region in Abbvie .